I Legislative acts

REGULATIONS


II Non-legislative acts

REGULATIONS


★ Commission Implementing Regulation (EU) 2023/1808 of 21 September 2023 setting out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council .......................................................................................... 105

(1) Text with EEA relevance.

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.
The titles of all other acts are printed in bold type and preceded by an asterisk.
DECISIONS

★ Commission Decision (EU) 2023/1809 of 14 September 2023 establishing the EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups (notified under document C(2023) 6024) (1) ……………………………………………………………………………………………… 142

★ Commission Decision (EU) 2023/1810 of 19 September 2023 on a request for extended cumulation between Cambodia and Vietnam, in accordance with Article 56(1) of Delegated Regulation (EU) 2015/2446, as regards the rules of origin used for the purposes of the scheme of generalized tariff preferences pursuant to Delegated Regulation (EU) 2015/2446 for certain materials or parts used in the production of bicycles ………………………………………………………………………………………….. 190

★ Commission Implementing Decision (EU) 2023/1811 of 20 September 2023 amending Implementing Decision (EU) 2020/1550 by establishing the programme of Commission controls for 2024 in the Member States to verify the application of Union agri-food chain legislation …… 196

RULES OF PROCEDURE

★ Decision No 37-2023 of the European Court of Auditors regarding public access to ECA documents…………………………………………………………………………………………………. 200

Corrigenda

★ Corrigendum to Council Decision (CFSP) 2023/432 of 25 February 2023 amending Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine (OJ L 100, 13.4.2023)…………………………………………………………………………………………………….. 206


(1) Text with EEA relevance.
I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2023/1804 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 13 September 2023
on the deployment of alternative fuels infrastructure, and repealing Directive 2014/94/EU

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

Having regard to the opinion of the Committee of the Regions (2),

Acting in accordance with the ordinary legislative procedure (3),

Whereas:

(1) Directive 2014/94/EU of the European Parliament and of the Council (4) laid down a framework for the deployment of alternative fuels infrastructure. The Commission Communication of 9 December 2020 entitled ‘Sustainable and Smart Mobility Strategy – putting European transport on track for the future’ points to the uneven development of recharging and refuelling infrastructure across the Union and the lack of interoperability and user friendliness. It notes that the absence of a clear common methodology for setting targets and adopting measures under the national policy frameworks required by Directive 2014/94/EU has led to a situation whereby the level of ambition in target setting and supporting policies differs greatly among Member States. Those differences have hindered the establishment of a comprehensive and complete network of alternative fuels infrastructure across the Union.


(1) OJ C 152, 6.4.2022, p. 138.
(2) OJ C 270, 13.7.2022, p. 38.
(3) Regulations (EU) 2019/631 (1) and (EU) 2019/1242 (2) of the European Parliament and of the Council already set CO₂ emission performance standards for new passenger cars and for new light-duty vehicles, as well as for certain new heavy-duty vehicles. Those Regulations should accelerate the uptake of, in particular, zero-emission vehicles and thereby create demand for recharging and refuelling infrastructure. It is important that Regulations (EU) 2019/631 and (EU) 2019/1242 and this Regulation ensure a coherent framework for the use and deployment of alternative fuels in road transport.

(4) Regulation of the European Parliament and of the Council on ensuring a level playing field for sustainable air transport and Regulation (EU) 2023/1805 of the European Parliament and of the Council (6) should boost the production and uptake of sustainable alternative fuels in aviation and maritime transport. While the fuel use requirements for sustainable aviation fuels can largely rely on the existing refuelling infrastructure, investments are needed for the electricity supply of stationary aircraft. Regulation (EU) 2023/1805 sets requirements in particular for the use of on-shore power that can only be fulfilled if an adequate level of shore-side electricity supply is deployed in the trans-European transport network (TEN-T) ports. However, those Regulations do not contain any requirements concerning fuel infrastructure, although such requirements are a prerequisite for achieving the targets.

(5) Therefore, all modes of transport should be addressed in a single legal act which should take into account a variety of alternative fuels. The use of zero-emission powertrain technologies is at different stages of maturity in the different modes of transport and in the different Member States. In particular, in the road sector, a rapid uptake of battery electric vehicles and plug-in hybrid vehicles is taking place. Hydrogen-powered vehicles are available on the market, as well. In addition, smaller hydrogen-powered vessels and battery electric vessels and hydrogen-powered trains are currently being deployed in different projects and in first commercial operations, with full commercial roll-out expected in the coming years. In contrast, the aviation and waterborne sectors continue to be dependent on liquid and gaseous fuels, as zero- and low-emission powertrain solutions are expected to enter the market only by approximately 2030 or even later, in particular for the aviation sector, with full commercialisation taking its time. The use of fossil gaseous or liquid fuels is only possible if it is clearly embedded into a clear decarbonisation pathway that is in line with the long-term objective of climate neutrality in the Union, requiring increasing blending with or replacement by renewable fuels such as bio-methane, advanced biofuels or renewable and low-carbon synthetic, paraffinic, gaseous and liquid fuels.

(6) Such biofuels, synthetic and paraffinic fuels, substituting diesel, petrol and jet fuels, can be produced from different feedstock and can be blended into fossil fuels at very high blending ratios. Those fuels are especially important for the reduction of greenhouse gas emissions in the aviation and maritime transport sectors, in which electrification is expected to be slower. Those fuels are technically compatible with the current vehicle technology, with minor adaptations. Moreover, renewable methanol can, among other things, be used for inland navigation and short-sea shipping. Synthetic and paraffinic fuels have the potential to reduce the use of fossil fuel sources in the transport sector. All of those fuels can be distributed, stored and used with the existing infrastructure or, where necessary, with infrastructure of the same kind.

(7) Liquefied methane is likely to continue to play a role in maritime transport, where no economically viable zero-emission powertrain technology is currently available. However, liquefied methane from fossil sources should be phased out in maritime transport as soon as possible and substituted by more sustainable alternatives. The Smart and Sustainable Mobility Strategy points to zero-emission seagoing ships becoming market ready by 2030 and projects for such ships are already underway. Fleet conversion is expected to take place gradually due to the long lifetime of seagoing ships. In contrast with the situation in maritime transport, in inland waterway transport, with normally smaller vessels and shorter distances, zero-emission powertrain technologies, such as for hydrogen and electricity, are becoming mature technologies and are therefore expected to enter the market more quickly. However, those zero-emission powertrain technologies could play an important role for maritime transport in

terms of creating scale regarding zero-emission propulsion solutions. Liquefied methane is expected to no longer play a significant role in that sector. Transport fuels such as liquefied methane need increasingly to be decarbonised by blending or by being substituted with, for example, liquefied biomethane or renewable and low-carbon synthetic gaseous e-fuels (e-gas). The same infrastructure can be used for those decarbonised fuels as for fossil gaseous fuels, thereby allowing for a gradual shift towards decarbonised fuels.

(8) In the heavy-duty road transport sector, technologies for liquefied methane driven trucks are fully mature. The common scenarios underpinning the Sustainable and Smart Mobility Strategy and the Commission Communication of 17 September 2020 entitled 'Stepping up Europe’s 2030 climate ambition - Investing in a climate-neutral future for the benefit of our people' (the 'Climate Target Plan') as well as the revised 'Fit for 55' package modelling scenarios suggest a limited role for gaseous fuels, that will increasingly be decarbonised in heavy-duty road transport and especially in the long-haul segment. Furthermore, liquefied petroleum gas (LPG) and compressed natural gas (CNG) vehicles, for which sufficient infrastructure network already exists across the Union, are expected gradually to be replaced by zero-emission powertrains and therefore only a limited targeted policy for liquefied methane infrastructure deployment that can equally supply decarbonised fuels is considered necessary to close remaining gaps in the main networks.

(9) This Regulation should lay down mandatory minimum targets for the deployment of publicly accessible recharging and refuelling infrastructures for road vehicles.

(10) A recharging station is a physical installation for the recharging of electric vehicles. Every recharging station has a theoretical maximum power output, expressed in kW, and has at least one recharging point that can serve only one vehicle at a time. The number of recharging points at a recharging station determines the number of vehicles that can be recharged at that station at any given time. Where more than one vehicle recharges at a recharging station at a given time, the maximum power output is distributed to the different recharging points in such a way that the power provided at each individual recharging point is lower than the power output of that recharging station. A recharging pool consists of one or more recharging stations at a specific location, including, as the case may be, the dedicated parking places adjacent to them. With regard to the targets set out in this Regulation for recharging pools, the minimum power output required for recharging pools could be provided by one or more recharging stations.

(11) Publicly accessible recharging or refuelling points include, for example, privately owned recharging or refuelling points accessible to the public that are located on public or private property, such as public parking areas or parking areas of supermarkets. A recharging or refuelling point located on private property that is accessible to the public should be considered to be publicly accessible also in cases where access is restricted to a certain general group of users, for example to clients. Recharging or refuelling points for car-sharing schemes should only be considered to be publicly accessible if they explicitly allow access for third party users. Recharging or refuelling points located on private property to which access is restricted to a limited and determinate group of persons, such as parking places in an office building to which only employees or authorised persons have access, should not be considered to be publicly accessible recharging or refuelling points.

(12) With a view to increasing consumer convenience, it is important that operators of publicly accessible recharging or refuelling points ensure that the opening hours of such points and uptime of their services fully meet the needs of end users.

(13) The deployment of publicly accessible recharging infrastructure for light-duty electric vehicles has been uneven across the Union. The continued uneven distribution of publicly accessible recharging infrastructure would jeopardise the uptake of light-duty electric vehicles, thereby limiting connectivity across the Union. Continuing divergence in policy ambitions and approaches at national level hinders the much-needed sustainable transition of the transport sector and is not conducive to creating the long-term certainty needed for substantive market investment. Mandatory minimum targets for Member States at national level should therefore provide policy orientations and should complement national policy frameworks. That approach should combine national fleet-based targets with distance-based targets for the TEN-T. National fleet-based targets should ensure that uptake of light-duty electric vehicles in each Member State is matched by the deployment of sufficient publicly accessible recharging infrastructure. Distance-based targets for the TEN-T network should ensure full coverage of recharging points along the Union’s main road networks and thereby ensure easy and seamless travel throughout the Union.
(14) National fleet-based targets should be established on the basis of the total number of electric vehicles registered in the Member State concerned. Those targets should be established on the basis of a common methodology that accounts for technological developments such as the increased driving range of electric vehicles or an increase in the number of fast recharging points, at which a greater number of electric vehicles can recharge than at a normal-power recharging point in a given period. That common methodology should also take into account the different recharging patterns of battery electric vehicles and plug-in hybrid vehicles. A methodology that sets out national fleet-based targets according to the total maximum power output of the publicly accessible recharging infrastructure would allow for flexibility in the implementation of different recharging technologies in Member States.

(15) Implementation by Member States of the national fleet-based targets should ensure that a sufficient number of publicly accessible recharging points is installed in a manner that also guarantees the accessibility of recharging points in their entire territory, in particular at public transport stations, such as port passenger terminals, airports or railway stations. Deployment of those publicly accessible recharging points is particularly important in residential areas where off-street parking is scarce and in areas where, typically, vehicles are parked for extended periods of time. A sufficient number of publicly accessible fast recharging points dedicated to light-duty electric vehicles should also be deployed to increase consumer convenience, in particular, across the TEN-T network to ensure full cross-border connectivity and to enable electric vehicles to circulate throughout the Union. It is important that the deployment of publicly accessible recharging infrastructure primarily be the result of private market investment. However, Member States should, subject to Union State aid rules, be able to support the deployment of the necessary publicly accessible recharging infrastructure in cases where, due to market conditions, public support is needed before a fully competitive market is established.

(16) Depending on the specific circumstances in a Member State, the requirements in terms of the level of fixed total power output to be provided through publicly accessible recharging stations for each light-duty battery electric vehicle registered in that Member State might no longer be justified where those requirements could have adverse effects by discouraging private investments or, in particular, by resulting in oversupply in the medium term. The risk of such adverse effects could arise due to the installation of a high number of private recharging points. The needs of users or the use-rate of publicly accessible recharging stations might be lower compared to initial assumptions, with the consequence that the total power output available through publicly accessible recharging stations reaches a disproportionately high level compared to the actual use of such stations. In such cases, the Member State concerned should be able to request authorisation to apply lower requirements than the ones laid down in this Regulation in terms of level of total power output or to cease to apply such requirements. For the Member State to be able to make such a request, the share of light-duty battery electric vehicles compared to the total fleet of light-duty vehicles registered in the Member State should have reached at least 15% and the Member State should duly justify its request.

(17) As part of the review of this Regulation, it is important that the Commission assess the need to include requirements for recharging infrastructure to serve electrically power-assisted bicycles and L-category vehicles such as powered electric bicycles and electric mopeds, and in particular the opportunity to equip recharging infrastructure with a household power socket that makes it possible for such vehicles to be easily charged, since they represent a mode of transport that can help further reduce CO₂ emissions and air pollution.

(18) Heavy-duty electric vehicles need a distinctively different recharging infrastructure than light-duty electric vehicles. Currently, however, there is almost no available publicly accessible infrastructure for heavy-duty electric vehicles in the Union and the deployment of such infrastructure needs to be accelerated. A combined approach of distance-based targets along the TEN-T network, with appropriate distinction between the TEN-T core network and TEN-T comprehensive network, targets for overnight recharging infrastructure and targets at urban nodes should ensure that a sufficient publicly accessible recharging infrastructure coverage for heavy-duty electric vehicles is established throughout the Union to support the expected market-share increase of heavy-duty battery electric vehicles.
A sufficient number of publicly accessible fast recharging points dedicated to heavy-duty vehicles should be deployed along the TEN-T network to ensure full connectivity throughout the Union. That infrastructure should have sufficient power output for heavy-duty vehicles to be recharged within the driver’s legal break time. In order to take into account the time needed for the planning, design and implementation of recharging infrastructure, which might include extending or upgrading the electricity grid in certain areas, land acquisition, environmental authorisations, and, if necessary, the awarding of public contracts, and in order to adapt to the progressive uptake of heavy-duty electric vehicles, publicly accessible recharging infrastructure for such vehicles should be deployed progressively from 2025 with a view to covering the entire TEN-T network by 2030.

For the purposes of deployment of recharging infrastructure along the TEN-T road network, all recharging stations to be deployed along the TEN-T road network should be located on the TEN-T road network or within 3 km driving distance from the nearest exit of a TEN-T road.

Some Member States are in the process of upgrading sections of the TEN-T network in order to meet the requirements laid down in Regulation (EU) No 1315/2013 of the European Parliament and of the Council (9). In doing so, Member States should strive to ensure that the requirements for the deployment of recharging and refuelling infrastructure along the TEN-T network set out in this Regulation are implemented in a comprehensive manner in order to avoid stranded assets and in a way that ensures the coordinated implementation of Regulation (EU) No 1315/2013 and this Regulation.

New recharging infrastructure standards for heavy-duty electric vehicles are currently being developed. Therefore, the Commission should consider increasing the individual power output of recharging stations at recharging pools once the new common technical specifications are available.

The recharging infrastructure along the TEN-T network should be complemented with publicly accessible fast recharging infrastructure in urban nodes. That infrastructure is necessary in particular for providing charging opportunities for delivery trucks and for destination charging for long-haul trucks. Recharging points for light-duty electric vehicles in urban areas, however, should fall within the national fleet-based target. In addition to fast recharging points along the TEN-T network and in urban nodes, heavy-duty electric vehicles should also be able to use publicly accessible recharging infrastructure for overnight recharging along the main transport network to specifically support the electrification of the long-haul sector.

In order to avoid investments that would be disproportionate compared to the traffic volumes on some roads of the TEN-T network in cases where the deployment of recharging infrastructure cannot be justified in socio-economic cost-benefit terms, Member States should be able to provide that one publicly accessible recharging pool serves both directions of travel, provided that the other applicable requirements are met in terms of the maximum distance between recharging pools, the total power output of the recharging pool and the number of recharging points at the recharging pools that are applicable for a single direction of travel. Alternatively, Member States should be able to reduce the total power output of the recharging pools dedicated to light-duty electric vehicles or heavy-duty electric vehicles located along the TEN-T road network with low traffic volumes of respectively light-duty electric vehicles or heavy-duty electric vehicles. For the same purpose, Member States should also be able to allow a higher maximum distance between the publicly accessible recharging pools dedicated to light-duty electric vehicles or heavy-duty electric vehicles along roads of the TEN-T core network with very low traffic volumes.

Given the insular character of Cyprus, the absence of any land connection with other Member States and the mainland and the limited extent of its TEN-T road network, the long-distance heavy-duty traffic circulating in that Member State is limited. In addition, given the limited daily mileage of heavy-duty electric vehicles in Cyprus, their recharging needs will mostly be covered by overnight recharging capacities in private locations, such as depots. Cyprus would therefore be under a disproportionate and unnecessary obligation if it had to meet the requirements set out in this Regulation concerning minimum coverage of publicly accessible recharging pools dedicated to heavy-duty vehicles in its territory in terms of the level of total power output of such recharging pools located along the

TEN-T network and the maximum distance between those recharging pools. Consequently, Cyprus should be able to submit to the Commission a reasoned request for authorisation to apply lower requirements in that respect, provided that such lower requirements would not impede the circulation of heavy-duty electric vehicles in that Member State.

(26) Owners of electric vehicles are expected to make use to a large extent of recharging points at their own premises or in collective parking places in residential and non-residential buildings. While the deployment of ducting infrastructure and of recharging points in such buildings is regulated by Directive 2010/31/EU of the European Parliament and of the Council (10), it is important that Member States take into account the availability of such private infrastructure when planning the deployment of publicly accessible recharging points.

(27) The deployment of recharging infrastructure for heavy-duty electric vehicles is equally important in private locations that are not accessible to public, such as in private depots and at logistics centres to ensure overnight and destination charging. Public authorities should consider taking measures in the context of setting up their revised national policy frameworks to ensure that appropriate infrastructure is provided for overnight and destination charging for heavy-duty electric vehicles.

(28) In accordance with the principles laid down in the Commission Communication of 23 March 2017 entitled ‘European Interoperability Framework – Implementation Strategy’, the possibility to develop advanced digital services, including contract-based payment solutions, and to ensure transparent user information by digital means depends on the deployment of digitally connected and smart recharging points that support the creation of a digitally connected and interoperable infrastructure. Those smart recharging points should comprise a set of physical attributes and technical specifications (hardware and software) that are necessary for sending and receiving data in real-time and enabling the flow of information between market actors that are dependent on those data for fully developing the recharging experience, including recharging point operators, mobility service providers, e-roaming platforms, distribution systems operators and, ultimately, end users.

(29) Smart metering systems as defined in Directive (EU) 2019/944 of the European Parliament and of the Council (11) enable real-time data to be produced, which is needed to ensure the stability of the electricity grid and to encourage rational use of recharging services. By providing energy metering in real-time and accurate and transparent information on cost, the smart metering systems encourage, in combination with smart recharging points, recharging at times of low general electricity demand and low energy prices. The use of smart metering systems in combination with smart recharging points can optimise recharging, with benefits for the electricity system and for the end user. Member States should encourage the use of smart metering systems for the recharging of electric vehicles at publicly accessible recharging stations, where technically feasible and economically reasonable, and should ensure that those systems comply with the requirements laid down in Article 20 of Directive (EU) 2019/944.

(30) The increasing number of electric vehicles in road, rail, maritime and other transport modes will require recharging operations to be optimised and managed in such a way that does not cause congestion and takes full advantage of the availability of renewable electricity and low electricity prices in the system. Smart recharging in particular can facilitate the further integration of electric vehicles into the electricity system as it enables a demand response through aggregation. System integration can be further facilitated through bidirectional recharging (vehicle-to-grid), while smart and bi-directional recharging can also reduce recharging costs for the consumer. All recharging points built or renovated after 13 April 2024 should therefore support smart recharging. In addition, communication standards supporting smart and bidirectional recharging should be adopted to ensure interoperability.


(31) The development of on-grid and off-grid infrastructure for electric vehicles, the interaction of that infrastructure with the electricity system, and the rights and responsibilities assigned to the different actors in the electric mobility market have to be consistent with the principles established by Directive (EU) 2019/944. In that context, distribution system operators should cooperate on a non-discriminatory basis with any person establishing or operating publicly accessible recharging points. The access of Union electricity suppliers to recharging points should be without prejudice to the derogations provided for in Article 66 of Directive (EU) 2019/944.

(32) The establishment and operation of recharging points for electric vehicles should be developed as a competitive market with open access to all parties interested in rolling-out or operating recharging infrastructure. In view of the limited alternative locations for recharging points for electric vehicles on motorways, existing motorway concessions such as for conventional refuelling stations or rest areas are a particular cause for concern, since they can run for very long periods or, sometimes, even lack a specific end-date altogether. Member States should seek, to the extent possible and in compliance with Directive 2014/23/EU of the European Parliament and of the Council (12), to competitively award new concessions specifically for recharging stations on or adjacent to existing motorway rest areas in order to prevent the encroachment of green spaces, as well as to limit deployment costs and to enable new market entrants.

(33) Price transparency is crucial to ensuring seamless and easy recharging and refuelling. Users of alternative fuel vehicles should be provided with accurate price information before the start of the recharging or refuelling session. The price should be communicated in a clearly structured manner to allow end users to identify the different price components charged by the operator when calculating the price of a recharging or refuelling session and to anticipate the total cost. The operators of recharging stations should also be allowed to charge additional fees with a view, inter alia, to avoiding blocking the recharging point from being used by other users, as long as those fees are clearly indicated and communicated before the start of the recharging session. If the price for the recharging on an ad hoc basis is provided on a dedicated webpage, it should be clearly provided on the same webpage as the one used for the payment of the session. Laying down requirements for operators and mobility service providers would provide guarantees and predictability for consumers and thus contribute to ensuring confidence during the initial stages of uptake of electric mobility. It would also encourage the rapid uptake of battery electric vehicles and hydrogen-powered vehicles, which is essential for achieving the increased climate ambitions of the Union and the priorities set out in Commission Communication of 11 December 2019 entitled ‘The European Green Deal’. Prices should be reasonable and should not exceed the costs incurred plus a reasonable profit margin. Those price requirements are without prejudice to the right of Member States to determine the applicable unit price of the electricity charged from a recharging station in accordance with Directive 98/6/EC of the European Parliament and of the Council (13).

(34) New services emerge over time in support of the use of electric vehicles. Incentives provided by Member States, as well as binding measures adopted by them, such as mandatory roaming capability on designated recharging points, have played a significant role in the development of such new services. Entities offering those new services, such as mobility service providers, should be able to operate under fair market conditions. In particular, operators of recharging points should not give unduly preferential treatment to some mobility service providers, for instance through unjustified price differentiation, that may impede competition and ultimately lead to higher prices for consumers. In order to ensure the transition to new services and to ensure that users of such vehicles can easily and without hindrance use recharging infrastructure everywhere in the Union, Member States should monitor the development of the recharging market. When reviewing this Regulation, the Commission should take action where required by market developments such as limitations of services for end users, services misleading consumers and hampering price transparency, or business practices that may limit competition.

(35) Hydrogen-powered vehicles have at present very low market penetration rates. However, a deployment of sufficient hydrogen refuelling infrastructure is essential in order to make large-scale use of hydrogen-powered vehicles possible as envisaged in the Commission Communication of 8 July 2020 entitled ‘A hydrogen strategy for a climate-neutral Europe’. Currently, hydrogen refuelling points are only deployed in a few Member States and are largely unsuitable for heavy-duty vehicles. It is therefore not possible for hydrogen-powered vehicles to circulate throughout the Union. Mandatory deployment targets for publicly accessible hydrogen refuelling points should ensure a sufficiently

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A dense network of hydrogen refuelling points across the TEN-T core network to allow for the seamless travel of hydrogen-powered light-duty and heavy-duty vehicles throughout the Union. For the purposes of deployment of hydrogen refuelling infrastructure along the TEN-T network, all hydrogen refuelling stations to be deployed along the TEN-T road network should be located on the TEN-T road network or within 10 km driving distance from the nearest exit of a TEN-T road.

(36) Users of alternative fuel vehicles should be able to recharge or refuel on an ad hoc basis and pay easily and conveniently at all publicly accessible recharging and refuelling points, without the need to enter into a contract with the operator of the recharging or refuelling point or a mobility service provider. Therefore, for recharging or refuelling on an ad hoc basis, all publicly accessible recharging and refuelling points should accept payment instruments that are widely used in the Union, and in particular electronic payments through terminals and devices used for payment services. As regards infrastructure deployed before the date of application of this Regulation, the application of those requirements should be deferred. That ad hoc payment method should always be available to consumers, even when contract-based payments are offered at the recharging or refuelling point.

(37) Regardless of the brand of their vehicle, end users should be able to access and use publicly accessible recharging stations in a user-friendly and non-discriminatory way.

(38) Transport infrastructure should allow seamless mobility and accessibility for all users, including older persons, persons with reduced mobility and persons with disabilities. In principle, the location of all recharging and refuelling stations, as well as the recharging and refuelling stations themselves, should be designed in such a way that they are accessible to and user-friendly for as much of the public as possible, in particular older persons, persons with reduced mobility and persons with disabilities. This should include, for example, providing sufficient space around the parking place, ensuring that the recharging station is not installed on a kerb surface, ensuring that the buttons or screen of the recharging station are at an appropriate height and the weight of the recharging and refuelling cables is such that persons with limited strength can handle them with ease. In addition, the user interface of the related recharging stations should be accessible. In that sense, the accessibility requirements set out in Directive (EU) 2019/882 of the European Parliament and of the Council (14) should be applicable to recharging and refuelling infrastructure.

(39) The safety and security of users, particularly at unattended recharging stations, could be addressed by equipping the recharging stations with emergency buttons, displaying emergency services contact information, ensuring adequate lighting or by any other appropriate measures.

(40) Hydrogen-powered vehicles should be able to refuel at or close to the destination, which is usually located in an urban area. To ensure that publicly accessible destination refuelling is possible at least in the main urban areas, such hydrogen refuelling stations should be provided for in all urban nodes as defined in Regulation (EU) No 1315/2013. Within the urban nodes, public authorities should consider deploying the hydrogen refuelling stations within multimodal hubs, as such hubs are a typical destination for heavy-duty vehicles and because they could also supply hydrogen to other transport modes, such as rail and inland shipping. It should be possible for one publicly accessible hydrogen refuelling station located within an urban node to be taken into account to fulfil the TEN-T requirement, provided the capacity target is achieved.

(41) At this early stage of market deployment there is still a degree of uncertainty with regard to the kind of vehicles that will come onto the market and to the kind of technologies that will be widely used. In the hydrogen strategy for a climate-neutral Europe, the heavy-duty segment was identified as the most likely segment for the early mass deployment of hydrogen-powered vehicles. Therefore, hydrogen refuelling infrastructure should focus on that segment initially, while also allowing light-duty vehicles to fuel at publicly accessible hydrogen refuelling stations. To ensure interoperability, all publicly accessible hydrogen stations should at least serve gaseous hydrogen at 700 bar. The roll out of the infrastructure should also take into account the emergence of new technologies, such as liquid hydrogen technology, that allow for a larger range for heavy-duty vehicles and are expected to be the preferred technology choice of some vehicle manufacturers.

The development of new technologies will require coordination among all stakeholders. For example, the Clean Hydrogen Joint Undertaking, set up by Council Regulation (EU) 2021/2083 (15), should also be used with a view to facilitating and leveraging private funding so that the relevant targets identified in this Regulation can be reached.

A number of liquefied methane refuelling points are established in the Union, already providing a backbone for the circulation of liquefied methane driven heavy-duty vehicles. The TEN-T core network should remain the basis for the deployment of liquefied methane infrastructure as it covers the main traffic flows and allows cross-border connectivity throughout the Union. Directive 2014/94/EU recommended that such refuelling points be deployed every 400 km along the TEN-T core network. However, the existence of a limited number of gaps along the network has prevented that target from being reached. Member States should reach that target and fill the remaining gaps by 2025, after which the target should cease to apply.

For the purposes of this Regulation, the term ‘liquefied methane’ should be understood to mean ‘LNG, liquefied biogas or synthetic liquefied methane, including blends of these fuels’. The use of the defined term ‘liquefied methane’ does not alter the definition or composition of the separate fuels (LNG, liquefied biogas or synthetic liquefied methane), as defined in other Union legal acts.

Shore-side electricity facilities, either fixed or mobile, can serve maritime transport and inland navigation in providing a clean power supply and can contribute to reducing the environmental, climate and health impact of seagoing ships and inland waterway vessels, in particular in terms of air quality for urban areas surrounding ports. Under Regulation (EU) 2023/1805 ship operators of seagoing container ships and seagoing passenger ships are to reduce the amount of emissions produced by their ships while moored at the quayside. Mandatory deployment targets should ensure that the sector finds sufficient shore-side electricity supply for ships that are moored at the quayside in TEN-T core maritime ports and TEN-T comprehensive maritime ports to comply with those requirements. Therefore, it is important to lay down clear targets for shore-side electricity infrastructure deployment in TEN-T ports. In view of the fact that Member States have different governance models for ports, in order to reach those targets, Member States should be able to decide on the best way for them in which to deploy infrastructure within their ports and in the different terminals according to their needs. It is important that within ports, and where relevant between terminals, infrastructure be deployed where the maximum return on investment and occupancy rate result in the highest environmental benefits in terms of greenhouse gas emissions reductions and air pollution reductions.

The planning, development and deployment of shore-side electricity supply for seagoing ships requires a coordinated approach to match supply and demand. Therefore, all public and private stakeholders on both the ship side and the port side, as well as any other relevant market actors, should coordinate to allow for smooth operation on an everyday basis.

It is important to avoid stranded assets and to make sure that the public and private investments that are made today are future-proof and contribute to the transition to climate neutrality as set out in the European Green Deal. The deployment of shore-side electricity supply in maritime ports has to be seen together with the current and future deployment of equivalent alternative zero-greenhouse gas emissions technologies and zero-pollution technologies, in particular those technologies that deliver emission and pollution reductions both at berth and during navigation.

As a priority, seagoing container ships and seagoing passenger ships, being the ship categories which produce the highest amount of emissions per ship while moored at the quayside, should be provided with a shore-side electricity supply. In order to take into account the power demand characteristics of different seagoing passenger ships moored at the quayside, as well as port operational characteristics, it is necessary to distinguish between the seagoing passenger ship requirements for ro-ro passenger ships and high-speed passenger crafts on the one hand, and those for other seagoing passenger ships, on the other.

(49) The mandatory deployment targets should take into account the types of vessels served and traffic volumes of maritime ports. In order to avoid the installation of capacity that will be underused, maritime ports with low traffic volumes of certain ship categories based on the average annual number of port calls should not be subject to the mandatory deployment targets for the corresponding ship categories. Similarly, the mandatory targets should not aim to target maximum demand, but a sufficiently high volume, in order to avoid underused capacity and to take account of port operational characteristics.

(50) When determining the number of the port calls, port calls of short duration, port calls of ships that use zero-emission technologies, unscheduled port calls for reasons of safety or saving lives at sea, port calls under exceptional circumstances requiring the use of on-board energy generation, port calls under emergency situations that represent immediate risk to life, the ship or the environment or port calls for other reasons of force majeure should not be taken into account.

(51) Maritime transport is an important factor in the cohesion and economic development of islands and the outermost regions of the Union, as well as for Ceuta and Melilla. Electricity production capacity in those islands, regions and territories may not always be sufficient to account for the power demand required to support the provision of shore-side electricity supply. In such cases, those islands, regions and territories are to be exempted from the requirement to provide shore-side electricity supply unless and until such an electrical connection with the mainland or neighbouring countries, as the case may be, has been completed or there is sufficient locally generated capacity from non-fossil energy sources.

(52) An appropriate number of refuelling points for liquefied methane in TEN-T core maritime ports should be available by 2025. The deployment of that infrastructure should be driven by market demand. Refuelling points for liquefied methane include liquefied methane terminals, tanks, tank truck trailers, truck tankers, mobile containers, bunker vessels and barges.

(53) Installations providing shore-side electricity supply should also be deployed in inland waterway ports of the TEN-T network.

(54) The use of an external electricity supply should replace the use of the engines when aircraft are stationary at airports. This should reduce pollutant and noise emissions, improve air quality and reduce the impact of aircraft on climate change. Therefore, for all commercial transport operations, an external electricity supply should be provided while aircraft are parked at the aircraft contact stands or aircraft remote stands at airports of the TEN-T network. The external electricity supply to aircraft could be ensured by fixed or mobile ground power units, both at aircraft contact stands and aircraft remote stands. While aircraft should be able to make use of external electricity supply at all aircraft contact stands and aircraft remote stands used for commercial air transport operations, it is not necessary for each stand to be equipped with a fixed or mobile ground power unit, since a single ground power unit, whether fixed or mobile, is capable of serving multiple stands and of being deployed to meet operational needs.

(55) When ensuring that stationary aircraft are provided with access to an electricity supply in airports, Member States should, where appropriate, promote cooperation of the airport managing body with suppliers of ground-handling services, as well as, where relevant, with self-handling airport users. Member States should in particular do so through the Airport Users' Committee set up pursuant to Council Directive 96/67/EC (16).

(56) Members States should be able to exempt airports of the TEN-T network with less than 10 000 commercial flight movements per year, calculated as an average over the previous three years, from the obligation to provide electricity to stationary aircraft at all remote stands. In view of the number of flights concerned, the investment and maintenance costs for providing the aircraft remote stands with electricity in those airports of the TEN-T network might not be proportionate to the environmental benefit, especially in comparison with more efficient investments to tackle airports’ CO₂ emissions.

In accordance with Directive 2014/94/EU, Member States have established national policy frameworks outlining their objectives and plans to ensure that those objectives are met. Both the assessment of the national policy frameworks and the evaluation of Directive 2014/94/EU have highlighted the need for higher ambition and a better coordinated approach across Member States in view of the expected acceleration in the uptake of alternative fuel vehicles, in particular of electric vehicles. Furthermore, alternatives to fossil fuels will be needed in all transport modes to meet the ambitions of the European Green Deal and the Union climate objectives. The existing national policy frameworks should be revised to clearly describe how the much greater need for publicly accessible recharging and refuelling infrastructure as expressed in the mandatory targets is going to be met by the Member States. The revised national policy frameworks could also address transport modes for which no mandatory deployment targets exist. Member States should regularly report on the progress made with regard to the implementation of those revised national policy frameworks.

Moreover, Member States should regularly assess how the deployment and operation of recharging points could enable electric vehicles to further contribute to the flexibility of the energy system and to the further absorption of renewable electricity. That assessment should identify the appropriate measures to be implemented to ensure consistency of the infrastructure planning with the respective grid planning in order to meet the requirements set out in this Regulation. Without prejudice to Regulation (EU) 2019/943 of the European Parliament and of the Council (17) and Directive (EU) 2019/944, Member States should take all necessary steps to ensure that the electricity grid meets the power demand of the recharging infrastructure provided for in this Regulation. To that end, Member States should upgrade and maintain the electricity grid so that it is able to handle present and future demand from the transport sector for electricity.

The revised national policy frameworks should include support measures for the development of the market as regards alternative fuels, including the deployment of the necessary alternative fuels infrastructure to be put into place, in close cooperation with regional and local authorities and with the industry concerned, while taking into account the needs of small and medium-sized enterprises. Additionally, the revised national policy frameworks should describe the overall national framework for planning, permitting and procuring of such infrastructure, identify any obstacles and the actions that will be taken to remove them so that the time between the deployment and use of the infrastructure is reasonable and a faster rollout of infrastructure can be achieved. When revising the national policy frameworks, it is important to observe the general principles of technological neutrality and energy efficiency first. Member States should list all measures that have been adopted or are planned.

The development and implementation of the revised national policy frameworks of the Member States should be facilitated by the Commission by means of exchanges of information and best practices between the Member States. Each Member State should also be able to decide to appoint a national coordinator for the deployment of alternative fuels infrastructure with the task of overseeing the national coordination and implementation of the national policy framework.

In order to promote alternative fuels and develop the relevant infrastructure, the national policy frameworks should provide an overview of the state of play, perspectives and planned initiatives to promote alternative fuels in sectors that are difficult to decarbonise such as aviation, maritime transport, inland navigation, as well as rail transport on rail sections that cannot be electrified. In particular, Member States should provide an overview of the state of play, perspectives and planned initiatives for the decarbonisation of inland navigation along the TEN-T network in close cooperation with the Member States concerned. Long term decarbonisation strategies could also be developed for ports of the TEN-T network and airports of the TEN-T network, in particular with a focus on the deployment of infrastructure for low- and zero-emission vessels and aircraft, as well as for railway lines that are not going to be electrified. On the basis of those strategies, and taking into consideration the national market and traffic share data and market projections, the Commission should review this Regulation with a view to setting additional mandatory targets for those sectors.

The development of alternative fuel technologies is also important for railways, where direct electrification of a rail section might not be possible for reasons such as the cost-efficiency of the service. Different technologies are available to which the rail sector can switch from diesel trains, including direct electrification, battery-powered trains and hydrogen applications. The development of those technologies requires the deployment of suitable recharging and refuelling infrastructure in Member States.

Member States should make use of a wide range of regulatory and non-regulatory incentives and measures to reach the mandatory targets and implement their national policy frameworks, in close cooperation with private sector actors, who should play a key role in supporting the development of alternative fuels infrastructure.

Pursuant to Directive 2009/33/EC of the European Parliament and of the Council, minimum national shares of public procurement are reserved for clean buses and zero-emission buses, where a clean bus uses alternative fuels as defined in this Regulation. With ever more public transport authorities and operators switching to clean buses and zero-emission buses in order to reach those mandatory targets, it is important that Member States include the targeted promotion and development of the necessary recharging and refuelling infrastructure for buses as a key element in their national policy frameworks. It is also important that Member States establish and maintain appropriate instruments to promote the deployment of recharging and refuelling infrastructure for buses also for captive fleets, in particular for clean buses and zero-emission buses at local level.

In light of the increasing diversity in the type of fuels for motorised vehicles coupled with on-going growth in the road mobility of citizens across the Union, it is necessary to provide consumers with clear and easy-to-understand information on the fuels available at refuelling stations and on the compatibility of their vehicles with different fuels or recharging points on the Union market.

Simple and easy-to-compare information on price of different fuels could play an important role in enabling consumers to better evaluate the relative cost of individual fuels available on the market. Therefore, a unit price comparison of certain alternative fuels and conventional fuels, expressed as ‘fuel price per 100 km’, should be shown for information purposes at all relevant refuelling stations. It should be made clear to consumers that such comparisons concern the average fuel prices in the Member State, which might differ from the actual prices charged at the refuelling station concerned. Moreover, the Commission should, if appropriate, review Directive 1999/94/EC of the European Parliament and of the Council in order to ensure that consumer information on fuel economy and CO₂ emissions in respect of the marketing of new passenger cars, as provided for by that Directive, takes into account and reflects the developments related to the transition to alternative fuels.

It is necessary to provide consumers with sufficient information regarding the geographic location, characteristics and services offered at the publicly accessible recharging and refuelling points of alternative fuels covered by this Regulation. Therefore, Member States should ensure that operators or owners of publicly accessible recharging and refuelling points make relevant static data and dynamic data available. Requirements on data types regarding the availability of and accessibility to relevant data related to recharging and refuelling should be laid down, building on the outcomes of the Programme Support Action on 'Data collection related to recharging/refuelling points for alternative fuels and the unique identification codes related to e-mobility actors' (IDACS), that was concluded in 2022.

This Regulation addresses data types that are necessary for the functioning of a competitive and open market, and essential for end users to make informed decisions on their recharging and refuelling sessions including through high-quality information services developed by relevant market actors. The data types requirements laid down in this Regulation should apply only to the data that are available in a digital machine-readable format.


Data should play a fundamental role in the adequate functioning of recharging and refuelling infrastructure. The format, the frequency and the quality in which those data should be made available and accessible determine the overall quality of an alternative fuels infrastructure that meets user needs. Moreover, those data should be accessible in a coherent manner in all Member States. Member States should make the data concerning alternative fuels infrastructure available as open data through their national access point in accordance with Commission Delegated Regulation (EU) 2022/670 and in compliance with the additional specifications that are complementary to those set out in that Delegated Regulation. It should also be possible for such data to be provided to a common European access point that the Commission should establish, which should function as a single Union data gateway for the data made available by operators in the national access points. The common European access point should, where possible, build on the existing structures and functions of the European Alternative Fuels Observatory (‘EAFO’) in conjunction with the TENtec Information System or, for example, be made accessible through a dedicated web portal. The common European access point should enable data users to easily access data, to compare information on price and to obtain information on the characteristics of the alternative fuels infrastructure, such as accessibility, availability or power capacity.

It is crucial that all actors in the electric mobility sector can interact easily through digital means to provide the best service quality to end users. Such interaction requires unique identifiers for the actors in the value chain. To that end, all Member States should establish an Identification Registration Organisation (‘IDRO’) for issuing and managing unique identification (‘ID’) codes to identify, as a minimum, operators of recharging points and mobility service providers. Each IDRO should collect information on e-mobility ID codes that are already in use in its Member State, issue new e-mobility ID codes, where needed, to recharging point operators and mobility service providers under an Union-wide common agreed logic in which e-mobility ID codes are formatted, and enable the exchange of those e-mobility codes and the verification of their uniqueness via a potential future common Identification Registration Repository (‘IDRR’). The Commission should issue technical guidance on the set up of such organisations, drawing on the outcome of IDACS.

Technical specifications for interoperability of recharging and refuelling points should be specified in European or international standards. The European standardisation organisations should adopt European standards in accordance with Article 10 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council. It is important that those standards be based on current international standards or ongoing international standardisation work, where applicable. To that end, it is important that European standardisation processes for recharging and refuelling infrastructure proceed quickly, supporting prompt adherence to the timeline necessary for planning, tendering and building the infrastructure required under this Regulation. It is also important to initiate or accelerate the standardisation processes for a Union-wide harmonised recharging infrastructure for stationary and dynamic recharging.

Maritime transport and inland navigation need new standards to facilitate and consolidate the entry into the market of alternative fuels, in relation to electricity supply and hydrogen, methanol and ammonia bunkering, as well as standards for communication exchange between vessels and infrastructure.

The International Maritime Organization (‘IMO’) develops uniform and internationally recognised safety and environmental standards for maritime transport. Conflicts with international standards should be avoided in view of the global nature of maritime transport. Therefore, the Union should ensure that technical specifications for maritime transport adopted pursuant to this Regulation are consistent with international rules adopted by the IMO.

In the application of this Regulation, the Commission should consult relevant expert groups, and in particular the Sustainable Transport Forum (STF) and the European Sustainable Shipping Forum (ESSF). Such expert consultation is of particular importance when the Commission intends to adopt delegated or implementing acts under this Regulation.

Alternative fuels infrastructure is a rapidly developing area. The lack of common technical specifications constitutes a barrier for the creation of a single market of alternative fuels infrastructure. Therefore, it is necessary to lay down technical specifications for areas where common technical specifications are necessary but do not yet exist. In particular, those technical specifications should cover the communication between the electric vehicle and the recharging point, the communication between the recharging point and the recharging software management system (back-end), the communication related to the electric vehicle roaming service and the communication with the electricity grid, while ensuring the highest level of cybersecurity protection and protection of final customers’ personal data. It is also necessary to establish a suitable governance framework and the roles of the different actors involved in the vehicle-to-grid communication sector. Moreover, emerging technological developments, such as electric road systems, in particular dynamic overhead power supply via a pantograph, dynamic ground level power supply through conductive rails and inductive power supply through coils in the road, have to be accounted for. As regards data provision, it is necessary for additional data types, such as the data related to the existence of facilities offering associated services to end users, the data related to the accepted payment methods, the data related to the available languages on the infrastructure and the data related to providing smart and bidirectional recharging services, to be added to the data on publicly accessible recharging.

In order to supplement this Regulation by establishing further technical specifications and to amend this Regulation by adding additional data types, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in respect of common technical requirements for a common application programme interface to enable an automated and uniform data exchange between the operators of publicly accessible recharging and refuelling points and data users. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making (22). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States’ experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with respect to the development of labelling provisions, to the format, frequency and quality of data on publicly accessible recharging and refuelling points to be made available and accessible under this Regulation and to the procedure enabling that availability and accessibility. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council (23).

The market for alternative fuels and in particular for zero-emission fuels is still in the early stages of development and technology is evolving fast. This development is likely to affect the demand for alternative fuels and consequently for alternative fuels infrastructure across all transport modes. The Commission should therefore, by 31 December 2024, present a technology and market readiness report dedicated to heavy-duty vehicles. That report should take into account the first indications of the preferences of the market and consider the technological development and the development of the technical specifications. By 31 December 2026 and every five years thereafter, the Commission should carry out a review of this Regulation.

\(^{(22)}\) Of L 123, 12.5.2016, p. 1.
Given that this Regulation will result in additional adjustment and administrative costs, the overall regulatory burden for the sectors covered by this Regulation should be kept under close review. Against that backdrop, in its report evaluating the functioning of this Regulation the Commission should assess the extent to which the objectives of this Regulation have been met and the extent to which it has impacted the competitiveness of the relevant sectors. That review should also cover the interaction of this Regulation with other relevant Union legal acts, including possible actions and measures that have been or could be taken to reduce the total cost pressure on the relevant sectors.

Since the objective of this Regulation, namely to ensure the deployment of sufficient alternative fuels infrastructure in the Union, in particular for road vehicles, trains, vessels and stationary aircraft, cannot be sufficiently achieved by the Member States but can rather, by reason of the need to enable Union-wide mobility of alternative fuel vehicles, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

Directive 2014/94/EU should therefore be repealed. Commission Delegated Regulations (EU) 2019/1745 (24) and (EU) 2021/1444 (25) set out undated technical specifications for certain types of alternative fuels infrastructure and those specifications are now dated and listed in Annex II to this Regulation. Therefore, those Delegated Regulations should also be repealed.

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

1. This Regulation establishes mandatory national targets leading to the deployment of sufficient alternative fuels infrastructure in the Union for road vehicles, trains, vessels and stationary aircraft. It lays down common technical specifications and requirements on user information, data provision and payment requirements for alternative fuels infrastructure.

2. This Regulation also establishes rules for the national policy frameworks referred to in Article 14 to be adopted by the Member States, including rules for the deployment of alternative fuels infrastructure in areas where no mandatory Union-wide targets are set and for reporting on the deployment of such infrastructure.

3. This Regulation establishes a reporting mechanism to encourage cooperation and ensures robust tracking of progress. The reporting mechanism shall take the form of a structured, transparent and iterative process taking place between the Commission and Member States for the purpose of finalising the national policy frameworks, taking into account existing local and regional strategies for the deployment of alternative fuels infrastructure, and their subsequent implementation and corresponding Commission action to support the coherent and more rapid deployment of alternative fuels infrastructure in the Member States.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) ‘accessibility of data’ means the possibility to request and obtain data at any time in a machine readable format;


‘ad hoc price’ means the price charged by the operator of a recharging or refuelling point to an end user for recharging or refuelling on an ad hoc basis;

‘along the TEN-T road network’ means:

(a) with regard to electric recharging stations: that they are located on the TEN-T road network or within 3 km driving distance from the nearest exit of a TEN-T road; and

(b) with regard to hydrogen refuelling stations: that they are located on the TEN-T road network or within 10 km driving distance from the nearest exit of a TEN-T road;

‘alternative fuels’ means fuels or power sources which serve, at least partly, as a substitute for fossil oil sources in the energy used for transport and which have the potential to contribute to its decarbonisation and enhance the environmental performance of the transport sector, including:

(a) ‘alternative fuels for zero-emission vehicles, trains, vessels or aircraft’:

— electricity,
— hydrogen,
— ammonia,

(b) ‘renewable fuels’:

— biomass fuels, including biogas, and biofuels as defined in Article 2, points (27), (28) and (33), respectively, of Directive (EU) 2018/2001,
— synthetic and paraffinic fuels, including ammonia, produced from renewable energy,

(c) ‘non-renewable alternative fuels and transitional fossil fuels’:

— natural gas in gaseous form (compressed natural gas (CNG)) and liquefied form (liquefied natural gas (LNG)),
— liquefied petroleum gas (LPG),
— synthetic and paraffinic fuels produced from non-renewable energy;

‘aircraft contact stand’ means a stand in a designated area of the airport apron equipped with a passenger boarding bridge;

‘aircraft remote stand’ means a stand in a designated area of the airport apron not equipped with a passenger boarding bridge;

‘airport of the TEN-T core network or airport of the TEN-T comprehensive network’ means an airport as listed and categorised in Annex II to Regulation (EU) No 1315/2013;

‘automatic authentication’ means the authentication of a vehicle at a recharging point through the recharging connector or telematics;

‘availability of data’ means the existence of data in a digital machine-readable format;

‘battery electric vehicle’ means an electric vehicle that runs exclusively on the electric motor, with no secondary source of propulsion;

‘bi-directional recharging’ means a smart recharging operation where the direction of the electricity flow can be reversed, allowing that electricity flows from the battery to the recharging point it is connected to;

‘connector’ means the physical interface between the recharging or refuelling point and the vehicle through which the fuel or electric energy is exchanged;

‘commercial air transport’ means ‘commercial air transport’ as defined in Article 3, point (24), of Regulation (EU) 2018/1139 of the European Parliament and of the Council (26);

‘container ship’ means a ship designed exclusively for the carriage of containers in holds and on deck;

(15) ‘contract-based payment’ means a payment for a recharging or refuelling service from the end user to a mobility service provider on the basis of a contract concluded between that end user and that mobility service provider;

(16) ‘data user’ means any public authority, road authority, road operator, recharging and refuelling point operator, research or non-governmental organisation, mobility service provider, e-roaming platform, digital map provider or any other entity interested in using data to provide information, create services or perform research or analysis on alternative fuels infrastructure;

(17) ‘digitally-connected recharging point’ means a recharging point that can send and receive information in real time, communicate bi-directionally with the electricity grid and the electric vehicle, and that can be remotely monitored and controlled, including in order to start and stop the recharging session and to measure electricity flows;

(18) ‘distribution system operator’ means a ‘distribution system operator’ as defined in Article 2, point (29), of Directive (EU) 2019/944;

(19) ‘distributor’ means a ‘distributor’ as defined in Article 3, point (43), of Regulation (EU) 2018/858 of the European Parliament and of the Council;

(20) ‘dynamic data’ means data that change often or on a regular basis;

(21) ‘electric road system’ means a physical installation along a road for the transfer of electricity to an electric vehicle while the vehicle is in motion;

(22) ‘electric vehicle’ means a motor vehicle equipped with a powertrain containing at least one non-peripheral electric machine as energy converter with an electric rechargeable energy storage system, which can be recharged externally;

(23) ‘electricity supply to stationary aircraft’ means the supply of electricity through a standardised fixed or mobile interface to an aircraft when stationed at an aircraft contact stand or at an aircraft remote stand;

(24) ‘end user’ means a natural or legal person purchasing an alternative fuel for direct use in a vehicle;

(25) ‘e-roaming’ means the exchange of data and payments between the operator of a recharging or refuelling point and a mobility service provider from which an end user purchases a recharging or refuelling service;

(26) ‘e-roaming platform’ means a platform connecting market actors, notably mobility service providers and operators of recharging or refuelling points, to enable the provision of services between them, including e-roaming;

(27) ‘European standard’ means a ‘European standard’ as defined in Article 2, point (1)(b), of Regulation (EU) No 1025/2012;

(28) ‘general aviation’ means all civil aviation operations other than scheduled air services and non-scheduled air transport operations for remuneration or hire;

(29) ‘gross tonnage’ (GT) means ‘gross tonnage’ as defined in Article 3, point (e), of Regulation (EU) 2015/757 of the European Parliament and of the Council (28);

(30) ‘heavy-duty vehicle’ means a Category M₂ motor vehicle as described in Article 4(1), point (a)(ii), a Category M₃ motor vehicle as described in Article 4(1), point (a)(iii), a Category N₂ motor vehicle as described in Article 4(1), point (b)(ii) or a Category N₃ motor vehicle as described in Article 4(1), point (b)(iii), of Regulation (EU) 2018/858;

(31) ‘high-power recharging point’ means a recharging point with a power output of more than 22 kW for the transfer of electricity to an electric vehicle;

(32) ‘high-speed passenger craft’ means a ‘high-speed craft’ as defined in Regulation 1 of Chapter X of the International Convention for the Safety of Life at Sea, 1974 (SOLAS 74), which carries more than 12 passengers;

(33) ‘light-duty vehicle’ means a Category M₁ motor vehicle as described in Article 4(1), point (a)(i) or a Category N₁ motor vehicle as described in Article 4(1), point (b)(i), of Regulation (EU) 2018/858;

(34) ‘liquefied methane’ means LNG, liquefied biogas or synthetic liquefied methane, including blends of those fuels;

(35) ‘manufacturer’ means a ‘manufacturer’ as defined in Article 3, point (40), of Regulation (EU) 2018/858;

(36) ‘mobility service provider’ means a legal person that provides services in return for remuneration to an end user, including the selling of recharging or refuelling services;

(37) ‘normal power recharging point’ means a recharging point with a power output less than or equal to 22 kW for the transfer of electricity to an electric vehicle;

(38) ‘National Access Point’ means a digital interface set up by a Member State that constitutes a single point of access to data;

(39) ‘operator of a recharging point’ means the entity that is responsible for the management and operation of a recharging point and that provides a recharging service to end users, including in the name and on behalf of a mobility service provider;

(40) ‘operator of a refuelling point’ means the entity that is responsible for the management and operation of a refuelling point and that provides a refuelling service to end users, including in the name and on behalf of a mobility service provider;

(41) ‘passenger ship’ means a ship which carries more than 12 passengers, including cruise ships, high-speed passenger crafts and ro-ro passenger ships;

(42) ‘payment service’ means a ‘payment service’ as defined in Article 4, point (3), of Directive (EU) 2015/2366 of the European Parliament and of the Council (29);

(43) ‘plug-in hybrid vehicle’ means an electric vehicle with a conventional combustion engine combined with an electric propulsion system which can be recharged from an external electric power source;

(44) ‘power output’ means the theoretical maximum power, expressed in kW, that a recharging point, station or pool, or a shore-side electricity supply installation can provide to vehicles or vessels connected to that recharging point, station, pool or installation;

(45) ‘publicly accessible alternative fuels infrastructure’ means an alternative fuels infrastructure which is located at a site or premises that are open to the general public, irrespective of whether the alternative fuels infrastructure is located on public or private property, whether limitations or conditions apply in terms of access to the site or premise and irrespective of the applicable use conditions of the alternative fuels infrastructure;

(46) ‘Quick Response code’ (QR code) means an ISO/IEC 18004:2015-compliant encoding and visualisation of data;


(47) ‘recharge on an ad hoc basis’ means a recharging service purchased by an end user without the need for that end user to register, conclude a written agreement or enter into a commercial relationship with the operator of that recharging point that goes beyond the mere purchase of the recharging service;

(48) ‘recharging point’ means a fixed or mobile, on-grid or off-grid interface for the transfer of electricity to an electric vehicle which, although it may have one or more connectors to accommodate different connector types, is capable of recharging only one electric vehicle at a time, and which excludes devices with a power output less than or equal to 3,7 kW the primary purpose of which is not the recharging of electric vehicles;

(49) ‘recharging point, station or pool dedicated to light-duty vehicles’ means a recharging point, station or pool intended for the recharging of light-duty vehicles, due to the specific design of the connectors/plugs or the design of the parking space adjacent to the recharging point, station or pool, or both;

(50) ‘recharging point, station or pool dedicated to heavy-duty vehicles’ means a recharging point, station or pool intended for the recharging of heavy-duty vehicles, either due to the specific design of the connectors/plugs or to the design of the parking space adjacent to the recharging point, station or pool, or both;

(51) ‘recharging pool’ means one or more recharging stations at a specific location;

(52) ‘recharging station’ means a physical installation at a specific location, consisting of one or more recharging points;

(53) ‘recharging service’ means the sale or provision of electricity, including related services, through a publicly accessible recharging point;

(54) ‘recharging session’ means the full process of recharging a vehicle at a publicly accessible recharging point from the moment the vehicle is connected to the moment the vehicle is disconnected;

(55) ‘refuel on an ad hoc basis’ means a refuelling service purchased by an end user without the need for that end user to register, conclude a written agreement, or enter into a commercial relationship with the operator of that refuelling point that goes beyond the mere purchase of the refuelling service;

(56) ‘refuelling point’ means a refuelling facility for the provision of any liquid or gaseous fuel, through a fixed or a mobile installation, which is capable of refuelling only one vehicle, one train, one vessel or one aircraft at a time;

(57) ‘refuelling service’ means the sale or provision of any liquid or gaseous fuel through a publicly accessible refuelling point;

(58) ‘refuelling session’ means the full process of refuelling a vehicle at a publicly accessible refuelling point from the moment the vehicle is connected to the moment the vehicle is disconnected;

(59) ‘refuelling station’ means a single physical installation at a specific location, consisting of one or more refuelling points;

(60) ‘regulatory authority’ means a regulatory authority designated by each Member State pursuant to Article 57(1) of Directive (EU) 2019/944;

(61) ‘renewable energy’ means ‘energy from renewable sources’ as defined in Article 2, second paragraph, point (1), of Directive (EU) 2018/2001;

(62) ‘ro-ro passenger ship’ means a ship with facilities to enable road or rail vehicles to roll on and roll off the vessel which carries more than 12 passengers;
Article 3

Targets for recharging infrastructure dedicated to light-duty electric vehicles

1. Member States shall ensure that, in their territory, publicly accessible recharging stations dedicated to light-duty electric vehicles are deployed in a way that is commensurate with the uptake of light-duty electric vehicles and that they provide sufficient power output for those vehicles.

To that end, Member States shall ensure that, at the end of each year, starting from 2024, the following power output targets are met cumulatively:

(a) for each light-duty battery electric vehicle registered in their territory, a total power output of at least 1,3 kW is provided through publicly accessible recharging stations; and

(b) for each light-duty plug-in hybrid vehicle registered in their territory, a total power output of at least 0,80 kW is provided through publicly accessible recharging stations.

2. When the share of light-duty battery electric vehicles compared to the total fleet of light-duty vehicles registered in the territory of a Member State reaches at least 15 % and the Member State demonstrates that the implementation of the requirements set out in paragraph 1, second subparagraph, has adverse effects in that Member State, in that it is discouraging private investments, and is no longer justified, that Member State may submit to the Commission a reasoned request for authorisation to apply lower requirements in terms of level of total power output or to cease to apply such requirements.

3. The Commission shall, within six months of receipt of a reasoned request submitted pursuant to paragraph 2, adopt a decision as justified in each case.

4. Member States shall ensure a minimum coverage of publicly accessible recharging points dedicated to light-duty electric vehicles on the road network in their territory.

To that end, Member States shall ensure that:

(a) along the TEN-T core road network, publicly accessible recharging pools dedicated to light-duty electric vehicles and meeting the following requirements are deployed in each direction of travel with a maximum distance of 60 km between them:

(i) by 31 December 2025, each recharging pool offers a power output of at least 400 kW and includes at least one recharging point with an individual power output of at least 150 kW;

(ii) by 31 December 2027, each recharging pool offers a power output of at least 600 kW and includes at least two recharging points with an individual power output of at least 150 kW;

(b) along the TEN-T comprehensive road network, publicly accessible recharging pools dedicated to light-duty electric vehicles and meeting the following requirements are deployed in each direction of travel with a maximum distance of 60 km between them:

(i) by 31 December 2027, along at least 50 % of the length of the TEN-T comprehensive road network, each recharging pool offers a power output of at least 300 kW and includes at least one recharging point with an individual power output of at least 150 kW;

(ii) by 31 December 2030, each recharging pool offers a power output of at least 300 kW and includes at least one recharging point with an individual power output of at least 150 kW;

(iii) by 31 December 2035, each recharging pool offers a power output of at least 600 kW and includes at least two recharging points with an individual power output of at least 150 kW.

5. The calculation of the percentage of the length of TEN-T comprehensive road network referred to in paragraph 4, point (b)(i), shall be based on the following elements:

(a) for the calculation of the denominator: the total length of the TEN-T comprehensive road network within the territory of the Member State;

(b) for the calculation of the numerator: the cumulated length of the sections of the TEN-T comprehensive road network between two publicly accessible recharging pools dedicated to light-duty electric vehicles meeting the requirements set out in paragraph 4, point (b)(i), excluding any sections of the TEN-T comprehensive road network between two of those recharging pools that are more than 60 km apart.

6. A single publicly accessible recharging pool dedicated to light-duty electric vehicles may be deployed along the TEN-T road network for both directions of travel provided that:

(a) that recharging pool is easily accessible from both directions of travel;

(b) that recharging pool is adequately signposted; and

(c) the requirements set out in paragraph 4 in terms of the maximum distance between recharging pools, total power output of the recharging pool, number of recharging points and power output of single recharging points applicable for a single direction of travel are complied with for both directions of travel.

7. By way of derogation from paragraph 4 of this Article, along roads of the TEN-T network with total annual average daily traffic of fewer than 8 500 light-duty vehicles and where the deployment of infrastructure cannot be justified in socio-economic cost-benefit terms, Member States may provide that a publicly accessible recharging pool dedicated to light-duty electric vehicles serves both directions of travel provided that the requirements set out in paragraph 4 of this Article, in terms of the maximum distance between recharging pools, the total power output of the recharging pool, the number of recharging points and the power output of single recharging points applicable for a single direction of travel, are complied with, and that the recharging pool is easily accessible from both directions of travel and adequately signposted. Member States shall notify the Commission of any cases in which they have made use of the derogation referred to in this paragraph. Member States shall review those cases every two years as part of the national progress reporting referred to in Article 15.
8. By way of derogation from paragraph 4 of this Article, along roads of the TEN-T network with a total annual average daily traffic of fewer than 8 500 light-duty vehicles and where the deployment of infrastructure cannot be justified in socio-economic cost-benefit terms, Member States may reduce, by up to 50 %, the total power output of a publicly accessible recharging pool dedicated to light-duty vehicles required pursuant to paragraph 4 of this Article, provided that that recharging pool serves only one direction of travel and that the other requirements set out in paragraph 4 of this Article, in terms of the maximum distance between recharging pools, the number of recharging points and the power output of single recharging points, are complied with. Member States shall notify the Commission of any cases in which they have made use of the derogation referred to in this paragraph. Member States shall review those cases every two years as part of the national progress reporting referred to in Article 15.

9. By way of derogation from the requirement relating to the maximum distance of 60 km between the publicly accessible recharging pools dedicated to light-duty vehicles set out in paragraph 4, points (a) and (b), of this Article, Member States may allow a longer distance, of up to 100 km, for such recharging pools along roads of the TEN-T network with a total annual average daily traffic of fewer than 3 000 light-duty vehicles, provided that the distance between recharging pools is adequately signposted. Member States shall notify the Commission of any cases in which they have made use of the derogation referred to in this paragraph. Member States shall review those cases every two years as part of the national progress reporting referred to in Article 15.

10. Where a Member State has notified the Commission of a case in which it has made use of a derogation referred to in paragraph 7, the requirements set out in paragraph 4, points (a) and (b), in terms of the maximum distance between recharging pools shall be deemed to have been complied with.

11. Neighbouring Member States shall ensure that the maximum distances referred to in paragraph 4, points (a) and (b), are not exceeded for cross-border sections of the TEN-T core road network and TEN-T comprehensive road network.

### Article 4

**Targets for recharging infrastructure dedicated to heavy-duty electric vehicles**

1. Member States shall ensure a minimum coverage of publicly accessible recharging points dedicated to heavy-duty electric vehicles in their territory.

To that end, Member States shall ensure that:

(a) by 31 December 2025, along at least 15 % of the length of the TEN-T road network, publicly accessible recharging pools dedicated to heavy-duty electric vehicles are deployed in each direction of travel and that each recharging pool offers a power output of at least 1 400 kW and includes at least one recharging point with an individual power output of at least 350 kW;

(b) by 31 December 2027, along at least 50 % of the length of the TEN-T road network, publicly accessible recharging pools dedicated to heavy-duty electric vehicles are deployed in each direction of travel and that each recharging pool:

(i) along the TEN-T core road network, offers a power output of at least 2 800 kW and includes at least two recharging points with an individual power output of at least 350 kW;

(ii) along the TEN-T comprehensive road network, offers a power output of at least 1 400 kW and includes at least one recharging point with an individual power output of at least 350 kW;

(c) by 31 December 2030, along the TEN-T core road network, publicly accessible recharging pools dedicated to heavy-duty electric vehicles are deployed in each direction of travel with a maximum distance of 60 km between them and that each recharging pool offers a power output of at least 3 600 kW and includes at least two recharging points with an individual power output of at least 350 kW;
(d) by 31 December 2030, along the TEN-T comprehensive road network, publicly accessible recharging pools dedicated to heavy-duty electric vehicles are deployed in each direction of travel with a maximum distance of 100 km between them and each recharging pool offers a power output of at least 1 500 kW and includes at least one recharging point with an individual power output of at least 350 kW;

(e) by 31 December 2027, in each safe and secure parking area at least two publicly accessible recharging stations dedicated to heavy-duty electric vehicles with an individual power output of at least 100 kW are deployed;

(f) by 31 December 2030, in each safe and secure parking area at least four publicly accessible recharging stations dedicated to heavy-duty electric vehicles with an individual power output of at least 100 kW are deployed;

(g) by 31 December 2025, in each urban node publicly accessible recharging points dedicated to heavy-duty electric vehicles with an aggregated power output of at least 900 kW are deployed, provided by recharging stations with an individual power output of at least 150 kW;

(h) by 31 December 2030, in each urban node publicly accessible recharging points dedicated to heavy-duty electric vehicles with an aggregated power output of at least 1 800 kW are deployed, provided by recharging stations with an individual power output of at least 150 kW.

2. The calculation of the percentage of the length of TEN-T road network referred to in paragraph 1, points (a) and (b), shall be based on the following elements:

(a) for the calculation of the denominator: the total length of the TEN-T road network within the territory of the Member State;

(b) for the calculation of the numerator: the cumulated length of the sections of the TEN-T road network between two publicly accessible recharging pools dedicated to heavy-duty electric vehicles meeting the requirements set out in paragraph 1, points (a) or (b) respectively, excluding any sections of the TEN-T road network between two of those recharging pools that are more than 120 km apart.

3. A single publicly accessible recharging pool dedicated to heavy-duty electric vehicles may be deployed along the TEN-T road network for both directions of travel provided that:

(a) that recharging pool is easily accessible from both directions of travel;

(b) that recharging pool is adequately signposted; and

(c) the requirements set out in paragraph 1 in terms of the maximum distance between recharging pools, total power output of the recharging pool, number of recharging points and power output of single points applicable for a single direction of travel are complied with for both directions of travel.

4. By way of derogation from paragraph 1 of this Article, along roads of the TEN-T network with a total annual average daily traffic of fewer than 2 000 heavy-duty vehicles and where the deployment of infrastructure cannot be justified in socio-economic cost-benefit terms, Member States may provide that a publicly accessible recharging pool dedicated to heavy-duty electric vehicles serves both directions of travel provided that the requirements set out in paragraph 1 of this Article, in terms of the maximum distance between recharging pools, the total power output of the recharging pool, the number of recharging points and the power output of single recharging points applicable for a single direction of travel, are complied with, and that the recharging pool is easily accessible from both directions of travel and adequately signposted. Member States shall notify the Commission of any cases in which they have made use of the derogation referred to in this paragraph. Member States shall review those cases every two years as part of the national progress reporting referred to in Article 15.

5. By way of derogation from paragraph 1 of this Article, along roads of the TEN-T network with a total annual average daily traffic of fewer than 2 000 heavy-duty vehicles and where the deployment of infrastructure cannot be justified in socio-economic cost-benefit terms, Member States may reduce by up to 50 % the total power output of a publicly accessible recharging pool dedicated to heavy-duty electric vehicles required pursuant to paragraph 1 of this Article, provided that that recharging pool serves only one direction of travel and that the other requirements set out in paragraph 1 of this Article, in terms of the maximum distance between recharging pools, the number of recharging points and the
power output of single recharging points, are complied with. Member States shall notify the Commission of any cases in which they have made use of the derogation referred to in this paragraph. Member States shall review those cases every two years as part of the national progress reporting referred to in Article 15.

6. By way of derogation from the requirement relating to the maximum distance of 60 km between the publicly accessible recharging pools dedicated to heavy-duty electric vehicles set out in paragraph 1, point (c), of this Article, Member States may allow a longer distance, of up to 100 km, for such recharging pools along roads of the TEN-T core network with a total annual average daily traffic of fewer than 800 heavy-duty vehicles, provided that the distance between recharging pools is adequately signposted. Member States shall notify the Commission of any cases in which they have made use of the derogations referred to in this paragraph. Member States shall review those cases every two years as part of the national progress reporting referred to in Article 15.

7. Where a Member State has notified the Commission of a case in which it has made use of a derogation referred to in paragraph 6, the requirement set out in paragraph 1, point (c), in terms of the maximum distance between recharging pools, shall be deemed to have been complied with.

8. By way of derogation from the requirements set out in paragraph 1, points (a), (b), (c) and (d), relating to the total power output of publicly accessible recharging pools dedicated to heavy-duty electric vehicles and from the requirement set out in paragraph 1, point (c), relating to the maximum distance between those recharging pools, Cyprus may submit to the Commission a reasoned request for authorisation to apply lower requirements in terms of level of total power output of publicly accessible recharging pools dedicated to heavy-duty electric vehicles or to apply a longer maximum distance, of up to 100 km, between those recharging pools, or both, provided that such request, if authorised, would not impede the circulation of heavy-duty electric vehicles in that Member State.

The Commission shall, within six months of receipt of a reasoned request submitted pursuant to the first subparagraph, adopt a decision as justified in each case. Any authorisation granted to Cyprus pursuant to such decision shall be valid for a maximum of four years. Where Cyprus seeks to extend the validity of the authorisation, it may submit a further reasoned request to the Commission before the expiry of the authorisation.

9. By 31 December 2030, neighbouring Member States shall ensure that the maximum distances between recharging pools referred to in paragraph 1, points (c) and (d), are not exceeded for cross-border sections of the TEN-T core road network and TEN-T comprehensive road network. Before that date, particular attention shall be paid to cross-border sections and neighbouring Member States shall make all possible efforts to respect those maximum distances as soon as they deploy the recharging infrastructure along the cross-border sections of the TEN-T road network.

Article 5

Recharging infrastructure

1. Operators of recharging points shall, at the publicly accessible recharging points operated by them, provide end users with the possibility to recharge their electric vehicle on an ad hoc basis.

At publicly accessible recharging points deployed from 13 April 2024, recharging on an ad hoc basis shall be possible using a payment instrument that is widely used in the Union. To that end, operators of recharging points shall accept electronic payments at those points through terminals and devices used for payment services, including at least one of the following:

(a) payment card readers;

(b) devices with a contactless functionality that is at least able to read payment cards;

(c) for publicly accessible recharging points with a power output below 50 kW, devices using an internet connection and allowing for secure payment transactions such as those generating a specific Quick Response code.
From 1 January 2027, operators of recharging points shall ensure that all publicly accessible recharging points operated by them, with a power output equal to or more than 50 kW deployed along the TEN-T road network or deployed on a safe and secure parking area, including recharging points deployed before 13 April 2024, comply with the requirements set out in points (a) or (b).

A single payment terminal or device referred to in the second subparagraph may serve a number of publicly accessible recharging points within a recharging pool.

The requirements laid down in this paragraph shall not apply to publicly accessible recharging points that do not require payment for the recharging service.

2. Operators of recharging points shall ensure that when they offer automatic authentication at a publicly accessible recharging point operated by them, end users always have the right to not make use of the automatic authentication and instead either to recharge their vehicle on an ad hoc basis, as provided for in paragraph 1, or to use another contract-based recharging solution offered at that recharging point. Operators of recharging points shall clearly show that option to end users and offer it to them in a convenient manner at each publicly accessible recharging point operated by them, at which they make available automatic authentication.

3. Prices charged by operators of publicly accessible recharging points shall be reasonable, easily and clearly comparable, transparent and non-discriminatory. Operators of publicly accessible recharging points shall not discriminate, through the prices charged, between end users and mobility service providers or between different mobility service providers. However, the level of prices may be differentiated, but only if the differentiation is proportionate and objectively justified.

4. At publicly accessible recharging points with a power output equal to or more than 50 kW, the ad hoc price charged by the operator shall be based on the price per kWh for the electricity delivered. In addition, the operators of those recharging points can charge an occupancy fee as a price per minute to discourage long occupancy of the recharging point.

Operators of publicly accessible recharging points with a power output equal to or more than 50 kW shall, at the recharging stations, show the ad hoc price per kWh and any possible occupancy fee expressed in price per minute so that that information is known to end users before they initiate a recharging session and price comparison is facilitated.

Operators of publicly accessible recharging points with a power output of less than 50 kW shall, at the recharging stations operated by them, make the information on the ad hoc price clearly and easily available, with all its price components, so that that information is known to end users before they initiate a recharging session and price comparison is facilitated.

The applicable price components shall be presented in the following order:

— price per kWh;
— price per minute;
— price per session; and
— any other price component that applies.

The first and second subparagraphs shall apply to all recharging points deployed from 13 April 2024.

5. Prices charged by mobility service providers to end users shall be reasonable, transparent and non-discriminatory. Mobility service providers shall make available to end users, prior to the start of an intended recharging session, all price information specific to that recharging session, through freely available, widely supported electronic means, clearly distinguishing all price components, including applicable e-roaming costs and other fees or charges applied by the mobility service provider. The fees shall be reasonable, transparent and non-discriminatory. Mobility service providers shall not apply any extra charges for cross-border e-roaming.

6. Member States shall ensure that their authorities regularly monitor the recharging infrastructure market, and in particular, that they monitor the compliance of operators of recharging points and mobility service providers with paragraphs 3 and 5. Member States shall also seek to ensure that their authorities regularly monitor possibly unfair commercial practices affecting consumers.
7. By 14 October 2024, operators of recharging points shall ensure that all publicly accessible recharging points operated by them are digitally-connected recharging points.

8. Operators of recharging points shall ensure that all publicly accessible recharging points operated by them and built after 13 April 2024 or renovated after 14 October 2024 are capable of smart recharging.

9. Member States shall take the necessary measures to ensure that within parking and rest areas along the TEN-T road network where alternative fuels infrastructure is deployed, the exact location of the alternative fuels infrastructure is adequately signposted.

10. By 14 April 2025, the operators of publicly accessible recharging points shall ensure that all direct current (DC) publicly accessible recharging points operated by them have a fixed recharging cable installed.

11. Where the operator of a recharging point is not the owner of that point, the owner shall make available to the operator, in accordance with the arrangements between them, a recharging point with the technical characteristics which enable the operator to comply with the obligations set out in paragraphs 2, 7, 8 and 10.

Article 6

Targets for hydrogen refuelling infrastructure of road vehicles

1. Member States shall ensure that, in their territory, a minimum number of publicly accessible hydrogen refuelling stations are deployed by 31 December 2030.

To that end, Member States shall ensure that by 31 December 2030 publicly accessible hydrogen refuelling stations designed for a minimum cumulative capacity of 1 tonne per day and equipped with at least a 700 bar dispenser are deployed with a maximum distance of 200 km between them along the TEN-T core network.

Member States shall ensure that, by 31 December 2030, at least one publicly accessible hydrogen refuelling station is deployed in each urban node. Member States shall ensure that an analysis is carried out to determine the best location for such refuelling stations and that the analysis examines in particular the deployment of such refuelling stations in multimodal hubs where other transport modes could also be supplied.

Member States shall set out in their national policy frameworks a clear linear trajectory towards meeting the 2030 targets, along with a clear indicative target for 2027 that delivers sufficient coverage of the TEN-T core network with a view to meeting developing market demands.

2. Neighbouring Member States shall ensure that the maximum distance referred to in paragraph 1, second subparagraph, is not exceeded for cross-border sections of the TEN-T core network.

3. The operator of a publicly accessible refuelling station, or, where the operator is not the owner, the owner of that station in accordance with the arrangements between them, shall ensure that the station is designed to serve light-duty and heavy-duty vehicles.

4. By way of derogation from paragraph 1 of this Article, along roads of the TEN-T core network with a total annual average daily traffic of fewer than 2 000 heavy-duty vehicles and where the deployment of infrastructure cannot be justified in socio-economic cost-benefit terms, Member States may reduce by up to 50 % the capacity of a publicly accessible hydrogen refuelling station required pursuant to paragraph 1 of this Article, provided that the requirements set out in that paragraph in terms of the maximum distance between hydrogen refuelling stations and the dispenser pressure are complied with. Member States shall notify the Commission of any cases in which they have made use of the derogation referred to in this paragraph. Member States shall review those cases every two years as part of the national progress reporting referred to in Article 15.

5. By way of derogation from paragraph 1 of this Article, if the costs of the deployment of the infrastructure are disproportionate to the benefits, including the environmental benefits, Member States may decide not to apply paragraph 1 of this Article to:

(a) outermost regions of the Union referred to in Article 349 TFEU; or
(b) islands falling within the definition of small connected systems or small isolated systems according to Directive (EU) 2019/944.

In such cases, Member States shall justify their decisions to the Commission and shall make available all relevant information in their national policy frameworks.

Article 7

Hydrogen refuelling infrastructure

1. Operators of hydrogen refuelling points shall, at the publicly accessible refuelling points operated by them, provide end users with the possibility to refuel on an ad hoc basis.

Ad hoc refuelling shall be possible at all publicly accessible hydrogen refuelling points using a payment instrument that is widely used in the Union. To that end, operators of those points shall accept electronic payments through terminals and devices used for payment services, including at least one of the following:

(a) payment card readers;
(b) devices with a contactless functionality that is at least able to read payment cards.

For publicly accessible hydrogen refuelling points deployed after 13 April 2024, the requirements set out in this paragraph shall apply from their deployment. For publicly accessible refuelling points deployed before 13 April 2024, the requirements set out in this paragraph shall apply from 14 October 2024.

Where the operator of the hydrogen refuelling point is not the owner of that point, the owner shall make available to the operator, in accordance with the arrangements between them, hydrogen refuelling points with the technical characteristics which enable the operator to comply with the obligations set out in this paragraph.

2. Prices charged by the operators of publicly accessible hydrogen refuelling points shall be reasonable, easily and clearly comparable, transparent and non-discriminatory. Operators of publicly accessible hydrogen refuelling points shall not discriminate, through the prices charged, between end users and mobility service providers or between different mobility service providers. However, the level of prices may be differentiated, but only if the differentiation is objectively justified.

3. Operators of hydrogen refuelling points shall clearly show information on the ad hoc price per kg at the publicly accessible hydrogen refuelling stations operated by them, so that that information is known to end users before they initiate a refuelling session and price comparison is facilitated.

4. Operators of publicly accessible hydrogen refuelling stations may provide hydrogen refuelling services to customers on a contractual basis, including in the name and on behalf of other mobility service providers. Mobility service providers shall charge prices to end users that are reasonable, transparent and non-discriminatory. Mobility service providers shall make available to end users all price information specific to their intended refuelling session prior to its start, through freely available, widely supported electronic means, clearly distinguishing all price components charged by the operator of the hydrogen refuelling point, including applicable e-roaming costs and other fees or charges applied by them.

Article 8

Infrastructure for liquefied methane for road transport vehicles

Until 31 December 2024, Member States shall ensure that an appropriate number of publicly accessible refuelling points for liquefied methane are deployed, at least along the TEN-T core network, in order to allow heavy-duty motor vehicles using liquefied methane to circulate throughout the Union, where there is demand, unless the costs of doing so are disproportionate to the benefits, including environmental benefits.
Article 9

Targets for shore-side electricity supply in maritime ports

1. Member States shall ensure that a minimum shore-side electricity supply for seagoing container ships and seagoing passenger ships is provided in TEN-T maritime ports.

To that end, Member States shall take the necessary measures to ensure that by 31 December 2029:

(a) TEN-T core maritime ports and TEN-T comprehensive maritime ports for which the annual number of port calls of ships that are moored at the quayside, averaged over the last three years, by seagoing container ships above 5 000 gross tonnes is above 100 are equipped to provide each year shore-side electricity supply for at least 90 % of the total number of port calls of seagoing container ships above 5 000 gross tonnes that are moored at the quayside at the maritime port concerned;

(b) TEN-T core maritime ports and TEN-T comprehensive maritime ports for which the annual number of port calls of ships that are moored at the quayside, averaged over the last three years, by seagoing ro-ro passenger ships above 5 000 gross tonnes and seagoing high-speed passenger craft above 5 000 gross tonnes is above 40 are equipped to provide each year shore-side electricity supply for at least 90 % of the total number of port calls of seagoing ro-ro passenger ships above 5 000 gross tonnes and seagoing high-speed passenger craft above 5 000 gross tonnes that are moored at the quayside at the maritime port concerned;

(c) TEN-T core maritime ports and TEN-T comprehensive maritime ports for which the annual number of port calls of ships that are moored at the quayside, averaged over the last three years, by seagoing passenger ships above 5 000 gross tonnes other than seagoing ro-ro passenger ships and seagoing high-speed passenger craft is above 25 are equipped to provide each year shore-side electricity supply for at least 90 % of the total number of port calls of seagoing passenger ships above 5 000 gross tonnes other than seagoing ro-ro passenger ships and seagoing high-speed passenger craft that are moored at the quayside at the maritime port concerned.

2. The port calls of ships referred to in Article 6(5), points (a), (b), (c), (e) and (g) of Regulation (EU) 2023/1805 shall not be taken into account for the purposes of determining the total number of port calls of ships that are moored at the quayside at the maritime port concerned under paragraph 1 of this Article.

3. Where the TEN-T core maritime port or TEN-T comprehensive maritime port is located on an island, or in an outermost region referred to in Article 349 TFEU or on the territory of Ceuta and Melilla, which is not connected directly to the electricity grid of the mainland, or in the case of an outermost region or of Ceuta and Melilla to the electricity grid of a neighbouring country, paragraph 1 of this Article shall not apply until such a connection has been completed or there is sufficient locally generated electricity capacity from non-fossil energy sources to cover the needs of the island, the outermost region or of Ceuta and Melilla, whichever is relevant.

Article 10

Targets for shore-side electricity supply in inland waterway ports

Member States shall ensure that:

(a) at least one installation providing shore-side electricity supply to inland waterway vessels is deployed at all TEN-T core inland waterway ports by 31 December 2024;

(b) at least one installation providing shore-side electricity supply to inland waterway vessels is deployed at all TEN-T comprehensive inland waterway ports by 31 December 2029.
Article 11

Targets for supply of liquefied methane in maritime ports

1. Member States shall ensure that an appropriate number of refuelling points for liquefied methane are deployed at TEN-T core maritime ports referred to in paragraph 2 to enable seagoing ships to circulate throughout the TEN-T core network by 31 December 2024. Member States shall cooperate with neighbouring Member States where that is necessary in order to ensure adequate coverage of the TEN-T core network.

2. Member States shall designate in their national policy frameworks TEN-T core maritime ports that provide access to the refuelling points for liquefied methane referred to in paragraph 1, taking into consideration port development, existing liquefied methane refuelling points and actual market demand, both in the short- and long-term, as well as other developments.

Article 12

Targets for supply of electricity to stationary aircraft

1. Member States shall ensure that, at all airports of the TEN-T core network and TEN-T comprehensive network, the provision of electricity supply to stationary aircraft is ensured as follows:

(a) by 31 December 2024, at all aircraft contact stands used for commercial air transport operations to embark or disembark passengers or to load or unload goods;

(b) by 31 December 2029, at all aircraft remote stands used for commercial air transport operations to embark or disembark passengers or to load or unload goods.

2. Member States may exempt airports of the TEN-T network with fewer than 10 000 commercial flight movements per year, averaged over the last three years, from the obligation to supply electricity to stationary aircraft at all aircraft remote stands.

3. Paragraph 1 shall not apply to specially dedicated de-icing stands, stands inside designated military areas and stands specially dedicated to general aviation aircraft below 5,7 tonnes of maximum take-off weight.

4. As of 1 January 2030 at the latest, Member States shall take the necessary measures to ensure that the electricity supplied pursuant to paragraph 1 originates from the electricity grid or is generated on site without using fossil fuels.

Article 13

Railway infrastructure

As regards railway infrastructure that is not covered by Regulation (EU) No 1315/2013, Member States shall assess the development of alternative fuel technologies and propulsion systems for rail sections that cannot be fully electrified for technical or cost-efficiency reasons, such as hydrogen- or battery-powered trains, and, if relevant, any recharging and refuelling infrastructure needs.

Article 14

National policy frameworks

1. By 31 December 2024, each Member State shall prepare and transmit to the Commission a draft national policy framework for the development of the market as regards alternative fuels in the transport sector and the deployment of the relevant infrastructure.
2. The national policy framework shall contain at least the following elements:

(a) an assessment of the current state and future development of the market as regards alternative fuels in the transport sector, and of the development of alternative fuels infrastructure, considering intermodal access of alternative fuels infrastructure and, where relevant, cross-border continuity and the development of alternative fuels infrastructure on islands and in the outermost regions;

(b) national targets and objectives pursuant to Articles 3, 4, 6, 8, 9, 10, 11 and 12 for which mandatory national targets are set out in this Regulation;

(c) policies and measures necessary to ensure that the mandatory targets and objectives referred to in point (b) are reached;

(d) measures, planned or adopted, to promote the deployment of alternative fuels infrastructure for captive fleets, in particular for recharging stations and hydrogen refuelling stations for public transport services and recharging stations for car sharing;

(e) measures, planned or adopted, to encourage and facilitate the deployment of recharging stations for light-duty and heavy-duty vehicles in private locations that are not accessible to the public;

(f) measures, planned or adopted, to promote alternative fuels infrastructure in urban nodes, in particular with respect to publicly accessible recharging points;

(g) measures, planned or adopted, to promote a sufficient number of publicly accessible high-power recharging points;

(h) measures, planned or adopted, necessary to ensure that the deployment and operation of recharging points, including the geographical distribution of bidirectional recharging points, contribute to the flexibility of the energy system and to the penetration of renewable electricity into the electric system;

(i) measures to ensure that publicly accessible recharging and refuelling points for alternative fuels are accessible to older persons, persons with reduced mobility and persons with disabilities in accordance with the accessibility requirements of Directive (EU) 2019/882;

(j) measures, planned or adopted, to remove possible obstacles with regard to planning, permitting, procuring and operating of alternative fuels infrastructure;

(k) an overview of the state of play, perspectives and planned measures in respect of the deployment of alternative fuels infrastructure in maritime ports other than for liquefied methane and shore-side electricity supply for use by seagoing vessels, such as for hydrogen, ammonia, methanol and electricity;

(l) an overview of the state of play, perspectives and planned measures in respect of deployment of alternative fuels infrastructure including targets, key milestones and financing needed, for hydrogen- or battery-powered trains on TEN-T rail sections that cannot be electrified;

(m) an overview of the state of play, perspectives and planned measures in respect of deployment of alternative fuels infrastructure in airports other than for electricity supply to stationary aircraft, such as for electric recharging and hydrogen refuelling for aircrafts;

(n) an overview of the state of play, perspectives, and planned measures in respect of deployment of alternative fuels infrastructure in inland navigation, such as for electricity and hydrogen.
3. The national policy framework may contain the following elements:

(a) an overview of the state of play, perspectives and planned measures for the deployment of alternative fuels infrastructure in maritime ports, such as for electricity and hydrogen, for port services as defined in Regulation (EU) 2017/352 of the European Parliament and of the Council (*);

(b) national targets and measures to promote alternative fuels infrastructure along the road networks which are not included in the TEN-T core network or TEN-T comprehensive network, in particular with respect to publicly accessible recharging points;

(c) measures to guarantee accessibility of recharging and refuelling infrastructure in the entire territory of the Member State, paying particular attention to rural areas to ensure their accessibility and territorial cohesion;

(d) measures to ensure that the density of publicly accessible alternative fuels infrastructure available at national level takes into account population density;

(e) national targets and objectives for the deployment of alternative fuels infrastructure related to points (a), (b), (c) and (d) for which no mandatory targets are laid down in this Regulation.

4. Member States shall ensure that the national policy frameworks take into account the needs of the different transport modes existing on their territory.

5. Member States shall ensure that national policy frameworks take into account, as appropriate, the interests of regional and local authorities, in particular where recharging and refuelling infrastructure for public transport is concerned, as well as those of the stakeholders concerned.

6. Where necessary, Member States shall cooperate, by means of consultations or joint policy frameworks, to ensure that the measures required to achieve the objectives of this Regulation are coherent and coordinated. In particular, Member States shall cooperate on establishing strategies on the use of alternative fuels and on the deployment of corresponding infrastructure in waterborne transport. The Commission shall assist the Member States in the cooperation process.

7. Support measures for alternative fuels infrastructure shall comply with the relevant Union State aid rules.

8. Each Member State shall make its draft national policy framework publicly available and shall ensure that the public is given early and effective opportunities to participate in the preparation of the draft national policy framework.

9. The Commission shall assess the draft national policy frameworks and may issue recommendations to Member States. Those recommendations shall be issued no later than six months after the submission of the draft national policy frameworks as referred to in paragraph 1 of this Article. They may, in particular, address:

(a) the level of ambition of targets and objectives with a view to complying with the obligations set out in Articles 3, 4, 6, 8, 9, 10, 11, 12 and 13;

(b) policies and measures relating to national targets and objectives.

10. Each Member State shall take due account of any recommendations from the Commission in its final national policy framework. If the Member State concerned does not address a recommendation or a substantial part thereof, that Member State shall provide a written explanation to the Commission.

11. By 31 December 2025, each Member State shall draft its final national policy framework in an easily readable and understandable form and notify it to the Commission. Those final national policy frameworks shall be made publicly available by the Commission.

Article 15

National reporting

1. By 31 December 2027 and every two years thereafter, each Member State shall submit to the Commission a standalone national progress report on the implementation of its national policy framework. The report shall be drafted in an easily readable and understandable form and shall be made publicly available by the Commission.

2. The national progress report shall cover the information listed in Annex I and shall, where appropriate, include a relevant justification of the level of achievement of the national targets and objectives referred to in Article 14(2), as well as an indication of the measures to be taken to achieve those targets and objectives in the future.

3. By 30 June 2024 and every three years thereafter, Member States shall assess how the deployment and operation of recharging points could enable electric vehicles to further contribute to the flexibility of the energy system, including their participation in the balancing market, and to the further absorption of renewable electricity. That assessment shall take into account all types of recharging points, including those offering smart and bi-directional recharging, and all power outputs, whether public or private, and provide recommendations in terms of type of recharging point, supporting technology and geographical distribution in order to facilitate the ability of users to integrate their electric vehicles in the system. That assessment shall identify appropriate measures to be implemented in order to meet the requirements set out in this Regulation including those to ensure the consistency of infrastructure planning with the corresponding grid planning. That assessment shall take into account input from all stakeholders and shall be made publicly available. Each Member State may request its regulatory authority to carry out that assessment. On the basis of the results of the assessment, Member States shall, if necessary, take appropriate measures for the deployment of additional recharging points and include those measures in the national progress reports referred to in paragraph 1 of this Article. The assessment and measures shall be taken into account by the system operators in the network development plans referred to in Article 32(3) and Article 51 of Directive (EU) 2019/944.

4. On the basis of input from transmission system operators and distribution system operators, the regulatory authority of each Member State shall assess, by 30 June 2024 and every three years thereafter, the potential contribution of bidirectional recharging to reducing user and system costs and increasing the renewable electricity share in the electricity system. That assessment shall be made publicly available. On the basis of the results of the assessment, Member States shall, if necessary, take appropriate measures to adjust the availability and geographical distribution of bidirectional recharging points in private areas and include them in the national progress reports referred to in paragraph 1.

Article 16

Content, structure and format of national policy frameworks and national progress reports

By 14 October 2024, the Commission shall adopt guidance and templates concerning the content, structure and format of the national policy frameworks to be submitted by the Member States pursuant to Article 14 and the content of the national progress reports to be submitted by the Member States pursuant to Article 15(1). The Commission may adopt guidance and templates to facilitate the effective application across the Union of any other provisions of this Regulation.

Article 17

Review of national policy frameworks and national progress reports

1. By 31 December 2026, the Commission shall assess the national policy framework notified by Member States pursuant to Article 14(11) and shall submit to the European Parliament and to the Council a report on the assessment of those national policy frameworks and their coherence at Union level, including a first assessment of the expected level of achievement of the national targets and objectives referred to in Article 14(2).

2. The Commission shall assess the national progress reports submitted by Member States pursuant to Article 15(1) and shall, as appropriate, issue recommendations to Member States to ensure the achievement of the objectives and compliance with the obligations laid down in this Regulation.
3. The Member State concerned shall, within six months of receipt of the recommendations referred to in paragraph 2, notify the Commission of how it intends to implement the recommendations. If the Member State concerned decides not to implement the recommendations or a substantial part thereof, it shall provide the Commission with its reasons.

4. After the submission by the Member State of the notification or the reasoning referred to in paragraph 3, the Member State concerned shall set out in its next national progress report how it has implemented the recommendations.

5. The Commission shall submit to the European Parliament and to the Council a report on its assessment of the national progress reports one year after submission of those national progress reports by Member States pursuant to Article 15(1). That assessment shall contain an evaluation of:

(a) the progress made by Member States with regard to the achievement of the targets and objectives referred to in Article 14(2), including the Member States’ responses to the Commission recommendations pursuant to paragraph 2 of this Article;

(b) the coherence of the development of alternative fuel infrastructure at Union level.

6. On the basis of the final national policy frameworks referred to in Article 14(11), the national progress reports referred to in Article 15(1) and the reports referred to in Article 18(1), the Commission shall make publicly available and regularly update information on the national targets and the objectives submitted by each Member State regarding:

(a) the number of publicly accessible recharging points and recharging stations, separately for recharging points dedicated to light-duty vehicles and recharging points and recharging stations dedicated to heavy-duty vehicles, and in accordance with the categorisation provided for in Annex III;

(b) the number of publicly accessible hydrogen refuelling points;

(c) the infrastructure for shore-side electricity supply in maritime ports and inland waterway ports of the TEN-T core network and TEN-T comprehensive network;

(d) the infrastructure for electricity supply for stationary aircraft in airports of the TEN-T core network and TEN-T comprehensive network;

(e) the number of refuelling points for liquefied methane in maritime ports and inland waterway ports of the TEN-T core network and TEN-T comprehensive network;

(f) the number of publicly accessible refuelling points for liquefied methane for motor vehicles;

(g) the number of publicly accessible refuelling points for CNG for motor vehicles;

(h) recharging and refuelling points for other alternative fuels in maritime ports and inland waterway ports of the TEN-T core network and TEN-T comprehensive network;

(i) recharging and refuelling points for other alternative fuels at airports of the TEN-T core network and TEN-T comprehensive network;

(j) recharging and refuelling points for alternative fuels for rail transport.

Article 18

Progress tracking

1. By 31 March 2025 and by 31 March of every year thereafter, Member States shall report to the Commission the total aggregated recharging power output and the number of publicly accessible recharging points deployed and the number of battery electric vehicles and plug-in hybrid vehicles registered on their territory on 31 December of the previous year, in accordance with the requirements set out in Annex III.
2. Without prejudice to the procedure laid down in Article 258 TFEU, where it is evident from the report referred to in paragraph 1 of this Article or from any information available to the Commission that a Member State is at risk of not achieving its national targets set out in Article 3(1) of this Regulation, the Commission may issue a finding to that effect and recommend the Member State concerned to take corrective measures to achieve the national targets. Within three months following the receipt of the Commission's findings, the Member State concerned shall notify to the Commission:
(a) the corrective measures that it plans to implement in order to achieve the national targets set out in Article 3(1) of this Regulation, including any additional actions that the Member State intends to implement in order to achieve those targets; and
(b) a clear timetable for actions that will enable the assessment of annual progress towards achievement of those targets.

Where the Commission finds that the corrective measures are satisfactory, the Member State concerned shall update its latest national progress report referred to in Article 15 with those corrective measures and submit it to the Commission.

The Commission shall make its recommendations and the corrective measures and additional actions by the Member State concerned publicly available.

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**Article 19**

**User information**

1. Relevant, consistent and clear information shall be made available as regards motor vehicles placed on the market which are capable of being regularly recharged or refuelled.

That information shall be made available:
(a) in motor vehicle manuals and on motor vehicles, by the manufacturers, when those vehicles are placed on the market;
(b) at recharging and refuelling points, by recharging and refuelling point operators; and
(c) in motor vehicle dealerships, by the distributors.

2. Whether vehicles and infrastructures or fuels and vehicles covered by paragraph 1 of this Article are compatible shall be determined in compliance with the technical specifications referred to in points 10.1 and 10.2 of Annex II.

Where such technical specifications refer to a graphical expression, including a colour coding scheme, the graphical expression shall be simple and easy to understand.

That graphical expression shall be placed in a clearly visible manner:
(a) by refuelling point operators, on corresponding pumps and their nozzles at all refuelling points operated by them, from the date on which fuels are placed on the market;
(b) by manufacturer, in the immediate proximity of all fuel tanks’ filling caps of motor vehicles recommended for and compatible with that fuel and in motor vehicle manuals, when such motor vehicles are placed on the market.

3. When fuel prices are shown at a refuelling station, Member States shall ensure that a comparison of the relevant unit prices is shown, where appropriate, and in particular for hydrogen, for information purposes following the common methodology for alternative fuels unit price comparison referred to in point 10.3 of Annex II.

4. In situations where European standards setting the technical specifications of a fuel do not include labelling requirements to indicate compliance with the standards concerned, where the labelling requirements do not refer to a graphical expression, including colour coding schemes, or where the labelling requirements are not suitable for achieving the objectives of this Regulation, the Commission may, for the purposes of the uniform implementation of paragraphs 1 and 2, mandate the European standardisation organisations to develop compatibility labelling specifications.
On the basis of the compatibility labelling specifications developed by the European standardisation organisations pursuant to the mandate referred to in the first subparagraph, the Commission shall adopt implementing acts determining the graphical expression, including a colour coding scheme, of compatibility for fuels introduced in the Union market which reach the level of 1 % of the total volume of sales, in the assessment of the Commission, in more than one Member State.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

5. Where provisions on labelling of the respective European standards are updated or new European standards for alternative fuels are developed, the corresponding requirements on labelling shall apply to all recharging and refuelling points no later than 24 months after the corresponding implementing act is adopted and to all motor vehicles placed on the market from the date that the corresponding implementing act enters into force.

**Article 20**

**Data provisions**

1. Member States shall appoint an Identification Registration Organisation (‘IDRO’). The IDRO shall issue and manage unique identification (‘ID’) codes to identify at least operators of recharging points and mobility service providers, by 14 April 2025.

2. By 14 April 2025, operators of publicly accessible recharging points and refuelling points for alternative fuels, or, in accordance with the arrangements between them, the owners of those points, shall ensure the availability of static data and dynamic data concerning alternative fuels infrastructure operated by them, or services inherently linked to such infrastructure that they provide or they outsource, at no cost. The following data types shall be made available:

   (a) static data for publicly accessible recharging points and refuelling points for alternative fuels operated by them:
      
      (i) geographic location of the recharging points and refuelling points for alternative fuels,
      (ii) number of connectors,
      (iii) number of parking spaces for people with disabilities,
      (iv) contact information of the owner and operator of the recharging station and refuelling station,
      (v) opening hours;
   
   (b) further static data for publicly accessible recharging points operated by them:
      
      (i) ID codes, at least of the recharging point operator,
      (ii) type of connector,
      (iii) type of current (AC/DC),
      (iv) maximum power output (kW) of the recharging station,
      (v) maximum power output (kW) of the recharging point,
      (vi) vehicle type compatibility;
   
   (c) dynamic data for publicly accessible recharging points and refuelling points for alternative fuels operated by them:
      
      (i) operational status (operational/out of order),
      (ii) availability (in use/not in use),
      (iii) ad hoc price,
      (iv) electricity supplied is 100 % renewable (yes/no).
The requirements laid down in point (c) shall not apply to publicly accessible recharging points that do not require payment for the recharging service.

3. Each operator of publicly accessible recharging and refuelling points for alternative fuels, or, in accordance with the arrangements between them, the owner of those points, shall set up an Application Programme Interface (API) that provides free and unrestricted access to the data referred to in paragraph 2, and shall submit information on that API to the national access points.

The API of each operator of recharging and refuelling points, or, in accordance with the arrangements between them, the API of the owner of those points, shall comply with common technical requirements established by the Commission in the delegated acts referred to in paragraph 6 to enable an automated and uniform data exchange between the operators of publicly accessible recharging and refuelling points and data users.

4. By 31 December 2024, Member States shall ensure that the data referred to in paragraph 2 of this Article are made accessible on an open and non-discriminatory basis to all data users through their national access points in accordance with the relevant provisions related to such data in Delegated Regulation (EU) 2022/670 and in compliance with the additional complementary specifications that may be adopted in accordance with paragraph 7 of this Article. Where Member States aggregate data under their national access points, they may provide those data to a common European access point by means of an API.

5. By 31 December 2026, the Commission shall establish a common European access point to function as a data gateway facilitating the access to the data referred to in paragraph 2 from the different national access points. The Commission shall ensure that the common European access point is easily accessible and can be used by all data users, for example through the creation of a dedicated web portal.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to:

(a) amend paragraph 2 of this Article to include additional data types concerning publicly accessible recharging points and refuelling points for alternative fuels or services inherently linked to such infrastructure that the operators of that infrastructure provide or outsource in view of technological developments or new services made available on the market; and

(b) supplement this Regulation by laying down common technical requirements for a common application programme interface to enable an automated and uniform data exchange between the operators of publicly accessible recharging points and refuelling points for alternative fuels and data users.

7. The Commission may adopt implementing acts laying down:

(a) specifications that are complementary to those set out in Delegated Regulation (EU) 2022/670, related to the data format, frequency and quality in which the data referred to in paragraph 2 of this Article and in the delegated acts adopted on the basis of paragraph 6 of this Article shall be made available;

(b) detailed procedures enabling the availability and accessibility of data required pursuant to this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

Those implementing acts shall be without prejudice to Directive 2010/40/EU of the European Parliament and of the Council (32) and the delegated and implementing acts adopted on the basis thereof.

8. The delegated and implementing acts referred to in paragraphs 6 and 7 shall provide for reasonable transitional periods before the provisions contained therein, or amendments thereof, become binding on the operators or owners of recharging points and refuelling points for alternative fuels.

Article 21

Common technical specifications

1. The technical specifications set out in Annex II shall apply.

2. In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission may request European standardisation organisations to draft European standards setting technical specifications for areas referred to in Annex II to this Regulation for which no common technical specifications have been adopted by the Commission.

3. The Commission shall adopt delegated acts in accordance with Article 22 to:
   (a) amend Annex II by introducing technical specifications for the areas listed in that Annex to enable full technical interoperability of the recharging and refuelling infrastructure in terms of physical connections, communication exchanges and access for persons with reduced mobility to those areas; and
   (b) without undue delay and at the latest 12 months after the adoption of the relevant standards, amend Annex II by updating the references to the standards referred to in the technical specifications set out in that Annex.

4. Where delegated acts referred to in paragraph 3 are to apply to existing infrastructures, those delegated acts shall be based on a cost-benefit analysis to be submitted to the European Parliament and the Council together with those delegated acts.

5. Where European standards setting the technical specifications of a fuel are developed after the adoption by the Commission of an implementing act referred to in Article 19(4), second subparagraph, and they include provisions requiring labelling to indicate compliance with the standards concerned and refer to a graphical expression, including colour coding schemes, the amendments of Annex II adopted by the delegated acts referred to in paragraph 3 of this Article shall include an indication of which of those standards or implementing acts are to apply and, where appropriate, repeal the relevant implementing acts.

6. The amendments of Annex II adopted by the delegated acts referred to in paragraph 3 shall include reasonable transitional periods for any technical specifications that those delegated acts introduce or amend, during which they shall not be binding in respect of the infrastructure concerned.

Article 22

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 20 and 21 shall be conferred on the Commission for a period of five years from 13 April 2024. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred in Articles 20 and 21 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 20 and 21 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

**Article 23**

**Committee procedure**

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and of Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.

**Article 24**

**Reporting and review**

1. By 31 December 2024, the Commission shall submit to the European Parliament and to the Council a technology and market-readiness report dedicated to heavy-duty vehicles. That report shall take into account the initial indications of the preferences of the market. It shall also consider technological developments and the development of the technical specifications achieved by that date and developments expected in the short term, in particular regarding recharging and refuelling standards and technologies, such as high-power recharging standards and electric road systems, and the use of liquid hydrogen.

Regarding hydrogen refuelling stations, the Commission shall further assess the requirements referred to in Article 6 in light of the technological and market developments, the need to specify a higher capacity for those stations, the need to specify targets for liquid hydrogen refuelling infrastructure, as well as the date for the extension of the requirements for the deployment of hydrogen refuelling stations to the TEN-T comprehensive network.

2. By 31 December 2026 and every five years thereafter, the Commission shall review this Regulation.

In its review, the Commission shall assess, in particular, the following elements:

(a) whether the traffic thresholds referred to in Article 3(6) and (7), in Article 4(4) and (5) and in Article 6(4) are still relevant in view of the expected increase of the share of hydrogen-powered vehicles or battery electric vehicles compared to the total fleet of vehicles circulating in the Union;

(b) whether the electronic means of payment referred to in Article 5(1) are still appropriate;

(c) the functioning of the pricing mechanism for publicly accessible recharging stations and whether the pricing components laid down in Article 5(4), provide consumers with clear and sufficient information;

(d) a possible decrease of the gross tonnage threshold, laid down in Article 9, as well as a possible extension of the scope of this Regulation to other ship types following relevant adjustments in other relevant Union legal acts;

(e) the current state and future development of the market for hydrogen and electric propulsion aviation;

(f) the effects of this Regulation as regards the potential and the magnitude of carbon leakage.
As part of this review, the Commission shall also assess the extent to which the implementation of this Regulation has met its objectives and the extent to which it has impacted the competitiveness of the relevant sectors covered by it. That review shall also cover the interaction of this Regulation with other relevant Union legal acts and shall identify any provisions that could be updated and simplified, as well as actions and measures that have been or could be taken to reduce the total cost pressure on relevant sectors. As part of the Commission's analysis of the efficiency of this Regulation, the review shall also include an assessment of the burden this Regulation imposes on businesses.

3. The Commission shall consider, if appropriate, whether to accompany that review with a proposal to amend this Regulation, in view of the outcome of the assessment referred to in paragraph 2.

Article 25

Repeal


2. References to Directive 2014/94/EU shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex IV.

Article 26

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 13 April 2024.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 13 September 2023.

For the European Parliament
The President
R. METSOLA

For the Council
The President
J. M. ALBARES BUENO
ANNEX I

Reporting

The national progress report referred to in Article 15(1) shall include at least the following elements:

1. target setting

   (a) vehicle uptake projections for 31 December of the years 2025, 2030 and 2035 for:
      — heavy-duty vehicles, separately for battery electric heavy-duty vehicles and hydrogen-powered heavy-duty vehicles;

   (b) targets for 31 December of the years 2025, 2027, 2030 and 2035 for:
      — recharging infrastructure dedicated to light-duty electric vehicles: number of recharging stations and power output (classification of recharging stations in accordance with Annex III);
      — development of recharging stations for light-duty electric vehicles not accessible to the public, if applicable;
      — recharging infrastructure dedicated to heavy-duty electric vehicles: number of recharging stations and power output;
      — development of recharging stations for heavy-duty electric vehicles not accessible to the public, if applicable;
      — hydrogen refuelling stations: number of refuelling stations, capacity of the refuelling stations and connector provided;
      — road refuelling stations for liquefied methane: number of refuelling stations and capacity of stations;
      — refuelling points for liquefied methane in maritime ports of the TEN-T core network and TEN-T comprehensive network, including location (port) and capacity per port;
      — shore-side electricity supply in maritime ports of the TEN-T core network and TEN-T comprehensive network, including exact location (port) and capacity of each installation within the port;
      — shore-side electricity supply in inland waterway ports of the TEN-T core network and TEN-T comprehensive network including location (port) and capacity;
      — electricity supply for stationary aircraft, number of installations per airport of the TEN-T core network or airport of the TEN-T comprehensive network;
      — other national targets and objectives for which no Union-wide mandatory national targets exist, if applicable. For alternative fuels infrastructure in ports, airports and for rail the location and capacity/size of the installation has to be reported;

2. utilisation rates: for the categories under point 1(b), reporting the utilisation of that infrastructure;

3. the level of achievement of the national targets reported for the deployment of alternative fuels in the different transport modes (road, rail, water and air):

   — level of achievement of the infrastructure deployment targets as referred to in point 1(b) for all applicable transport modes, in particular for recharging stations, electric road system (if applicable), hydrogen refuelling stations, shore-side electricity supply in maritime ports and inland waterway ports, liquefied methane bunkering in TEN-T core maritime ports, other alternative fuels infrastructure in ports, electricity supply to stationary aircrafts;
   — for recharging points, specifying the ratio of public to private infrastructure;
   — deployment of alternative fuels infrastructure within urban nodes;

4. the review of the cases in which the Member States have made use of the derogations laid down in Article 3, paragraphs (6), (7) and (8), Article 4, paragraphs (6), (7) and (8) and Article 6, paragraph (4);
5. legal measures: information on legal measures, which may consist of legislative, regulatory or administrative measures to support the build-up of alternative fuels infrastructure, such as building permits, parking place permits, certification of the environmental performance of businesses and recharging and refuelling stations concessions;

6. information on the policy measures supporting the implementation of the national policy framework, including:
   — direct incentives for the purchase of means of transport that use alternative fuels or for building the infrastructure;
   — availability of tax incentives to promote means of transport that use alternative fuels and the relevant infrastructure;
   — use of public procurement in support of alternative fuels, including joint procurement;
   — demand-side non-financial incentives, for example preferential access to restricted areas, parking policy and dedicated lanes;

7. public deployment and manufacturing support, including:
   — annual public budget allocated for the deployment of alternative fuels infrastructure, broken down by alternative fuel and by transport mode (road, rail, water and air);
   — annual public budget allocated to support manufacturing plants for alternative fuel technologies, broken down by alternative fuel;
   — consideration of any particular needs during the initial phase of the deployment of alternative fuels infrastructure;

8. research, technological development and demonstration (RTD&D): annual public budget allocated to support alternative fuels RTD&D.
ANNEX II

Technical specifications

1. Technical specifications for electricity supply for road transport

1.1. Normal power recharging points for motor vehicles:
   — alternating current (AC) normal power recharging points for electric vehicles shall be equipped, for interoperability purposes, at least with socket outlets or vehicle connectors of Type 2 as described in standard EN 62196-2:2017.

1.2. High-power recharging points for motor vehicles:
   — direct current (DC) normal power recharging points for electric vehicles shall be equipped, for interoperability purposes, at least with connectors of the combined charging system ‘Combo 2’ as described in standard EN 62196-3:2014;
   — alternating current (AC) high-power recharging points for electric vehicles shall be equipped, for interoperability purposes, at least with connectors of Type 2 as described in standard EN 62196-2:2017;
   — direct current (DC) high-power recharging points for electric vehicles shall be equipped, for interoperability purposes, at least with connectors of the combined charging system ‘Combo 2’ as described in standard EN 62196-3:2014.

1.3. Recharging points for L-category motor vehicles:
   The publicly accessible alternating current (AC) recharging points reserved for L-category electric vehicles up to 3.7 kW shall be equipped, for interoperability purposes, with at least one of the following:
   (a) socket-outlets or vehicle connectors of Type 3A as described in standard EN 62196-2:2017 (for Mode 3 charging);
   (b) socket-outlets compliant with standard IEC 60884-1:2002 ’A1:2006 ’A2:2013 (for Mode 1 or Mode 2 charging).

1.4. Normal-power recharging points and high-power recharging points for electric buses:
   — alternating current (AC) normal-power recharging points and high-power recharging points for electric buses shall be equipped at least with connectors of Type 2 as described in standard EN 62196-2:2017;
   — direct current (DC) normal-power recharging points and high-power recharging points for electric buses shall be equipped at least with connectors of the combined charging system ‘Combo 2’ as described in standard EN 62196-3:2014.

1.5. Contact interface automated device for electric buses on conductive recharging in mode 4, in accordance with standard EN 61851-23-1:2020, shall be equipped at least with mechanical and electrical interfaces, as defined in the standard EN 50696:2021, concerning:
   — automated connection device (ACD) mounted on the infrastructure (pantograph);
   — automated connection device (ACD) mounted on the roof of the vehicle;
   — automated connection device (ACD) mounted underneath the vehicle;
   — automated connection device (ACD) mounted on the infrastructure and connecting to the side or on the roof of the vehicle.

1.6. Technical specifications regarding the connector for recharging heavy-duty electric vehicles (DC charging).

1.7. Technical specifications for inductive static wireless recharging for passenger cars and light-duty electric vehicles.

1.8. Technical specifications for inductive static wireless recharging for heavy-duty electric vehicles.

1.10. Technical specifications for inductive dynamic wireless recharging for heavy-duty-electric vehicles.

1.11. Technical specifications for inductive static wireless recharging for electric buses.

1.12. Technical specifications for inductive dynamic wireless recharging for electric buses.

1.13. Technical specifications for electric road system for dynamic overhead power supply via a pantograph for heavy-duty electric vehicles.

1.14. Technical specifications for electric road system for dynamic ground level power supply through conductive rails for passenger electric cars, light-duty electric vehicles and heavy-duty electric vehicles.

1.15. Technical specifications for battery swapping for L-category electric vehicles.

1.16. If technically feasible, technical specifications for battery swapping for passenger electric cars and light-duty electric vehicles.

1.17. If technically feasible, technical specifications for battery swapping for heavy-duty electric vehicles.

1.18. Technical specifications for recharging stations to ensure access to users with disabilities.

2. Technical specifications for communication exchange in the electric vehicle recharging sector

2.1. Technical specifications regarding communication between the electric vehicle and the recharging point (vehicle-to-grid communication).

2.2. Technical specifications regarding communication between the recharging point and the recharging point management system (back-end communication).

2.3. Technical specifications regarding communication between the recharging point operator, electromobility service providers and e-roaming platforms.

2.4. Technical specifications regarding communication between the recharging point operator and the distributed system operators.

3. Technical specifications for hydrogen supply for road transport vehicles

3.1. Outdoor hydrogen refuelling points dispensing gaseous hydrogen used as fuel on board motor vehicles shall comply at least with the interoperability requirements described in standard EN 17127:2020.

3.2. The quality characteristics of hydrogen dispensed by hydrogen refuelling points for motor vehicles shall comply with the requirements described in standard EN 17124:2022. The methods to ensure that the hydrogen quality is met are also described in the standard.

3.3. The fuelling algorithm shall comply with the requirements of standard EN 17127:2020.

3.4. Once the process of certification of standard EN ISO 17268:2020 is concluded, connectors for motor vehicles for the refuelling of gaseous hydrogen shall comply at least with that standard.
3.5. Technical specifications for connectors for refuelling points dispensing gaseous (compressed) hydrogen for heavy-duty vehicles.

3.6. Technical specifications for connectors for refuelling points dispensing liquefied hydrogen for heavy-duty vehicles.

4. Technical specifications for methane for road transport

4.1. Refuelling points for compressed natural gas (CNG) for motor vehicles shall comply with a fuelling pressure (service pressure) of 20,0 MPa gauge (200 bar) at 15 °C. A maximum fuelling pressure of 26,0 MPa with 'temperature compensation' is permitted in accordance with standard EN ISO 16923:2018.


4.3. Refuelling points for liquefied methane for motor vehicles shall comply with a fuelling pressure lower than the maximum allowable working pressure of the vehicle tank as addressed in standard EN ISO 16924:2018, 'Natural gas fuelling stations – LNG stations for fuelling vehicles'. In addition, the connector profile shall comply with standard EN ISO 12617:2017 'Road vehicles – Liquefied natural gas (LNG) refuelling connector –3,1 MPa connector'.

5. Technical specifications for electricity supply for maritime transport and inland navigation

5.1. Shore-side electricity supply for seagoing ships, including the design, installation and testing of the systems, shall comply at least with the technical specifications of standard IEC/IEEE 80005-1:2019/AMD1:2022 for high-voltage shore connections.

5.2. Plugs, socket-outlets and ship couplers for high-voltage shore connection shall comply at least with the technical specification of standard IEC 62613-1:2019.

5.3. Shore-side electricity supply for inland waterway vessels shall comply at least with the standard EN 15869-2:2019 or standard EN 16840:2017 depending on energy requirements.

5.4. Technical specifications for shore-side battery recharging points for maritime vessels, featuring interconnectivity and system interoperability for maritime vessels.

5.5. Technical specifications for shore-side battery recharging points for inland navigation vessels, featuring interconnectivity and system interoperability for inland navigation vessels.

5.6. Technical specifications for vessel-to-port grid communication interfaces in automated on-shore power supply (OPS) and battery recharging systems for maritime vessels.

5.7. Technical specifications for vessel-to-port grid communication interfaces in automated on-shore power supply (OPS) and battery recharging systems for inland navigation vessels.

5.8. If technically feasible, technical specifications for battery swapping and recharging at onshore stations for inland navigation vessels.

6. Technical specifications for hydrogen bunkering for maritime transport and inland navigation

6.2. Technical specifications for refuelling points and bunkering for gaseous (compressed) hydrogen inland navigation hydrogen-powered vessels.

6.3. Technical specifications for refuelling points and bunkering for liquefied hydrogen for maritime hydrogen-powered vessels.

6.4. Technical specifications for refuelling points and bunkering for liquefied hydrogen inland navigation hydrogen-powered vessels.

7. Technical specifications for methanol bunkering for maritime transport and inland navigation

7.1. Technical specifications for refuelling points and bunkering for methanol for maritime methanol-fuelled vessels.

7.2. Technical specifications for refuelling points and bunkering for methanol for inland navigation methanol-fuelled vessels.

8. Technical specifications for ammonia bunkering for maritime transport and inland navigation

8.1. Technical specifications for refuelling points and bunkering for ammonia for maritime ammonia-fuelled vessels.

8.2. Technical specifications for refuelling points and bunkering for ammonia for inland navigation ammonia-fuelled vessels.

9. Technical specifications for liquefied methane refuelling points for maritime transport and inland navigation


9.2. Refuelling points for liquefied methane for inland waterway vessels shall comply at least with standard EN ISO 20519:2017 (parts 5.3 to 5.7) for interoperability purposes only.

10. Technical specifications related to fuel labelling


10.2. The 'Identification of vehicles and infrastructures compatibility - Graphical expression for consumer information on EV power supply' shall comply at least with standard EN 17186:2019.

10.3. The common methodology for alternative fuels unit price comparison set out by Commission Implementing Regulation (EU) 2018/732 (*)

10.4. Technical specifications for electric recharging stations and hydrogen refuelling facilities for rail transport.

ANNEX III

Reporting requirements on deployment of electric vehicles and publicly accessible recharging infrastructure

1. Member States must categorise their reporting on the deployment of electric vehicles as follows:
   — battery electric vehicles, separately for categories M₁, N₁, M₂/₃ and N₂/₃
   — plug-in hybrid vehicles, separately for categories M₁, N₁, M₂/₃ and N₂/₃

2. Member States must categorise their reporting on the deployment of publicly accessible recharging points as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Sub-category</th>
<th>Maximum power output</th>
<th>Definition pursuant to Article 2 of this Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1 (AC)</td>
<td>Slow AC recharging point, single-phase</td>
<td>P &lt; 7.4 kW</td>
<td>Normal-power recharging point</td>
</tr>
<tr>
<td>Category 1 (AC)</td>
<td>Medium-speed AC recharging point, triple-phase</td>
<td>7.4 kW ≤ P ≤ 22 kW</td>
<td>High-power recharging point</td>
</tr>
<tr>
<td>Category 1 (AC)</td>
<td>Fast AC recharging point, triple-phase</td>
<td>P &gt; 22 kW</td>
<td></td>
</tr>
<tr>
<td>Category 2 (DC)</td>
<td>Slow DC recharging point</td>
<td>P &lt; 50 kW</td>
<td></td>
</tr>
<tr>
<td>Category 2 (DC)</td>
<td>Fast DC recharging point</td>
<td>50 kW ≤ P &lt; 150 kW</td>
<td></td>
</tr>
<tr>
<td>Category 2 (DC)</td>
<td>Level 1 - Ultra-fast DC recharging point</td>
<td>150 kW ≤ P &lt; 350 kW</td>
<td></td>
</tr>
<tr>
<td>Category 2 (DC)</td>
<td>Level 2 - Ultra-fast DC recharging point</td>
<td>P ≥ 350 kW</td>
<td></td>
</tr>
</tbody>
</table>

3. The following data must be provided separately for publicly accessible recharging infrastructure dedicated to light-duty vehicles and heavy-duty vehicles:
   — number of recharging points, to be reported for each of the categories under point 2;
   — number of recharging stations, to be reported for each of the categories under point 2;
   — total aggregated power output of the recharging stations.
## ANNEX IV

### Correlation table

<table>
<thead>
<tr>
<th>Directive 2014/94/EU</th>
<th>This Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 1</td>
<td>Article 1</td>
</tr>
<tr>
<td>Article 2</td>
<td>Article 2</td>
</tr>
<tr>
<td>Article 3</td>
<td>Article 14</td>
</tr>
<tr>
<td>Article 4</td>
<td>Articles 3, 4, 5, 9 and 10</td>
</tr>
<tr>
<td>Article 5</td>
<td>Article 6</td>
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<tr>
<td>−</td>
<td>Article 7</td>
</tr>
<tr>
<td>Article 6</td>
<td>Articles 8 and 11</td>
</tr>
<tr>
<td>−</td>
<td>Article 12</td>
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<tr>
<td>−</td>
<td>Article 13</td>
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<tr>
<td>Article 7</td>
<td>Article 19</td>
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<td>Article 8</td>
<td>Article 22</td>
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<tr>
<td>Article 9</td>
<td>Article 23</td>
</tr>
<tr>
<td>Article 10</td>
<td>Articles 15, 16 and 24</td>
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<tr>
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<td>Article 17</td>
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<td>Article 18</td>
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<td>Article 26</td>
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<td>Article 13</td>
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<td>Annex I</td>
<td>Annex I</td>
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<td>Annex II</td>
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<td>Annex III</td>
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REGULATION (EU) 2023/1805 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 September 2023

on the use of renewable and low-carbon fuels in maritime transport, and amending Directive 2009/16/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 100(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) Maritime transport accounts for around 75% of the Union’s external trade and 31% of its internal trade in terms of volume. 400 million passengers embark or disembark annually in ports of Member States, including around 14 million on cruise passenger ships. Maritime transport is therefore an essential component of the Union’s transport system and plays a critical role for the Union’s economy. The maritime transport market is subject to strong competition between economic actors within and outside the Union for which a level playing field is indispensable. The stability and prosperity of the maritime transport market and its economic actors rely on a clear and harmonised policy framework within which maritime transport operators, ports and other actors in the sector can operate on the basis of equal opportunities. Where market distortions occur, they risk putting maritime transport operators or ports at a disadvantage compared to their competitors within the maritime transport sector or in other transport sectors. In turn, it is possible for that disadvantage to result in a loss of competitiveness of the maritime transport industry, fewer jobs and a loss of connectivity for citizens and businesses.

(2) According to the EU Blue Economy Report, 2022, the EU Blue Economy created a total of approximately 5.7 million jobs in 2014, of which 3.2 million were created through direct employment in the established sectors and an additional 2.5 million were generated via the respective supply chains. That report also states that Union maritime ports alone create approximately 2.5 million jobs (direct and indirect) in 2014. Of that amount of jobs, only approximately 0.5 million are captured by sectoral statistics, because maritime ports generate employment and economic benefits in other sectors such as logistics and maritime shipping services. The seven established sectors of the EU Blue Economy generated a gross value added of EUR 183.9 billion in 2019 (3).

(1) OJ C 152, 6.4.2022, p. 145.
According to the Commission Staff Working Document accompanying the Commission Communication of 9 December 2020 entitled 'Sustainable and Smart Mobility Strategy – putting European transport on track for the future', compared to other modes of transport, maritime transport remains the most carbon-efficient mode of transport per ton km. At the same time, ship traffic to or from ports in the European Economic Area accounts for some 11% of all Union carbon dioxide (CO₂) emissions from transport and 3 to 4% of total Union CO₂ emissions. CO₂ emissions from maritime transport are expected to increase, unless further action is taken. All sectors of the Union economy are to contribute to the swift reduction of greenhouse gas (GHG) emissions to net zero at the latest by 2050, as enshrined in Regulation (EU) 2021/1119 of the European Parliament and of the Council (4). It is therefore essential for the Union to set out an appropriate pathway for the swift ecological transition of the maritime transport sector, which would also contribute to maintaining and further promoting the Union’s global leadership in relation to green technologies, services and solutions, and to further stimulating job creation in the related value chains while maintaining competitiveness.

To enhance the Union’s climate commitment under the Paris Agreement (5), adopted under the United Nations Framework Convention on Climate Change (the ‘Paris Agreement’), Regulation (EU) 2021/1119 aims to reduce GHG emissions (emissions after deduction of removals) by at least 55% compared to 1990 levels by 2030 and puts the Union on a path to becoming climate neutral by 2050 at the latest. Additionally, various complementary policy instruments are needed to promote and speed up the use of sustainably produced renewable and low-carbon fuels, including in the maritime transport sector, while respecting the principle of technological neutrality. The necessary technology development and its deployment have to be under way by 2030 to prepare for much more rapid change thereafter. It is also essential to foster innovation and to support research for emerging and future innovation such as emerging alternative fuels, eco-design, bio-based materials, wind propulsion and wind-assisted propulsion.

In the context of fuel transition to renewable and low-carbon fuels and substitute sources of energy, it is essential to ensure the proper functioning of and fair competition in the Union maritime transport market regarding maritime fuels, which account for a substantial share of companies’ and operators’ costs. Policy measures should therefore be cost-effective. Differences in fuel requirements across Member States can significantly affect ship operators’ economic performance and negatively impact competition in the market. Due to the international nature of shipping, ship operators may easily bunker in third countries and carry large amounts of fuel, which could also contribute to a risk of loss of competitiveness of Union ports in comparison to non-Union ports. That situation could lead to carbon leakage and detrimental effects on the competitiveness of the sector if the availability of renewable and low-carbon fuels in maritime ports under the jurisdiction of a Member State is not accompanied by requirements for their use that apply to all ships arriving at and departing from maritime ports under the jurisdiction of Member States. Therefore, this Regulation should lay down measures to ensure that the penetration of renewable and low-carbon fuels in the maritime fuels market takes place under the conditions of fair competition on the Union maritime transport market.

The maritime transport sector is subject to strong international competition. Major differences in regulatory burdens across flag states have often led to unwanted practices such as the reflagging of ships. The sector’s intrinsic global character underlines the importance of a flag-neutral approach and of a favourable regulatory environment, which would help to attract new investment and safeguard the competitiveness of Union ports, shipowners and ship operators.


In order to produce an effect on all activities in the maritime transport sector, this Regulation should apply to half of the energy used by a ship performing voyages arriving at a port under the jurisdiction of a Member State from a port outside the jurisdiction of a Member State, half of the energy used by a ship performing voyages departing from a port under the jurisdiction of a Member State and arriving at a port outside the jurisdiction of a Member State, the entirety of the energy used by a ship performing voyages arriving at a port under the jurisdiction of a Member State from a port under the jurisdiction of a Member State, and the energy used within a port under the jurisdiction of a Member State. Such a framework of application would ensure the effectiveness of this Regulation, including by increasing the positive impact on the environment of such framework. That framework should limit the risk of evasive port calls and the risk of delocalisation or rerouting of activities outside the Union. In order to ensure smooth operation of maritime traffic and to avoid distortions in the internal market, a level playing field among maritime transport operators and among ports with regard to all journeys arriving at or departing from ports under jurisdiction of Member States, as well as the stay of ships in those ports, should be ensured by consistent rules set out in this Regulation.

It is essential for the Commission and the competent authorities of Member States to continuously ensure that their administrative procedures reflect best practices and to take measures in order to ensure consistency, avoid duplication in sectoral legislation and simplify the enforcement of this Regulation, thereby keeping the administrative burden on shipowners, ship operators, ports and verifiers to a minimum.


Consultations between the managing body of the port and port users and other relevant stakeholders, as provided for in Article 15(2) of Regulation (EU) 2017/352 of the European Parliament and of the Council (⁷), should take place in order to coordinate the availability of port services with regard to the alternative fuel supply that is planned and deployed in ports, as well as with regard to the demand expected from ships calling at those ports.

(11) The rules laid down in this Regulation should apply in a non-discriminatory manner to ships regardless of their flag. For reasons of coherence with Union and international rules in the area of maritime transport, and in order to limit the administrative burden, this Regulation should apply to ships with a gross tonnage (GT) above 5 000, but should not apply to warships, naval auxiliaries, fish-catching or fish-processing ships, wooden ships of a primitive build, ships not propelled by mechanical means, or government ships used for non-commercial purposes. Although ships above 5 000 GT represent only approximately 55 % of all ships calling at ports under Regulation (EU) 2015/757 of the European Parliament and of the Council (13), they are responsible for approximately 90 % of CO₂ emissions from the maritime transport sector. The Commission should regularly reassess the situation, with a view to eventually extending the scope of this Regulation to ships below 5 000 GT.

(12) Member States which have no maritime ports on their territory, no accredited verifier, no ships flying their flag that fall under the scope of this Regulation, and which are not an administering state within the meaning of this Regulation do not need to take any action concerning the respective requirements under this Regulation for as long as those circumstances are present.

(13) Given the increased costs for ships which comply with the requirements of this Regulation, the absence of a global measure exacerbates the risk of circumvention. Evasive port calls to ports outside of the Union and relocation of transhipment activities to ports outside of the Union will not only diminish the environmental benefits of internalising the cost of emissions from maritime transport activities but may lead to additional emissions due to the additional distance travelled by ships in order to evade the application of this Regulation. It is therefore appropriate to exclude from the concept of ‘port of call’ certain stops at non-Union ports. That exclusion should target ports in the Union’s vicinity where the risk of evasion is most significant. A limit of 300 nautical miles from a port under the jurisdiction of a Member State constitutes a proportionate response to evasive behaviour, balancing the additional burden and the risk of evasion. Moreover, the exclusion from the concept of port of call should only target stops by containerships at certain non-Union ports, where the transhipment of containers accounts for most container traffic. For such shipments, the risk of evasion, in the absence of mitigating measures, also consists in a shift of port hub to ports outside the Union, aggravating the effects of the evasion. To ensure the proportionality and equal treatment of the global measure, account should be taken of measures in third countries that are equivalent to this Regulation.

(14) In order to take into account the specific situation of island regions, as underlined by Article 174 of the Treaty on the Functioning of the European Union (TFEU), and the need to preserve connectivity between islands and peripheral regions of the Union with central regions of the Union, temporary exemptions should be allowed for voyages performed by passenger ships other than cruise passenger ships between a port of call under the jurisdiction of a Member State and a port of call under the jurisdiction of the same Member State located on an island with fewer than 200 000 permanent residents.

(15) Taking into account the special characteristics and constraints of the outermost regions of the Union, in particular their remoteness and insularity, special consideration should be given to preserving their accessibility and efficient connectivity by maritime transport. Therefore, for ships falling under the scope of this Regulation only half of the energy used on voyages departing from or arriving at a port of call located in an outermost region should be included in the scope of this Regulation. For the same reasons, temporary exemptions should be allowed for voyages between a port of call located in an outermost region and another port of call located in an outermost region, and in respect of the energy used by ships during their stay within the ports of call of the corresponding outermost regions.

(16) Member States that do not share a land border with any other Member State are particularly dependent on their maritime connection to the rest of the Union, in particular to maintain necessary connectivity for their citizens. Such Member States have to rely on public service contracts or public service obligations in order to achieve the goal of maintaining connectivity through passenger ships. A temporary exemption should be allowed in order to enable Member States to address the compelling need of providing a service of general economic interest and ensure connectivity as well as economic, social and territorial cohesion.

(17) In addition to a general possibility for Member States to exempt voyages performed by passenger ships, other than cruise passenger ships, to islands with fewer than 200,000 permanent residents, a similar exemption should be allowed with regard to domestic voyages to islands which are performed within the framework of a public service contract or subject to a public service obligation. Such contracts and obligations have been established by Member States in order to ensure an appropriate level of connectivity to island regions at affordable prices, which would otherwise not have been achieved by market forces. Member States should be entitled to temporarily exempt such voyages performed by passenger ships between its mainland and an island of the same Member State, in order to maintain the conditions under which the public service contracts or public service obligations were established and ensure the sustained connectivity, as well as the economic, social and territorial cohesion, of the island concerned.

(18) Article 2, point 1, of Council Regulation (EEC) No 3577/92 (14) establishes that the ports situated in Ceuta and Melilla are to be treated in the same way as island ports. Although they are not island ports by nature, their geographical position in mainland Africa and absence of land links with Spain means that, in relation to mainland Europe and in particular to Spain, those ports are comparable to island ports. Therefore, Ceuta and Melilla should be considered to be island ports in relation to the temporary exemption for the maritime cabotage between the mainland of a Member State and the islands under its jurisdiction.

(19) Sailing in ice conditions, especially in the northern parts of the Baltic Sea, and the technical properties of ice-class ships cause additional costs for maritime transport and such costs could be further increased by this Regulation. Such additional costs for ice-class ships due to sailing in ice conditions and due to their technical properties should be mitigated in order to maintain a level playing field. Companies should therefore be allowed to apply a limited adjusted amount of energy used on board for ice-class ships. In addition, for a limited period of time, this Regulation should enable a share of the additional energy used during sailing in ice conditions to be exempted for the specific periods during which ice-class ships face conditions of navigation in ice. To that end, a verifiable methodology should be established to enable correlation between exempted share of energy and actual ice navigation conditions. The Commission should reassess such methodology, in particular in light of the robustness of the monitoring of the data necessary to report the distance and the additional energy of navigation in ice conditions, with a view to possibly extending that measure.

(20) The entity responsible for ensuring compliance with this Regulation should be the company, defined as the shipowner or any other organisation or person, such as the manager or the bareboat charterer, that has assumed responsibility for the operation of the ship from the shipowner and that, on assuming such responsibility, has agreed to take over all the duties and responsibilities imposed by the International Management Code for the Safe Operation of Ships and for Pollution Prevention as implemented within the Union by Regulation (EC) No 336/2006 of the European Parliament and of the Council (15). The definition of company under this Regulation is in line with the global data collection system established in 2016 by the International Maritime Organization (IMO).


The development and deployment of new fuels and energy solutions requires a coordinated approach to match supply, demand and the provision of appropriate distribution infrastructure. While the current Union regulatory framework already partly addresses fuel production by means of Directive (EU) 2018/2001 and fuel distribution by means of Directive 2014/94/EU of the European Parliament and of the Council (16), there is also a need for a tool that establishes increasing levels of demand for renewable and low-carbon maritime fuels.

While instruments such as carbon pricing or targets for the carbon intensity of activity promote improvements in energy efficiency, they are not suited to bring about a significant shift towards renewable and low-carbon fuels in the short and medium term. A specific regulatory approach dedicated to the deployment of renewable and low-carbon maritime fuels and substitute sources of energy, such as wind or electricity, is therefore necessary.

Policy intervention to stimulate demand for renewable and low-carbon maritime fuels should be goal-based and respect the principle of technological neutrality. Accordingly, limits should be set on the GHG intensity of the energy used on board by ships without prescribing the use of any particular fuel or technology. Such limits should be set in relation to a reference value, corresponding to the fleet average GHG intensity of the energy used on board by ships in 2020 determined on the basis of the data monitored and reported in the framework of Regulation (EU) 2015/757, of the methodology and of the default values laid down in Annexes I and II to this Regulation.

Development and deployment of renewable and low-carbon fuels with a high potential for sustainability, commercial maturity and a high potential for innovation and growth to meet future needs should be promoted. This will support creating innovative and competitive fuels markets and ensure sufficient supply of sustainable maritime fuels in the short and long term to contribute to Union transport decarbonisation ambitions, while strengthening the Union's efforts towards a high level of environmental protection. For this purpose, sustainable maritime fuels produced from feedstock listed in Parts A and B of Annex IX to Directive (EU) 2018/2001, as well as synthetic maritime fuels, should be eligible. In particular, sustainable maritime fuels produced from feedstock listed in Part B of Annex IX to Directive (EU) 2018/2001 are essential, as the most commercially mature technology for the production of such maritime fuels with a view to decarbonising maritime transport will already be available in the short term.

Indirect land-use change occurs when the cultivation of crops for biofuels, bioliquids and biomass fuels displaces traditional production of crops for food and feed purposes. Such additional demand increases the pressure on land and can lead to the extension of agricultural land into areas with high-carbon stock, such as forests, wetlands and peatland, causing additional GHG emissions and loss of biodiversity. Research has shown that the scale of the effect depends on a variety of factors, including the type of feedstock used for fuel production, the level of additional demand for feedstock triggered by the use of biofuels, bioliquids and biomass fuels, and the extent to which land with high-carbon stock is protected worldwide. The level of GHG emissions caused by indirect land-use change cannot be unequivocally determined with the level of precision required for the establishment of emission factors required by the application of this Regulation. However, there is evidence that all fuels produced from feedstock cause indirect land-use change to various degrees. In addition to the GHG emissions linked to indirect land-use change, which is capable of negating some or all GHG emissions savings of individual biofuels, bioliquids or biomass fuels, indirect land-use change poses risks to biodiversity. Those risks are particularly serious in connection with a potentially large expansion of production determined by a significant increase in demand. Accordingly, the use of food and feed crop-based fuels should not be promoted under this Regulation. Directive (EU) 2018/2001 already limits and sets a cap on the contribution of such biofuels, bioliquids and biomass fuels to the GHG emissions savings targets in the road and rail transport sector considering their lower environmental benefits, lower performance in terms of GHG reduction potential and broader sustainability concerns.

In order to create a clear and predictable legal framework and thereby encourage the early market development and deployment of the most sustainable and innovative fuel technologies with growth potential to meet future needs, a dedicated incentive for renewable fuels of non-biological origin (RFNBO) is necessary. This incentive is justified by the fact that those types of fuels have high potential to introduce renewable energy into the marine bunker fuel mix, by their significant decarbonisation potential, as well as by their estimated production costs in the short- and mid-term. When produced from renewable electricity and carbon captured directly from the air, synthetic fuels can achieve up to 100% emissions savings compared to fossil fuels. They also have considerable advantages compared to other types of sustainable fuels with regard to resource efficiency of the production process, in particular as regards water consumption. However, the production costs of RFNBO are currently much higher than the market price of conventional fuel and are expected to retain such higher costs in the mid-term. Therefore, this Regulation should provide for a combination of measures to ensure the support for the uptake of sustainable RFNBO, including the possibility to use a 'multiplier' until the end of 2033, allowing the energy from RFNBO to count twice. In addition, a 2% RFNBO subtarget should apply as of 2034 if, further to monitoring of the market, the Commission reports that the share of RFNBO in the maritime bunker fuels used by ships falling under the scope of this Regulation is less than 1% by 2031. That combination of measures to support RFNBO is intended to give ship operators and fuel suppliers a signal of opportunity for investment for the uptake of that type of renewable, scalable and sustainable fuel, as it provides both an end target giving the fuel suppliers certainty regarding future minimum demand as well as the opportunity for the market to find the most efficient way to adjust accordingly. Given that a market for maritime RFNBO is yet to develop, this Regulation includes safeguards and flexibility towards different possible market uptake scenarios.

Although RFNBO present a high potential to meet decarbonisation needs in the maritime sector, it is possible that other fuels will also present comparable decarbonisation potential. Factors such as technology maturity or availability to the maritime sector may affect the uptake of renewable and low-carbon fuels in different ports. Therefore, it is essential to ensure technological neutrality and avoid unduly discriminating against other fuels that achieve similar GHG intensity reductions as RFNBO, as well as to avoid penalising ships that use such fuels. To this end, it is important to note the GHG saving threshold of 70% required for RFNBO, as set out by a Directive of the European Parliament and of the Council amending Directive (EU) 2018/2001 of the European Parliament and of the Council, Regulation (EU) 2018/1999 of the European Parliament and of the Council, Regulation (EU) 2018/1999 of the European Parliament and of the Council and Directive 98/70/EC of the European Parliament and of the Council as regards the promotion of energy from renewable sources, and repealing Council Directive (EU) 2015/652. Such threshold can also be met by fuels other than RFNBO, of biologic or synthetic origin.

The maritime transport sector currently has insignificant levels of demand for food- and feed crop-based biofuels, bioliquids and biomass fuels, since over 99% of currently used maritime fuels are of fossil origin. The non-eligibility of food- and feed crop-based fuels for contributing to the objectives of this Regulation also minimises any risk to the slowing down of decarbonisation of the transport sector, which could otherwise result from a shift of crop-based biofuels from road transport to maritime transport. It is essential to minimise such a shift, as road transport currently remains by far the most polluting transport sector and maritime transport currently uses predominantly fuels of fossil origin. It is therefore appropriate to avoid the creation of a potentially large demand for food- and feed crop-based biofuels, bioliquids and biomass fuels by promoting their use under this Regulation. Accordingly, the additional GHG emissions and loss of biodiversity caused by all types of food- and feed crop-based fuels require that those fuels be considered to have the same emission factors as the least favourable pathway.

The long lead times associated with the development and deployment of new fuels and energy solutions for maritime transport, as well as the long average lifespan of ships, which typically ranges between 25 and 30 years, require rapid action and the establishment of a clear and predictable long-term regulatory framework that facilitates planning and investment from all the stakeholders concerned. Such regulatory framework will facilitate the development and deployment of new fuels and energy solutions for maritime transport, and encourage investment from stakeholders. Such regulatory framework should also define limits for the GHG intensity of the energy used on board by ships until 2050. Those limits should become more ambitious over time to reflect the expected technology development and increased production of renewable and low-carbon maritime fuels.
This Regulation should establish the methodology and the formula for the calculation of the yearly average GHG intensity of the energy used on board by a ship. That formula should be based on the fuel consumption reported by ships and consider the relevant emission factors of the consumed fuels. The use of substitute sources of energy, such as wind or electricity, should also be reflected in the methodology.

In order to provide a more complete picture of the environmental performance of the various energy sources, the GHG performance of fuels should be assessed on a well-to-wake basis, taking into account the impacts of energy production, transport, distribution and use on board. This is to provide incentives regarding technologies and production pathways that provide a lower GHG footprint and real benefits compared to the existing conventional fuels.

The well-to-wake performance of renewable and low-carbon maritime fuels should be established using default or actual and certified emission factors covering the well-to-tank and tank-to-wake emissions. For the purpose of this Regulation, only default well-to-tank emission factors and default tank-to-wake CO$_2$ emission factors for fossil fuels should be used.

In the event of technological progress concerning new GHG abatement technologies, such as onboard carbon capture, the Commission should assess the possibility to reflect, in the GHG intensity and compliance balance formulas set out in Annexes I and IV respectively, the contribution of such technologies to lowering the GHG direct emissions on board ships.

A comprehensive approach to the most relevant GHG emissions (CO$_2$, CH$_4$ and N$_2$O) is necessary to promote the use of energy sources providing a lower GHG footprint overall. In order to reflect the global warming potential of methane and nitrous oxides, the limit set by this Regulation should therefore be expressed in terms of 'CO$_2$ equivalent'.

The use of renewable energy sources and alternative propulsion, such as wind and solar energy, greatly reduces the GHG intensity of the overall ship energy use. The difficulty to accurately measure and quantify those energy sources (intermittence of the energy use, direct transfer as propulsion, etc.) should not impede their recognition in the overall ship energy use through means of approximations of their contribution to the ship’s compliance balance.

Air pollution produced by ships (sulphur oxides, nitrogen oxides and particulate matter) in ports is a significant concern for coastal areas and port cities. Therefore, specific and stringent obligations should be imposed to reduce emissions from ships moored at the quayside.

The obligation for ports to provide on-shore power supply (OPS), laid down in Regulation (EU) 2023/1804, should be matched by a corresponding obligation set out in this Regulation for ships to connect to OPS infrastructure while moored at the quayside, in order to ensure the effectiveness of that infrastructure and avoid the risk of stranded assets.

The use of OPS abates air pollution produced by ships and reduces the amount of GHG emissions generated by maritime transport. OPS represents an increasingly clean power supply available to ships, in view of the growing shares of renewables and fossil-free energy sources in the Union electricity mix. While only the provision on OPS connection points is covered by Directive 2014/94/EU, the demand for, and as a result the deployment of, that technology have remained limited. Therefore, specific rules should be established to mandate the use of OPS by containerships and passenger ships, since those are the ship categories that produce the highest amount of emissions per ship while moored at the quayside, according to the data collected within the framework of Regulation (EU) 2015/757 in 2018.
(39) In addition to OPS, other technologies might be capable of offering equivalent environmental benefits in ports. When the use of an alternative technology is demonstrated to be equivalent to the use of OPS, a ship should be exempted from the obligation to use OPS.

(40) Different OPS projects and solutions have been tested for ships at anchorage, but there is currently no mature and scalable technical solution available. For that reason, the obligation to use OPS should be, in principle, limited to ships moored at the quayside. Nevertheless, the Commission should regularly reassess the situation, with a view to extending that obligation to ships at anchorage, when the necessary technologies are sufficiently mature. In the meantime, Member States should be allowed to impose, in certain cases, the obligation to use OPS on ships at anchorage, for example in ports that are already equipped with such technology or are located in areas where any pollution should be avoided.

(41) Exceptions from the obligation to use OPS should also be provided for a number of objective reasons, subject to verification by the competent authority of the Member State of the port of call or any duly authorised entity, after consulting relevant entities where appropriate. Such exceptions should be limited to unscheduled port calls, which are not made on a systematic basis, for reasons of safety or saving life at sea, to short stays of ships moored at the quayside of less than two hours as this is the minimum time required for connection, to cases of unavailability or incompatibility of OPS, to the use of onboard energy generation under emergency situations and to maintenance and functional tests.

(42) In ports falling under the requirements of Article 9 of Regulation (EU) 2023/1804, exceptions applicable in the event of unavailability or incompatibility of OPS should be limited after shipowners and port operators have had sufficient time to make the necessary investments, in order to provide the necessary incentives for those investments and avoid unfair competition. Ship operators should plan carefully their port calls to make sure that they can carry out their activities when moored at the quayside without emitting air pollutants and GHG, in order to protect the environment in coastal areas and port cities. A limited number of exceptions applicable in the event of unavailability or incompatibility of OPS should be provided for to cater for situations where OPS was not provided, for reasons beyond the control of the ship operator. In order to mitigate the risk of stranded assets, incompatibility of OPS infrastructure on board and at berth as well as alternative fuel demand and supply imbalances, frequent consultation meetings between relevant stakeholders should be organised to discuss and take decisions on requirements and future plans.

(43) The requirement for ports to provide OPS, laid down in Regulation (EU) 2023/1804, takes into account the types of ships served and the respective traffic volumes of maritime ports. The requirement for ships to connect to OPS should not apply to ships when calling at ports that are not covered by the OPS requirement set out in that Regulation, unless the port has OPS installed and available at the visited quayside, in which case the ship should be required to connect to OPS from 1 January 2035.

(44) Considering the positive effects of the use of OPS on local air pollution and the need to incentivise the uptake of that technology in the short term, the carbon intensity of the production of the electricity supplied at berth should be counted as zero. The Commission should envisage the possibility to take into account the actual GHG emissions related to the electricity delivered through OPS at a later stage.

(45) The implementation of this Regulation should take due account of the diverse governance models for ports across the Union, in particular as regards the responsibility for issuing a certificate exempting a ship from the obligation to connect to OPS.

(46) Coordination between ports and ship operators is crucial to ensure smooth connection procedures to OPS in ports. Ship operators should inform the ports they call at about their intention to connect to OPS and about the amount of power needed during the given call, in particular when it exceeds the estimated needs for that ship category.
(47) From 2035, the number of exceptions granted under this Regulation from the obligation to connect to OPS, which apply to certain cases where the ship is unable to connect to OPS, should be limited per ship during a reporting period. To ensure fair treatment of ships and to reflect the differences in their operating profiles, the number of exceptions should reflect the frequency of their port calls but should never amount to more than ten port calls per reporting period. However, a ship should not be penalised and port calls should not be counted against the maximum number of exceptions where, prior to arrival to a port, the ship has requested to connect to OPS and that request has been accepted by the port or the duly authorised entity, but the ship is unable to connect to OPS, and it is able to demonstrate that it could not have reasonably known it would be unable to connect to OPS.

(48) A robust and transparent monitoring, reporting and verification system should be put in place by this Regulation in order to trace compliance with its provisions. Such system should apply in a non-discriminatory way to all ships and require third party verification in order to ensure the accuracy of the data submitted within that system. In order to facilitate the fulfilment of those monitoring and reporting obligations and the carrying-out of verification activities by the verifiers, similarly to Regulation (EU) 2015/757, companies should document the envisaged monitoring method and provide further details on the application of this Regulation in a monitoring plan. The monitoring plan, as well as its subsequent modifications, if applicable, should be submitted to and assessed by the verifier.

(49) Companies should be responsible for monitoring and reporting the amount and type of energy used on board by ships in navigation and at berth, as well as other relevant information, such as information on the type of engine on board or presence of wind-assisted propulsion technologies, with a view to showing compliance with the limit on the GHG intensity of the energy used on board by a ship set out by this Regulation. To facilitate the fulfilment of those monitoring and reporting obligations and the carrying-out of verification activities by the verifiers, similarly to Regulation (EU) 2015/757, companies should document the envisaged monitoring method and provide further details on the application of this Regulation in a monitoring plan. The monitoring plan, as well as its subsequent modifications, if applicable, should be submitted to and assessed by the verifier.

(50) In order to limit the administrative burden, a unique monitoring, reporting and verification system for companies should be established for the purpose of implementing Union legal acts on reduction of GHG emissions from maritime transport. To that purpose, shortly after the publication of this Regulation, the Commission should examine the consistency of this Regulation with Regulation (EU) 2015/757 and possible duplication between those two regulations and, where appropriate, prepare a legislative proposal to amend this Regulation or Regulation (EU) 2015/757.

(51) A robust certification and monitoring of fuels is essential to achieve the objectives of this Regulation and guarantee the environmental integrity of the renewable and low-carbon fuels that are expected to be deployed in the maritime sector. Such certification should be undertaken by means of a transparent and non-discriminatory procedure. With a view to facilitating certification and limiting the administrative burden, the certification of fuels defined in accordance with Directive (EU) 2018/2001 or, where applicable, with the relevant provisions of a Union legal act concerning the internal markets in renewable and natural gases and in hydrogen, should rely on the rules established by those Union legal acts for certification. That approach to certification should also apply to fuels bunkered outside the Union, which should be considered to be imported fuels, in a similar way as in Directive (EU) 2018/2001. Where companies intend to depart from the default values provided for by those Union legal acts or by this new framework, that should only be done when values can be certified by one of the voluntary schemes recognised under Directive (EU) 2018/2001 or, where applicable, under a Union legal act which concerns the internal markets in renewable and natural gases and in hydrogen, and which establishes certain GHG emissions savings thresholds as well as the methodologies for their calculation (for well-to-tank values).

(52) The possibility to calculate actual tank-to-wake emission factors, deviating from those defined in Annex II, should be made available to companies, provided that such calculation is determined in accordance with and supported by recognised international standards relevant for the subject matter. Such calculation of tank-to-wake emission factors should be primarily scoped to laboratory testing or direct emissions measurement of slipped emissions from energy converters, including internal combustion engines, fuel cells and associated reforming units, gas turbines or boilers.
Since actual tank-to-wake CO₂ emission factors are related to the fuel composition rather than the energy converter, they should not be different from the default values contained in Annex II. Those tank-to-wake emission factors should only be recalculated, in particular for synthetic fuels or biofuels, in the event that any relevant international standard is developed to that effect. It should not be possible to deviate from the default values presented for the CO₂ combustion emission factors for fossil fuels.

(53) Verification activities are carried out by verifiers. In order to ensure impartiality and effectiveness, verifiers should be independent and competent legal entities and should be accredited by national accreditation bodies established pursuant to Regulation (EC) No 765/2008 of the European Parliament and of the Council (17). Verifiers should be equipped with means and staff commensurate with the size of the fleet for which they perform verification activities under this Regulation. Verification should ensure the accuracy and completeness of the monitoring and reporting by companies and the compliance with this Regulation.

(54) Based on the data and information monitored and reported by companies, the verifiers should calculate and establish the yearly average GHG intensity of energy used on board by a ship and the ship's compliance balance with respect to the limit, including any compliance surplus or deficit, as well as determine whether the ship has complied with the obligation to use OPS. The verifier should notify that information to the company concerned. Where the verifier is the same entity as the verifier for the purposes of Regulation (EU) 2015/757, such notification could be done together with the verification report under that Regulation.

(55) The Commission should establish and ensure the functioning of an electronic database that registers the performance of each ship and ensures its compliance with this Regulation (the 'FuelEU database'). The FuelEU database should be used for all most important actions necessary to fulfil the obligations set out in this Regulation. In order to facilitate reporting and limit administrative burden to companies, verifiers and other users, the FuelEU database should build upon the existing THETIS-MRV module or, to the extent possible, should be developed as an upgraded version of it. The FuelEU database should also enable information and data collected for the purposes of Regulation (EU) 2015/757 to be used.

(56) Compliance with this Regulation will depend on elements that might be beyond the control of the company, such as issues related to fuel availability or fuel quality. Therefore, companies should be allowed the flexibility of rolling-over a compliance surplus from one year to another or borrowing an advance compliance surplus, within certain limits, from the following year. The use of OPS at berth, being of high importance for local air quality in port cities and coastal areas, should not be eligible for similar flexibility provisions.

(57) In order to avoid technology lock-in and continue supporting the deployment of the most performant solutions, companies should be allowed to pool the performances of different ships. To that effect, it should be possible to use the over-performance of one ship to compensate the under-performance of other ships, provided that the total pooled compliance is positive. This creates a possibility to reward over-compliance and provides incentives for investment in more advanced technologies. The possibility to opt for pooled compliance should remain voluntary and should be subject to agreement of the companies concerned.

(58) A document of compliance (the 'FuelEU document of compliance') issued by a verifier or, where applicable, the competent authority of the administering State, following the procedures established by this Regulation, should be held by ships as evidence of compliance with the limits on the GHG intensity of the energy used on board by a ship and with the obligation to use OPS. Verifiers or, where applicable, the competent authority of the administering State should record in the FuelEU database the issuance of the FuelEU document of compliance.

The number of non-compliant port calls should be determined by verifiers in accordance with a set of clear and objective criteria taking into account all relevant information, including time of stay, the amount and type of energy consumed, and the application of any exceptions, for each port call falling under the scope of this Regulation. That information should be made available by the companies to the verifiers for the purpose of determining compliance.

Without prejudice to the possibility of complying through the flexibility and pooling provisions, ships that do not meet the limits on the yearly average GHG intensity of the energy used on board should be subject to a penalty that has dissuasive effect, is proportionate to the extent of the non-compliance and removes any economic advantage of non-compliance, thus preserving a level playing field in the sector (the ‘FuelEU penalty’). The FuelEU penalty should be based on the amount and cost of renewable and low-carbon fuels that the ships should have used to meet the requirements of this Regulation.

A FuelEU penalty should be imposed also for each non-compliant port call. That FuelEU penalty should be proportionate to the cost of using the electricity at sufficient level, should have a dissuasive effect as regards the use of more polluting energy sources and should be expressed in a fixed amount in EUR, multiplied by the established total electrical power demand of the ship at berth and by the total number of hours, rounded up to the nearest whole hour, spent at berth in non-compliance with OPS requirements. Due to lack of accurate figures on the cost of providing OPS in the Union, this rate should be based on the average electricity price in the Union for non-household consumers multiplied by a factor of two to account for other charges related to the provision of the service, including, inter alia, connection costs and investment recovery elements.

The revenue generated by the payment of FuelEU penalties and collected by the administering States should be used to promote the distribution and use of renewable and low-carbon fuels in the maritime transport sector and help maritime transport operators to meet their climate and environmental goals.

While the company should remain responsible for fulfilling monitoring and reporting obligations under this Regulation, as well as for paying the FuelEU penalties, in line with the ‘polluter pays’ principle and in order to promote the uptake of cleaner fuels, the entity responsible for purchasing the fuel or for taking operational decisions that affect the GHG intensity of the energy used by the ship could, through contractual agreements with the company, in the event of compliance deficit, be put under the obligation to reimburse or otherwise compensate the company with respect to the cost of the FuelEU penalties resulting from the operation of the ship. That company should be able to, on a contractual basis, request the verifier to calculate the amount of the FuelEU penalties corresponding to the operation of the ship by the other entity during the reporting period. Within this context, operation of the ship should be understood to mean determining the cargo carried, the route and the speed of the ship. Similarly, while the company should remain responsible for fulfilling monitoring and reporting obligations under this Regulation, as well as for paying the FuelEU penalties, companies and fuel suppliers should be able to, by means of contractual agreements, agree on mutual commitments to produce, supply and purchase predetermined quantities of certain fuels. Such contractual agreements could provide for the liability of fuel suppliers to compensate the company for the payment of penalties in cases where fuels were not made available to the company as agreed.

Enforcement of the obligations relating to this Regulation should be based on existing instruments, including those established under Directives 2009/16/EC (*) and 2009/21/EC (**) of the European Parliament and of the Council. Additionally, Member States should lay down the rules on sanctions applicable to infringements of this Regulation. The sanctions provided for should be effective, proportionate and dissuasive. To avoid undue or double punishment for the same infringements, such sanctions should not duplicate the FuelEU penalties applied in a case where a ship has a compliance deficit or made non-compliant port calls. The document confirming compliance of the ship with the requirements of this Regulation should be added to the list of certificates and documents referred to in Annex IV to Directive 2009/16/EC.

In order to reduce the administrative burden on companies, for each company only one Member State should be responsible for supervising the enforcement of this Regulation. The relevant provisions of Directive 2003/87/EC of the European Parliament and of the Council (20) should be applied to determine the administering State in respect of each company. The administering State should be allowed to conduct additional checks on the compliance of a specific ship with this Regulation, for the two previous reporting periods, and should also ensure that the FuelEU penalties are paid in due time.

Given the importance of consequences that the measures taken by the verifiers under this Regulation may have for the companies concerned, in particular regarding the determination of non-compliant port calls, calculation of the amounts of FuelEU penalties and refusal to issue a FuelEU document of compliance, those companies should be entitled to apply for a review of such measures to the competent authority of the Member State where the verifier was accredited. In light of the right to an effective remedy, enshrined in Article 47 of the Charter of Fundamental Rights of the European Union, decisions taken by the competent authorities under this Regulation should be subject to review by a court of the Member State of that competent authority, carried out in accordance with its national law.

In order to maintain a level playing field through the efficient functioning of this Regulation, the power to adopt acts in accordance with Article 290 of the TFEU should be delegated to the Commission in respect of: amendment of the list of well-to-wake emission factors; information about the RFNBO subtarget; amending the existing table set out in Annex III by adding other zero-emission technologies; establishment of further methods and criteria of accreditation of verifiers; adaptation of a FuelEU penalty factor based on the developments in the cost of energy; and amendment of the numerical factor amount of the FuelEU penalty, based on the indexation of the average cost of electricity in the Union. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making (21). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States’ experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council (22). The Commission should take into account the possibility of reusing information and data collected for the purposes of Regulation (EU) 2015/757 when it establishes, by means of implementing acts, the list of neighbouring container transhipment ports excluded from the definition of ports of call; the criteria for assessment of the production capacity and availability of RFNBO in the maritime transport sector and the method to calculate the factor of price difference between RFNBO and fossil fuels; the specification of rules for the application of the RFNBO subtarget, if applicable; the detailed criteria for acceptance of the technologies and the way they are operated to be considered as zero-emission technologies; the information from ships intending to connect to OPS or use a zero-emission technology in ports and the procedure for providing such information; the templates for standardised monitoring plans, including the technical rules for their uniform application; the list of international standards and certification references to demonstrate actual tank-to-wake emission factors; further specifications of the rules for verification activities referred to in this Regulation; rules for access rights to and the functional and technical specifications of the FuelEU database; and models for the FuelEU document of compliance.


Given the international dimension of the maritime transport sector, a global approach to limiting the GHG intensity of the energy used by ships is preferable as such an approach would be significantly more effective due to its broader scope. In that context, and with a view to facilitating the development of international rules within the IMO, the Commission should share relevant information on the implementation of this Regulation with the IMO and other relevant international bodies, and relevant submissions should be made to the IMO, continuing the Union's efforts to promote ambitious maritime decarbonisation targets at an international level. Where an agreement on a global approach is reached on matters of relevance to this Regulation, the Commission should review this Regulation with a view to aligning it, where appropriate, with the international rules.

The Commission should ensure implementation and availability of tools for collaboration and exchange of best practices for the maritime transport sector, as defined in the Commission Staff Working Document entitled 'Better Regulation Guidelines'.

Given that this Regulation will result in additional adjustment costs and administrative costs, the overall regulatory burden for the maritime transport sector should be kept under close review. To that end, the Commission should present a report to the European Parliament and to the Council evaluating the functioning of this Regulation. The Commission should assess in that report the extent to which the objectives of this Regulation have been met and to which extent it has impacted the competitiveness of the sector. That report should also cover the interaction of this Regulation with other relevant Union legal acts, including possible actions and measures that have been or could be taken to reduce the total cost pressure on the maritime transport sector.

Since the objective of this Regulation, namely the uptake of renewable and low-carbon fuels and substitute sources of energy by ships arriving at, staying within or departing from ports under the jurisdiction of a Member State across the Union, cannot be sufficiently achieved by the Member States without risking to introduce barriers to the internal market and distortions of competition between ports and between maritime transport operators, but can rather, by reason of its scale and effects, be better achieved by introducing uniform rules at Union level that create economic incentives for maritime operators to continue operating unimpededly while meeting obligations on the use of renewable and low-carbon fuels, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

Chapter I

General provisions

Article 1

Subject matter and objective

This Regulation lays down uniform rules imposing:

(a) a limit on the greenhouse gas (GHG) intensity of energy used on board by a ship arriving at, staying within or departing from ports under the jurisdiction of a Member State; and

(b) an obligation to use on-shore power supply (OPS) or zero-emission technology in ports under the jurisdiction of a Member State.

Its objective in doing so is to increase consistent use of renewable and low-carbon fuels and substitute sources of energy in maritime transport across the Union, in line with the objective of reaching Union-wide climate neutrality at the latest by 2050, while ensuring the smooth operation of maritime transport, creating regulatory certainty for the uptake of renewable and low-carbon fuels and sustainable technologies and avoiding distortions in the internal market.
Article 2

Scope

1. This Regulation applies to all ships of above 5 000 gross tonnage that serve the purpose of transporting passengers or cargo for commercial purposes, regardless of their flag, in respect of:

(a) the energy used during their stay within a port of call under the jurisdiction of a Member State;

(b) the entirety of the energy used on voyages from a port of call under the jurisdiction of a Member State to a port of call under the jurisdiction of a Member State;

(c) notwithstanding point (b), one half of the energy used on voyages arriving at or departing from a port of call located in an outermost region under the jurisdiction of a Member State; and

(d) one half of the energy used on voyages arriving at or departing from a port of call under the jurisdiction of a Member State, where the previous or the next port of call is under the jurisdiction of a third country.

2. By 31 December 2025, the Commission shall adopt implementing acts establishing a list of neighbouring container transhipment ports. The Commission shall update that list by 31 December every two years thereafter.

The implementing acts referred to in the first subparagraph shall list a port as a neighbouring container transhipment port where the share of transhipment of containers, measured in 20 foot equivalent units, exceeds 65 % of the total container traffic of that port during the most recent 12-month period for which relevant data are available and where that port is located outside the Union but less than 300 nautical miles from a port under the jurisdiction of a Member State.

For the purpose of those implementing acts, containers shall be considered to be transhipped when they are unloaded from a ship to a port for the sole purpose of being loaded onto another ship.

The list of neighbouring container transhipment ports established by the Commission shall not include ports located in a third country for which that third country effectively applies measures equivalent to this Regulation.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 29(3).

3. Member States may exempt from the application of paragraph 1, points (a) and (b) specific routes and ports in respect of the energy used on voyages performed by passenger ships other than cruise passenger ships between a port of call under the jurisdiction of a Member State and a port of call under the jurisdiction of the same Member State located on an island with fewer than 200 000 permanent residents, and in respect of the energy used during their stay within a port of call of that island. No such exemptions shall apply beyond 31 December 2029. Prior to the entry into force of those exemptions, Member States shall notify them to the Commission. The Commission shall publish those exemptions in the Official Journal of the European Union.

4. Member States may exempt from the application of paragraph 1, points (a) and (c) specific routes and ports in respect of the energy used by ships on voyages between a port of call located in an outermost region and another port of call located in an outermost region, and in respect of the energy used during their stay within the ports of call of those outermost regions. No such exemptions shall apply beyond 31 December 2029. Prior to the entry into force of those exemptions, Member States shall notify them to the Commission. The Commission shall publish those exemptions in the Official Journal of the European Union.
5. Member States that do not share a land border with any other Member State may exempt from the application of paragraph 1 passenger ships performing transnational voyages under public service obligations or public service contracts to the ports of call of other Member States. No such exemptions shall apply beyond 31 December 2029. Prior to the entry into force of those exemptions, Member States shall notify them to the Commission. The Commission shall publish those exemptions in the *Official Journal of the European Union*.

6. Member States may exempt from the application of paragraph 1 passenger ships providing maritime transport services within the meaning of Regulation (EEC) No 3577/92 under public service obligations or public service contracts, operating before 12 October 2023, for the specific routes between their mainland ports of call and ports of call under their jurisdiction located on an island or the cities of Ceuta and Melilla. No such exemptions shall apply beyond 31 December 2029. Prior to the entry into force of those exemptions, Member States shall notify them to the Commission. The Commission shall publish those exemptions in the *Official Journal of the European Union*.

For the purposes of the application of this paragraph, the cities of Ceuta and Melilla shall be considered as ports of call located on an island.

7. This Regulation does not apply to warships, naval auxiliaries, fish-catching or fish-processing ships, wooden ships of a primitive build, ships not propelled by mechanical means, or ships owned or operated by a government and used only for non-commercial purposes.

**Article 3**

**Definitions**

For the purposes of this Regulation, the following definitions apply:

1. ‘greenhouse gas emissions’ or ‘GHG emissions’ means the release of carbon dioxide (CO₂), methane (CH₄) and nitrous oxide (N₂O) into the atmosphere;

2. ‘biofuels’ means biofuels as defined in Article 2, second paragraph, point (33), of Directive (EU) 2018/2001;

3. ‘biogas’ means biogas as defined in Article 2, second paragraph, point (28), of Directive (EU) 2018/2001;

4. ‘recycled carbon fuels’ means recycled carbon fuels as defined in Article 2, second paragraph, point (35), of Directive (EU) 2018/2001;

5. ‘renewable fuels of non-biological origin’ (RFNBO) means renewable fuels of non-biological origin as defined in Article 2, second paragraph, point (36), of Directive (EU) 2018/2001;

6. ‘food and feed crops’ means food and feed crops as defined in Article 2, second paragraph, point (40), of Directive (EU) 2018/2001;

7. ‘zero-emission technology’ means a technology that, when used to provide energy, does not result in the release of the following greenhouse gases and air pollutants into the atmosphere by ships: carbon dioxide (CO₂), methane (CH₄), nitrous oxide (N₂O), sulphur oxides (SOₓ), nitrogen oxides (NOₓ) and particulate matter (PM);

8. ‘substitute sources of energy’ means renewable energy generated on board or electricity supplied from OPS;

9. ‘wind-assisted propulsion’ means propulsion, whether partial or full, of a ship by wind energy harnessed by means of wind-assistance propulsion systems such as, inter alia, rotor sails, kites, hard or rigid sails, soft sails, suction wings or turbines;
(10) ‘port of call’ means a port where ships stop to load or unload cargo or to embark or disembark passengers with the exclusion of stops for the sole purposes of refuelling, obtaining supplies, relieving the crew, going into dry-dock or making repairs to the ship, its equipment or both; stops in port because the ship is in need of assistance or in distress; ship-to-ship transfers carried out outside ports; stops for the sole purpose of taking shelter from adverse weather or rendered necessary by search and rescue activities; and stops of containerships in a neighbouring container transhipment port listed in the implementing act adopted pursuant to Article 2(2);

(11) ‘voyage’ means voyage as defined in Article 3, point (c), of Regulation (EU) 2015/757;

(12) ‘outermost region’ means a territory referred to in Article 349 TFEU;

(13) ‘company’ means the shipowner or any other organisation or person such as the manager or the bareboat charterer, which has assumed the responsibility for the operation of the ship from the shipowner and has agreed to take over all the duties and responsibilities imposed by the International Management Code for the Safe Operation of Ships and for Pollution Prevention;

(14) ‘gross tonnage’ (GT) means gross tonnage as defined in Article 3, point (e), of Regulation (EU) 2015/757;

(15) ‘ship at berth’ means ship at berth as defined in Article 3, point (n), of Regulation (EU) 2015/757;

(16) ‘ship at anchorage’ means a ship at berth which is not moored at the quayside;

(17) ‘energy used on board’ means the amount of energy, expressed in mega joules (MJ), used by a ship for propulsion and for the operation of any onboard equipment, at sea or at berth;

(18) ‘well-to-wake’ means a method for calculating emissions that takes into account the GHG impact of energy production, transport, distribution and use on board, including during combustion;

(19) ‘GHG intensity of the energy used on board’ means the amount of GHG emissions, expressed in grams of CO₂ equivalent established on a well-to-wake basis, per MJ of energy used on board;

(20) ‘emission factor’ means the average emission rate of a GHG relative to the activity data of a source stream, assuming complete oxidation for combustion and complete conversion for all other chemical reactions;

(21) ‘ice class’ means the notation assigned to the ship by the competent national authorities of the flag state or an organisation recognised by that state, showing that the ship has been designed for navigation in sea-ice conditions;

(22) ‘ice edge’ means the demarcation at any given time between the open sea and sea ice of any kind, whether fast or drifting, as set out in paragraph 4.4.8 of the World Meteorological Organisation Sea-Ice Nomenclature, March 2014;

(23) ‘sailing in ice conditions’ means the sailing by an ice-class ship in a sea area within the ice edge;

(24) ‘on-shore power supply’ (OPS) means the system to supply electricity to ships at berth, at low or high voltage, alternate or direct current, including ship-side and port-side installations, when feeding directly the ship main distribution switchboard for powering hotel and service workloads or charging secondary batteries;

(25) ‘electrical power demand at berth’ means the demand for electricity of a ship at berth for meeting all energy needs based on electricity on board;
(26) ‘established total electrical power demand of the ship at berth’ means the highest value, expressed in kilowatts, of the total demand for electricity of a ship at berth, including hotel and cargo handling workloads;

(27) ‘verifier’ means a legal entity carrying out verification activities, which is accredited by a national accreditation body pursuant to Regulation (EC) No 765/2008 and this Regulation;

(28) ‘FuelEU document of compliance’ means a document specific to a ship, issued to a company by a verifier, which confirms that that ship has complied with this Regulation for a specific reporting period;

(29) ‘passenger ship’ means a passenger ship as defined in Article 2, point (i), of Directive (EU) 2016/802 of the European Parliament and of the Council (23);

(30) ‘cruise passenger ship’ means a passenger ship that has no cargo deck and is designed exclusively for commercial transportation of passengers in overnight accommodation on a sea voyage;

(31) ‘containership’ means a ship designed exclusively for the carriage of containers in holds and on deck;

(32) ‘non-compliant port call’ means a port call during which the ship does not comply with the requirement set out in Article 6(1), and to which none of the exceptions provided for in Article 6(5) apply;

(33) ‘least favourable pathway’ means the most carbon-intensive production pathway used for any given fuel;

(34) ‘CO₂ equivalent’ means the metric measure used to compute the emissions from CO₂, CH₄ and N₂O on the basis of their global-warming potential, by converting amounts of CH₄ and N₂O to the equivalent amount of CO₂ with the same global warming potential;

(35) ‘compliance balance’ means the measure of a ship’s over- or under-compliance with regard to the limits for the yearly average GHG intensity of the energy used on board by a ship or the RFNBO subtarget, which is calculated in accordance with Part A of Annex IV;

(36) ‘compliance surplus’ means a compliance balance with a positive value;

(37) ‘compliance deficit’ means a compliance balance with a negative value;

(38) ‘total pool compliance balance’ means the sum of the compliance balances of all ships included in the pool;

(39) ‘managing body of the port’ means managing body of the port as defined in Article 2, point (5), of Regulation (EU) 2017/352;

(40) ‘administering State’ means a Member State determined by applying Article 3gf(1) of Directive 2003/87/EC in relation to a company within the meaning of this Regulation, without prejudice to the choice of the competent authorities in charge within the relevant Member State;

(41) ‘reporting period’ means a period from 1 January to 31 December of the year during which information referred to in this Regulation is monitored and recorded, where data for voyages starting and ending in two different calendar years is accounted under the calendar year concerned;

(42) ‘verification period’ means the calendar year directly following the reporting period.

Chapter II

Requirements for energy used on board by ships

Article 4

GHG intensity limit on energy used on board by a ship

1. The yearly average GHG intensity of the energy used on board by a ship during a reporting period shall not exceed the limit set out in paragraph 2.

2. The limit referred to in paragraph 1 shall be calculated by reducing the reference value of 91.16 grams of CO₂ equivalent per MJ by the following percentage:
   — 2% from 1 January 2025;
   — 6% from 1 January 2030;
   — 14.5% from 1 January 2035;
   — 31% from 1 January 2040;
   — 62% from 1 January 2045;
   — 80% from 1 January 2050.

3. The GHG intensity of the energy used on board by a ship shall be calculated as the amount of GHG emissions per unit of energy in accordance with the methodology set out in Annex I.

4. The Commission is empowered to adopt delegated acts in accordance with Article 28 to amend Annex II in order to include the well-to-wake emission factors related to any new sources of energy or to adapt the existing emission factors to ensure consistency with future international standards or Union legal acts in the field of energy, in accordance with the best available scientific and technical knowledge.

Article 5

Use of Renewable Fuels of Non-Biological Origin

1. For the calculation of the GHG intensity of the energy used on board by a ship, from 1 January 2025 to 31 December 2033 a multiplier of ‘2’ can be used to reward the ship for the use of RFNBO. The methodology for this calculation is set out in Annex I.

2. The Commission shall monitor, calculate and annually publish, on the basis of the data recorded in the FuelEU database referred to in Article 19 and at the latest 18 months after the end of each reporting period, the share of RFNBO in the yearly energy used on board by ships falling under the scope of this Regulation.

3. If the share of RFNBO referred to in paragraph 2 is less than 1% for the reporting period 2031, a subtarget of 2% shall apply for such fuels in the yearly energy used on board by a ship from 1 January 2034, subject to paragraph 5.

4. Paragraph 3 shall not apply where the monitoring results provided for in paragraph 2 that are available before 1 January 2033 demonstrate that the share referred to in paragraph 2 is more than 2%.

5. If, based on the monitoring activities referred to in paragraph 2 and following the Commission’s assessment, there is evidence of insufficient production capacity and availability of RFNBO to the maritime sector, uneven geographical distribution or a too high price of those fuels, the subtarget provided for in paragraph 3 shall not apply.
6. The Commission shall adopt implementing acts specifying the criteria for the assessment provided for in paragraph 5 and the method for calculating the factor of price difference between RFNBO and fossil fuels used in cell 14 of the table in Part B of Annex IV. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(3).

7. The Commission is empowered to adopt delegated acts in accordance with Article 28 to:
   (a) supplement paragraph 5 of this Article with additional elements;
   (b) inform about the non-applicability of the subtarget referred to in paragraph 3 of this Article, resulting from the monitoring referred to in paragraph 2 of this Article or the assessment referred to in paragraph 5 of this Article.

8. Where the subtarget referred to in paragraph 3 of this Article applies, the Commission shall adopt, by 31 December 2033, implementing acts to further specify the rules for the application of paragraph 3 of this Article as regards:
   (a) verification and calculation as referred to in Article 16;
   (b) applicable flexibility mechanisms set out in Articles 20 and 21;
   (c) applicable FuelEU penalties as referred to in Article 23 and Annex IV.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(3).

9. The subtarget referred to in paragraph 3 of this Article, if applicable, shall not apply to a ship which demonstrates that the same share of the yearly energy used on board is met by other fuels that provide equivalent GHG emissions savings and are certified pursuant to Article 10 of this Regulation, excluding biofuels referred to in Part B of Annex IX to Directive (EU) 2018/2001.

10. This Article shall not apply to the share of yearly energy used on board by ships from OPS.

**Article 6**

**Additional zero-emission requirements for energy used at berth**

1. From 1 January 2030, a ship moored at the quayside in a port of call which is covered by Article 9 of Regulation (EU) 2023/1804 and which is under the jurisdiction of a Member State shall connect to OPS and use it for all its electrical power demand at berth.

2. From 1 January 2035, a ship moored at the quayside in a port of call which is not covered by Article 9 of Regulation (EU) 2023/1804, which is under the jurisdiction of a Member State and where the quay is equipped with available OPS shall connect to that OPS and use it for all its electrical power demand at berth.

3. From 1 January 2030 and until 31 December 2034, and after consulting relevant stakeholders, including, where appropriate, the managing body of the port, a Member State may decide that a ship moored at the quayside in a port of call under its jurisdiction which is not covered by Article 9 of Regulation (EU) 2023/1804, or in certain parts of such port, shall connect to OPS and use it for all its electrical power demand at berth. The Member State shall notify its decision imposing such requirement to the Commission a year prior to the application thereof. Such decision must apply from the beginning of a reporting period. The Commission shall publish the information in the *Official Journal of the European Union* and make publicly available an updated list of the ports concerned. Such list shall be easily accessible.

4. Paragraphs 1, 2 and 3 shall apply to:
   (a) containerships;
   (b) passenger ships.
5. Paragraphs 1, 2 and 3 shall not apply to ships that:

(a) are moored at the quayside for less than two hours, calculated on the basis of time of arrival and time of departure monitored and recorded in accordance with Article 15;

(b) use zero-emission technologies which comply with the general requirements for such technologies provided for in Annex III and are listed and specified in the delegated and implementing acts adopted in accordance with paragraphs 6 and 7 of this Article, for all their electrical power demand at berth, while moored at the quayside;

(c) due to unforeseen circumstances beyond the control of the ship, have to make an unscheduled port call, which is not made on a systematic basis, for reasons of safety or saving life at sea, other than those already excluded under Article 3, point (10);

(d) are unable to connect to OPS due to the unavailability of OPS connection points in a port;

(e) are unable to connect to OPS because exceptionally the electrical grid stability is at risk, due to insufficient available shore-power to satisfy the ship's required electrical power demand at berth;

(f) are unable to connect to OPS because the shore installation at the port is not compatible with the onboard on-shore power equipment, provided that the installation for shore-connection on board the ship is certified in accordance with the technical specifications set out in Annex II to Regulation (EU) 2023/1804 for the shore-connection systems of seagoing ships;

(g) for a limited period of time, require the use of onboard energy generation, under emergency situations representing immediate risk to life, the ship or the environment or for other reasons of force majeure;

(h) while remaining connected to OPS, for a period of time limited to what is strictly necessary, require the use of onboard energy generation for maintenance tests or for functional tests carried out at the request of an officer of a competent authority or the representative of a recognised organisation undertaking a survey or inspection.

6. The Commission is empowered to adopt and regularly update delegated acts in accordance with Article 28 in order to amend the non-exhaustive table set out in Annex III by adding other zero-emission technologies, within the meaning of Article 3, point (7).

7. The Commission may adopt implementing acts to establish the detailed criteria for acceptance, including the definition of system boundaries and certification requirements, to be considered as fulfilling the general requirements for zero-emission technologies provided for in Annex III, including its future updates.

For the list of existing technologies provided for in Annex III, those implementing acts shall be adopted by 30 June 2024, where applicable. For any new technologies, those implementing acts shall be adopted, where other technologies as referred to in Annex III become available, without undue delay.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(3).

8. Ships shall inform in advance the competent authority of the Member State of the port of call or any duly authorised entity prior to entry into ports about their intention to connect to OPS or their intention to use a zero-emission technology in application of paragraph 5, point (b). Ships that intend to connect to OPS shall also indicate the amount of power they expect to require during that port call.

Upon receipt of the information from a ship regarding the connection to OPS referred to in the first subparagraph, the competent authority of the Member State of the port of call or any duly authorised entity shall confirm to the ship whether connection to OPS is available.
The Commission shall adopt implementing acts specifying the information to be provided in accordance with the first and second subparagraphs, as well as the procedure for providing that information. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(3).

9. The competent authority of the Member State of the port of call or any duly authorised entity, after consulting the managing body of the port where appropriate, shall determine and record in the FuelEU database, without delay, the following information:

(a) the application of an exception set out in paragraph 5;

(b) the non-compliance of a ship with the requirements set out in paragraphs 1, 2 and 3 where none of the exceptions set out in paragraph 5 apply.

10. From 1 January 2035, in ports falling under the requirements of Article 9 of Regulation (EU) 2023/1804, it shall only be possible to apply the exceptions provided for in paragraph 5, points (d), (e) and (f) to a maximum number of port calls corresponding to 10 % of a ship's total number of port calls that took place during a reporting period, rounded up to the nearest whole number, where relevant, or to a maximum of 10 port calls during the relevant reporting period, whichever is lower.

A port call shall not be counted for the purposes of compliance with this provision where the company demonstrates, on the basis of the exchange of information provided for in paragraph 8, that it could not have reasonably known that the ship would be unable to connect to OPS for any of the reasons referred to in paragraph 5, points (d), (e) or (f).

11. A Member State may decide that, in a port or in certain parts of a port under its jurisdiction, containerships or passenger ships at anchorage are covered by the same obligations set out in this Regulation applicable to ships moored at the quayside. The Member State shall notify its decision imposing such requirement to the Commission a year prior to the application thereof. Such decision must apply from the beginning of a reporting period. The Commission shall publish the information in the *Official Journal of the European Union* and make publicly available an updated list of the ports concerned. Such list shall be easily accessible.

**Chapter III**

**Common principles and certification**

**Article 7**

**Common principles for monitoring and reporting**

1. In accordance with Articles 8, 9 and 10, companies shall, for each of their ships, monitor and report on the relevant data during a reporting period. They shall carry out that monitoring and reporting within all ports under the jurisdiction of a Member State and for any voyages referred to in Article 2(1).

2. Monitoring and reporting shall be complete and cover the energy used on board by ships at any time, whether at sea or at berth. Companies shall apply appropriate measures to prevent any data gaps within the reporting period.

3. Monitoring and reporting shall be consistent and comparable over time. To that end, companies shall use the same monitoring methodologies and data sets subject to modifications assessed by the verifier. Companies shall enable reasonable assurance of the integrity of the data to be monitored and reported.
4. Companies shall obtain, analyse and store, for at least five years, all monitoring data and documentation, including assumptions, references, emission factors, fuel bunker delivery notes as complemented in accordance with Annex I and activity data, and any other information needed to verify compliance with this Regulation, in a transparent and accurate manner, in paper or electronic form, so that the verifier is able to determine the GHG intensity of the energy used on board by ships.

5. In undertaking the monitoring and reporting activities set out in Articles 8, 9, 10 and 15 of this Regulation, information and data collected for the purposes of Regulation (EU) 2015/757 shall be used where appropriate.

**Article 8**

**Monitoring plan**

1. By 31 August 2024, companies shall submit to the verifiers a monitoring plan for each of their ships indicating the method chosen from among methods set out in Annex I for monitoring and reporting the amount, type and emission factor of energy used on board by ships and other relevant information.

2. For ships falling under the scope of this Regulation for the first time after 31 August 2024, companies shall submit a monitoring plan to the verifier without undue delay and no later than two months after each ship's first call at a port under the jurisdiction of a Member State.

3. The monitoring plan shall consist of a complete and transparent documentation and shall contain at least the following elements:

   (a) the identification and type of the ship, including its name, its International Maritime Organization (IMO) identification number, its port of registry or home port, and the name of the shipowner;

   (b) the name of the company and the address, telephone and e-mail details of a contact person;

   (c) a description of the energy conversion systems installed on board, and the related power capacity expressed in megawatt (MW);

   (d) for ships referred to in Article 6(4), point (b), a description of the standards and characteristics of the equipment to allow connection to OPS, or a zero-emission technology;

   (e) the value of the established total electrical power demand of the ship at berth, as provided in its electrical load balance or electrical load study used to demonstrate compliance with Regulations 40 and 41 of Chapter II-1 of the International Convention for the Safety of Life at Sea (SOLAS), as approved by its flag administration or a recognised organisation as defined in the IMO Code for Recognized Organizations adopted by resolutions MEPC 237(65) and MSC.349(92). If a ship is not able to provide that reference, the value considered is 25 % of the total of the maximum continuous ratings of the main engines of the ship as specified in their EIAPP certificate delivered in application of the International Convention for the Prevention of Pollution from Ships (MARPOL) or, if the engines are not required to have an EIAPP certificate, on the nameplate of the engines;

   (f) a description of the intended sources of energy to be used on board while in navigation and at berth to comply with the requirements set out in Articles 4 and 6;

   (g) a description of the procedures for monitoring the fuel consumption of the ship as well as the energy provided by substitute sources of energy or a zero-emission technology;

   (h) a description of the procedures for monitoring and reporting the well-to-tank and tank-to-wake emission factors of energy to be used on board, in accordance with the methods specified in Article 10 and Annexes I and II;
(i) a description of the procedures used to monitor the completeness of the list of voyages;

(j) a description of the procedures used for determining activity data per voyage, including the procedures, responsibilities, formulas and data sources for determining and recording the time spent at sea between the port of departure and the port of arrival and the time spent at berth;

(k) a description of the procedures, systems and responsibilities used to update any of the data contained in the monitoring plan over the reporting period;

(l) a description of the method to be used to determine surrogate data that can be used for closing data gaps or for identifying and correcting data errors;

(m) a revision record sheet to record all details of the revision history;

(n) where the company requests to exclude the additional energy used due to the ship’s ice class from the calculation of the compliance balance set out in Annex IV, information on the ice class of the ship;

(o) where the company requests to exclude the additional energy used due to sailing in ice conditions from the calculation of the compliance balance set out in Annex IV, information on the ice class of the ship and a description of a verifiable procedure for monitoring the distance travelled for the whole voyage as well as the distance travelled when sailing in ice conditions, the date, time and position when entering and leaving the ice conditions and the fuel consumption when sailing in ice conditions;

(p) for a ship equipped with wind-assisted propulsion, a description of the installed wind propulsion equipment on board and the values of \( P_{\text{Wind}} \) and \( P_{\text{Prop}} \) as defined in Annex I.

4. Companies shall use standardised monitoring plans based on templates. The Commission shall adopt implementing acts determining those templates, including the technical rules for their uniform application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(3).

Article 9

Modifications to the monitoring plan

1. Companies shall check regularly, and at least annually, whether a ship’s monitoring plan reflects the nature and functioning of the ship and whether any of the data it contains can be improved, corrected or updated.

2. Companies shall modify the monitoring plan without undue delay where any of the following situations occurs:

(a) a change of company;

(b) new energy conversion systems, new types of energy, new systems for connection to OPS, or new substitute sources of energy or new zero-emission technologies enter into use;

(c) a change in availability of data, due to the use of new types of measuring equipment, new sampling methods or analysis methods, or for other reasons, may affect the accuracy of the data collected;

(d) companies, verifiers or competent authorities have found that data resulting from the monitoring method applied are incorrect;

(e) verifiers have identified any part of the monitoring plan as not being in conformity with the requirements of this Regulation and the company is required by the verifier to revise it in accordance with Article 11(1);
(f) companies, verifiers or competent authorities have found that the methods to prevent data gaps and identify data errors are inadequate to ensure data accuracy, completeness and transparency.

3. Companies shall notify to the verifiers without undue delay any proposals for modification of the monitoring plan.

Article 10

Certification of fuels and emission factors

1. Where biofuels, biogas, RFNBO and recycled carbon fuels, as defined in Directive (EU) 2018/2001, are to be taken into account for the purposes referred to in Article 4(1) of this Regulation, the following rules apply:

   (a) biofuels and biogas that do not comply with the sustainability and GHG emissions saving criteria set out in Article 29 of Directive (EU) 2018/2001 or that are produced from food and feed crops shall be considered to have the same emission factors as the least favourable fossil fuel pathway for that type of fuel;

   (b) RFNBO and recycled carbon fuels that do not comply with the GHG emissions savings threshold set out in Article 25(2) of Directive (EU) 2018/2001 shall be considered to have the same emission factors as the least favourable fossil fuel pathway for that type of fuel.

2. Fuels not covered in paragraph 1 shall be considered to have the same emission factors as the least favourable fossil fuel pathway for the type of fuel in question, unless they have been certified in accordance with Union legal acts concerning the internal markets in renewable and natural gases and in hydrogen, establishing a GHG emissions savings threshold and an associated methodology to calculate GHG emissions from production of such fuels.

3. On the basis of the fuel bunker delivery notes complemented in accordance with Annex I to this Regulation, companies shall provide accurate, complete and reliable data on the GHG emission intensity and the sustainability characteristics of fuels to be taken into account for the purposes referred to in Article 4(1) of this Regulation that have been certified under a scheme that is recognised by the Commission in accordance with Article 30(5) and (6) of Directive (EU) 2018/2001 or, where applicable, the relevant provisions of Union legal acts concerning the internal markets in renewable and natural gases and in hydrogen.

4. Companies shall not diverge from the default values for the well-to-tank emission factors set out in Annex II to this Regulation for fossil fuels. Without prejudice to paragraph 1, companies shall be entitled to diverge from the default values for the well-to-tank emission factors set out in Annex II to this Regulation provided that actual values are certified under a scheme that is recognised by the Commission. That certification shall be done, for biofuels, biogas, RFNBO and recycled carbon fuels, in accordance with Article 30(5) and (6) of Directive (EU) 2018/2001 or, where applicable, in accordance with the relevant provisions of Union legal acts concerning the internal markets in renewable and natural gases and in hydrogen.

5. Companies shall be entitled to diverge from the default values for the tank-to-wake emission factors set out in Annex II, with the exception of tank-to-wake CO₂ emission factors for fossil fuels, provided that actual values are certified by means of laboratory testing or direct emissions measurements.

6. The Commission shall adopt implementing acts in order to specify which international standards and certification references are accepted for demonstration of actual tank-to-wake emission factors. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(3).
Chapter IV

Verification and accreditation

Article 11

Assessment of the monitoring plan and of the modified monitoring plan

1. For each ship and in the event of a change of verifier, the verifier shall assess the conformity of the monitoring plan with the requirements set out in Articles 7, 8 and 9. Where the verifier’s assessment identifies non-conformities with those requirements, the company concerned shall without undue delay revise its monitoring plan accordingly and submit the revised plan for a final assessment by the verifier before the reporting period starts. The company concerned shall agree with the verifier on the timeframe necessary to introduce those revisions. That timeframe shall in any event not extend beyond the beginning of the reporting period.

2. Modifications to the monitoring plan under Article 9(2), points (b), (c) and (d), shall be subject to an assessment by the verifier. Following that assessment, the verifier shall notify the company concerned whether those modifications are in conformity with the requirements set out in Articles 7, 8 and 9.

3. Once the monitoring plan and the modified monitoring plan have been satisfactorily assessed, the verifier shall record them in the FuelEU database. The monitoring plan and the modified monitoring plan shall be accessible to the administering State.

Article 12

General obligations and principles for the verifiers

1. The verifier shall be independent from the company or from the ship operator and shall carry out the activities required under this Regulation in the public interest. For that purpose and in order to avoid potential conflicts of interest, neither the verifier nor any part of a legal entity of which it is part shall be a company, ship operator or the owner of a company. In addition, the verifier shall not be owned by a company, ship operator or the owner of a company nor shall it have relations with a company that could affect its independence and impartiality.

2. The verifier shall assess the reliability, credibility, accuracy and completeness of the data and information relating to the amount, type and emission factor of the energy used on board by ships, in particular:

   (a) the attribution of fuel consumption and the use of substitute sources of energy to voyages and at berth;

   (b) the reported fuel consumption data and related measurements and calculations;

   (c) the choice and the employment of emission factors;

   (d) the use of OPS or the application of any of the exceptions recorded in the FuelEU database in accordance with Article 6(9), point (a);

   (e) the data required under Article 10(3).

3. The assessment referred to in paragraph 2 shall be based on the following considerations:

   (a) whether the reported data are coherent in relation to estimated data that are based on ship tracking data and characteristics such as the installed engine power;

   (b) whether the reported data are free of inconsistencies, in particular when comparing the total volume of fuel purchased annually by each ship and the aggregate fuel consumption during voyages;
whether the collection of the data has been carried out in accordance with the applicable rules; and

whether the relevant records of the ship are complete and consistent.

**Article 13**

**Verification procedures**

1. The verifier shall identify potential risks related to the monitoring and reporting process by comparing the reported amount, type and emission factor of the energy used on board by ships with estimated data based on the ship's tracking data and characteristics, such as the installed engine power. Where significant divergences are found, the verifier shall carry out further analyses.

2. The verifier shall identify potential risks related to the different calculation steps by reviewing all data sources and methodologies used by the company concerned.

3. The verifier shall take into consideration any effective risk control methods applied by the company concerned to reduce levels of uncertainty associated with the accuracy specific to the monitoring methods used.

4. At the request of the verifier, the company concerned shall provide any additional information that enables the verifier to carry out its verification activities. Where necessary to determine the reliability, credibility, accuracy and completeness of reported data and information, the verifier shall conduct checks during the verification process. In case of doubt, the verifier may conduct site visits at the premises of the company or on board the ship. The company shall allow the verifier to access the premises of the company or the ship in order to facilitate the verification activities.

5. The Commission shall adopt implementing acts in order to further specify the rules for the verification activities referred to in this Regulation, as regards at least the following elements: competencies of verifiers; documents to be provided by companies to verifiers; assessment of the conformity of the monitoring plan and of the modified monitoring plan; risk assessment, including checks, to be carried out by verifiers; verification of the FuelEU report referred to in Article 15(3); materiality level; reasonable assurance from verifiers; misstatements and non-conformities; content of the verification report; recommendations for improvements; site visits; and communication between companies, verifiers, competent authorities and the Commission. The rules specified in those implementing acts shall be based on the principles for verification provided for in Articles 11 and 12 and in this Article and on relevant internationally accepted standards. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(3).

**Article 14**

**Accreditation of verifiers**

1. Verifiers shall be accredited for verification activities falling under the scope of this Regulation by a national accreditation body pursuant to Regulation (EC) No 765/2008. By the end of each year, the national accreditation body shall notify the list of accredited verifiers to the Commission, together with all relevant contact information.

2. Where no specific provisions concerning the accreditation of verifiers are laid down in this Regulation, the relevant provisions of Regulation (EC) No 765/2008 shall apply.

3. Verifiers shall always have sufficient means and staff to enable them to deal with the size of the fleet for which they perform verification activities under this Regulation. In particular, verifiers shall always have sufficient expertise, particularly in maritime transport, to enable them to carry out the tasks required under this Regulation. They shall be capable of assigning means and staff to every place of work, when and as needed to carry out the tasks required under this Regulation.
4. A competent authority that identifies the non-conformity of a verifier’s activities within the scope of this Regulation shall inform the competent authority of the Member State of the national accreditation body having accredited the verifier. The competent authority of the Member State of the national accreditation body shall request its national accreditation body to take into account that information as part of its surveillance activities.

5. The Commission is empowered to adopt delegated acts in accordance with Article 28 in order to supplement this Regulation by establishing further methods and criteria of accreditation of verifiers, on at least the following elements: request for accreditation for verification activities within the scope of this Regulation; assessment of verifiers by the national accreditation bodies; surveillance activities performed by the national accreditation bodies to confirm the continuation of the accreditation; administrative measures to be adopted if the verifier does not fulfil the requirements of this Regulation; and requirements for national accreditation bodies in order to be competent to provide accreditation to verifiers for verification activities within the scope of this Regulation, including a reference to harmonised standards. The methods and criteria specified in such delegated acts shall be based on the principles for verification provided for in Articles 11, 12 and 13 and on relevant internationally accepted standards.

Chapter V

Recording, verification, reporting and assessment of compliance

Article 15

Monitoring and recording

1. As of 1 January 2025, based on the monitoring plan referred to in Article 8 and following the assessment of that plan by the verifier, companies shall monitor and record, for each ship arriving at or departing from a port of call, and for each voyage referred to in Article 2(1), the following information:

(a) port of departure and port of arrival including the date and time of departure and arrival and time spent at berth;

(b) for each ship to which Article 6(1) applies, the connection to and use of OPS or the application of any of the exceptions provided for in Article 6(5) as confirmed pursuant to Article 6(9), point (a), where applicable;

(c) the amount of each type of fuel consumed at berth and at sea;

(d) the amount of electricity delivered to the ship through OPS;

(e) for each type of fuel consumed at berth and at sea, the well-to-tank emission factor, the tank-to-wake emission factors of combusted fuel and the tank-to-wake emission factors of slipped fuel associated with the different fuel consumers on board, covering all relevant greenhouse gases;

(f) the amount of each type of substitute source of energy consumed at berth and at sea;

(g) the ship’s ice class, if the company requests to exclude the additional energy used due to ship’s ice class from the calculation of the compliance balance set out in Annex IV, using the Baltic Marine Environment Protection Commission (HELCOM) Recommendation 25/7 on safety of winter navigation in the Baltic Sea to establish the correspondence between ice classes;

(h) the ship’s ice class, the date, time and position when entering and leaving the ice conditions, the amount of each type of fuel consumed and the distance travelled when sailing in ice conditions as well as the total distance travelled for all voyages during the reporting period, if the company requests to exclude the additional energy used due to sailing in ice conditions from the calculation of the compliance balance set out in Annex IV.
2. Companies shall record the information and data listed in paragraph 1 in a timely and transparent manner and compile them on an annual basis to enable the verifier to verify compliance with this Regulation.

3. By 31 January of the verification period, companies shall provide to the verifier a ship-specific report (the ‘FuelEU report’) containing all the information referred to in paragraph 1 of this Article and the monitoring data and documentation referred to in Article 7(4) for the reporting period.

4. In the event of the transfer of a ship from one company to another:

(a) the transferring company shall notify to the verifier the information referred to in paragraph 1 of this Article for the time during which it had responsibility for the operation of the ship;

(b) as close as practical to the day of completion of the transfer and no later than one month thereafter, the information referred to in point (a) shall be verified and recorded in the FuelEU database in accordance with Article 16 by the verifier that performed verification activities for the ship under the transferring company; and

(c) without prejudice to points (a) and (b), the company that has responsibility for the operation of the ship on 31 December of the reporting period shall be responsible for the compliance of the ship with the requirements set out in Articles 4 and 6 for the entire reporting period during which the transfer or multiple transfers took place.

Article 16

Verification and calculation

1. Following the verification as set out in Articles 11, 12 and 13, the verifier shall assess the quality, completeness and accuracy of the FuelEU report. To that end, the verifier shall use any information contained in the FuelEU database, including information provided on port calls in accordance with Article 6.

2. Where the verification assessment referred to paragraph 1 concludes, with reasonable assurance from the verifier, that the FuelEU report is free from material misstatements or non-conformities, the verifier shall notify to the company concerned a verification report stating that the FuelEU report complies with this Regulation. The verification report shall specify all issues relevant to the work carried out by the verifier.

3. Where the verification assessment identifies misstatements or non-conformities with this Regulation, the verifier shall inform the company concerned thereof in a timely manner. The company shall without undue delay correct the misstatements or non-conformities so as to enable the verification process to be completed in time and shall submit to the verifier an amended FuelEU report and any other information necessary to correct the misstatements or non-conformities identified. In its verification report, the verifier shall state whether the amended FuelEU report complies with this Regulation. Where the communicated misstatements or non-conformities have not been corrected and lead to material misstatements, the verifier shall notify to the company a verification report stating that the FuelEU report does not comply with this Regulation.

4. On the basis of the FuelEU report that complies with this Regulation, the verifier shall calculate:

(a) using the method specified in Annex I, the yearly average GHG intensity of the energy used on board by the ship concerned;

(b) using the formula specified in Part A of Annex IV, the ship’s compliance balance;
(c) the number of non-compliant port calls in the previous reporting period including the time spent moored at the quayside and, where applicable in accordance with Article 6(9), at anchorage, for each port call by the ship in non-compliance with the requirements set out in Article 6;

(d) the amount of the yearly energy used on board by a ship, excluding energy from OPS;

(e) the amount of the yearly energy used on board by a ship from the RFNBO.

5. By 31 March of the verification period, the verifier shall notify to the company the information referred to in paragraph 4 and record in the FuelEU database the FuelEU report that complies with this Regulation, the verification report and the information referred to in paragraph 4.

All information recorded in the FuelEU database shall be accessible to the administering State.

Article 17

Additional checks by a competent authority

1. At any time, the competent authority of the administering State in respect of a company may, for any of its ships, conduct, in relation to the two previous reporting periods, additional checks of any of the following:

(a) the FuelEU report that complies with this Regulation established in accordance with Articles 15 and 16;

(b) the verification report established in accordance with Article 16;

(c) the calculations made by the verifier in accordance with Article 16(4).

2. At the request of the competent authority referred to in paragraph 1, the company shall provide any necessary information or documents enabling the competent authority to conduct additional checks and shall allow access to the premises of the company or the ship to facilitate such additional checks.

3. The competent authority referred to in paragraph 1 of this Article shall issue an additional checks report including, where applicable, the updated calculations made in application of Article 17(1), point (c), the updated amount of the compliance surplus or of the advance compliance surplus and the updated amount of the FuelEU penalty.

4. Where the additional checks report referred to in paragraph 3 of this Article identifies misstatements, non-conformities or miscalculations resulting in a non-conformity with the requirements set out in Article 4 or 6 and, consequently, in a FuelEU penalty or a modification of the amount of a FuelEU penalty already paid, the competent authority referred to in paragraph 1 of this Article shall notify to the company concerned the corresponding amount of the FuelEU penalty or of the modified FuelEU penalty. Member States shall ensure that the company responsible for the ship during the period subject to the additional checks shall pay an amount equal to the FuelEU penalty or the modified FuelEU penalty within one month after its notification, in accordance with the arrangements provided for in Article 23.

5. The competent authority referred to in paragraph 1 shall remove without delay from the FuelEU database the FuelEU document of compliance of a ship in respect of which its company has not paid in due time the FuelEU penalties referred to in paragraph 4 and shall notify that removal to the company concerned in a timely manner. It shall re-issue the relevant FuelEU document of compliance only when an amount equal to the FuelEU penalty has been paid, provided that the other conditions set out in this Regulation for holding the FuelEU document of compliance are fulfilled by the company.
6. Paragraph 5 shall not apply to a ship which has been transferred to a company other than the company that assumed responsibility for its operation during the period subject to the additional checks.

7. The actions referred to in this Article, the additional checks report referred to in paragraph 3 and proof of the payments of the FuelEU penalties shall be recorded without delay in the FuelEU database by the entities that performed those actions or made that report or payment.

Article 18

Supporting tools and guidance

The Commission shall develop appropriate monitoring tools, as well as guidance and risk-based targeting tools, to facilitate and coordinate verification and enforcement activities related to this Regulation. As far as practicable, such guidance and tools shall be made available to the Member States, the verifiers and the national accreditation bodies for information-sharing purposes and in order to better ensure robust enforcement of this Regulation.

Article 19

FuelEU database and reporting

1. The Commission shall develop, ensure the functioning of and update an electronic database for the monitoring of compliance with this Regulation (the 'FuelEU database'). The FuelEU database shall be used to keep a record of actions related to verification activities, of the compliance balance of ships, including use of the flexibility mechanisms set out in Articles 20 and 21, of the application of the exceptions set out in Article 6(5), of actions related to payment of the FuelEU penalties imposed under Article 23 and of the issuance of the FuelEU document of compliance. It shall be accessible to the companies, the verifiers, the competent authorities and any duly authorised entity, the national accreditation bodies, the European Maritime Safety Agency established by Regulation (EC) No 1406/2002 of the European Parliament and of the Council (24) and the Commission, with appropriate access rights and functionalities corresponding to their respective responsibilities for the implementation of this Regulation.

2. Any elements recorded or modified in the FuelEU database shall be notified to the entities to which they are accessible.

3. The Commission shall adopt implementing acts laying down the rules for access rights and the functional and technical specifications, including notification rules and filtering, of the FuelEU database. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29(3).

Article 20

Banking and borrowing of compliance surplus between reporting periods

1. On the basis of the calculations undertaken in accordance with Article 16(4), where the ship has, for the reporting period, a compliance surplus on its GHG intensity as referred to in Article 4(2) or, if applicable, on the RFNBO subtarget as referred to in Article 5(3), the company may bank it to the same ship's compliance balance for the following reporting period. The company shall record the banking of the compliance surplus to the following reporting period in the FuelEU database subject to approval by its verifier. The company may no longer bank the compliance surplus once the FuelEU document of compliance has been issued.

2. On the basis of the calculations undertaken in accordance with Article 16(4), where the ship has, for the reporting period, a compliance deficit, the company may borrow an advance compliance surplus of the corresponding amount from the following reporting period. The advance compliance surplus shall be added to the ship's compliance balance in the reporting period and the advance compliance surplus multiplied by 1,1 shall be subtracted from the same ship's compliance balance in the following reporting period. The advance compliance surplus may not be borrowed:

(a) for an amount exceeding by more than 2 % the limit set out in Article 4(2), multiplied by the energy consumption of the ship calculated in accordance with Annex I;

(b) for two consecutive reporting periods.

3. By 30 April of the verification period, the company shall record the advance compliance surplus, following approval by its verifier, in the FuelEU database.

4. Where a ship does not have any port call in the Union during the reporting period and borrowed an advance compliance surplus in the previous reporting period, the competent authority of the administering State shall notify by 1 June of the verification period to the company concerned the amount of the FuelEU penalty as referred to in Article 23(2) that it initially avoided by means of borrowing that advance compliance surplus, multiplied by 1,1.

Article 21

Pooling of compliance

1. The compliance balances for GHG intensity referred to in Article 4(2) and, if applicable, the RFNBO subtarget as referred to in Article 5(3) of two or more ships, as calculated in accordance with Article 16(4), may be pooled for the purposes of complying with the requirements set out in Article 4 and, if applicable, Article 5(3). A ship's compliance balance may not be included in more than one pool in the same reporting period.

Two separate pools may be used for GHG intensity target and for the subtarget for RFNBO.

2. The company shall register in the FuelEU database its intention to include the ship's compliance balance in a pool, the allocation of the total pool compliance balance to each individual ship, and the choice of the verifier selected for verifying that allocation.

3. Where the ships participating in the pool are controlled by two or more companies, the pool details registered in the FuelEU database, including the allocation of the total pool compliance balance to the pool's ships and the choice of the verifier selected for verifying the allocation of the total compliance balance of the pool to each individual ship, shall be validated in the FuelEU database by all the companies concerned in the pool.

4. A pool is valid only if the total pooled compliance is positive, if ships which had a compliance deficit as calculated in accordance with Article 16(4) do not have a higher compliance deficit after the allocation of the pooled compliance, and if ships which had a compliance surplus as calculated in accordance with Article 16(4) do not have a compliance deficit after the allocation of the pooled compliance.

5. A ship shall not be included in a pool if it does not comply with the obligation set out in Article 24.

6. If the total pool compliance balance results in a compliance surplus for an individual ship, Article 20(1) shall apply.
7. Article 20(2) shall not apply to a ship participating in the pool.

8. By 30 April of the verification period, the selected verifier shall record in the FuelEU database the definitive composition of the pool and allocation of the total pool compliance balance to each individual ship.

**Article 22**

**FuelEU document of compliance**

1. By 30 June of the verification period, the verifier shall issue a FuelEU document of compliance for the ship concerned, provided that the ship does not have a compliance deficit further to application of Articles 20 and 21, does not have non-compliant port calls and complies with the obligation set out in Article 24.

2. Where FuelEU penalties referred to in Article 23(2) or 23(5) are due, the competent authority of the administering State shall, by 30 June of the verification period, issue a FuelEU document of compliance for the ship concerned, provided that an amount equal to the FuelEU penalties has been paid.

3. The FuelEU document of compliance shall include the following information:

(a) identity of the ship (name, IMO identification number and port of registry or home port);

(b) name, address and principal place of business of the shipowner;

(c) identity of the verifier;

(d) date of issue of that document, its period of validity and the reporting period it refers to.

4. The FuelEU document of compliance shall be valid for a period of 18 months after the end of the reporting period or until a new FuelEU document of compliance is issued, whichever occurs earlier.

5. The verifier or, where applicable, the competent authority of the administering State shall record the issued FuelEU document of compliance in the FuelEU database without delay.

6. The Commission shall adopt implementing acts establishing models for the FuelEU document of compliance, including electronic templates. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 29(2).

**Article 23**

**FuelEU penalties**

1. Before 1 May of the verification period, on the basis of the calculations undertaken pursuant to Article 16(4) and after possible application of Articles 20 and 21, the verifier shall record in the FuelEU database the verified compliance balances of the ship for GHG intensity as referred to in Article 4(2) and, if applicable, for the subtarget for RFNBO as referred to in Article 5(3).

If a ship has a compliance deficit for the subtarget for RFNBO as referred to in Article 5(3), the FuelEU penalty shall be calculated in accordance with the formula specified in Part B of Annex IV.

2. The administering State in respect of a company shall ensure that, for any of its ships having a compliance deficit for GHG intensity as referred to in Article 4(2) or, if applicable, for the subtarget for RFNBO as referred to in Article 5(3) on 1 June of the verification period, after a possible validation by its competent authority, the company shall pay by 30 June of the verification period an amount equal to the FuelEU penalty resulting from the application of the formulas specified in Part B of Annex IV. If a ship has a compliance deficit for two consecutive reporting periods or more, that amount shall be multiplied by 1 + (n -1)/10, where n is the number of consecutive reporting periods for which the company is subject to a FuelEU penalty for that ship.
3. The administering State in respect of a company shall ensure that, for any of its ships which is in the situation referred to in Article 20(4), the company pays by 30 June of the verification period an amount equal to the FuelEU penalty notified pursuant to that paragraph.

4. Before 1 May of the verification period, where applicable on the basis of the calculations undertaken in accordance with Article 16(4), the verifier shall record in the FuelEU database the total number of hours spent moored at the quayside by the ship in non-compliance with the requirements set out in Article 6.

5. The administering State in respect of a company shall ensure that for any of its ships which made at least one non-compliant port call, after a possible validation by its competent authority, the company shall pay by 30 June of the verification period an amount equal to the FuelEU penalty resulting from the multiplication of EUR 1.5 by the established total electrical power demand of the ship at berth and by the total number of hours rounded up to the nearest whole hour, spent at berth by the ship in non-compliance with the requirements set out in Article 6.

6. Member States shall have the necessary legal and administrative framework in place at national level to ensure the fulfilment of the obligations concerning the imposition, payment and collection of the FuelEU penalties.

7. The actions referred to in this Article as well as the proof of the payments of FuelEU penalties shall be recorded without delay in the FuelEU database by the entities that performed those actions or made that payment.

8. The company shall remain responsible for the payment of the FuelEU penalties, without prejudice to the possibility for the company to conclude contractual agreements with the commercial operators of the ship that provide for the liability of the commercial operators to reimburse the company for the payment of the FuelEU penalties, when the responsibility for the purchase of the fuel or the operation of the ship is assumed by the commercial operator. For the purposes of this paragraph, operation of the ship shall mean determining the cargo carried, the route and the speed of the ship.

9. The company shall remain responsible for the payment of the FuelEU penalties, without prejudice to the possibility for the company to conclude contractual agreements with fuel suppliers that provide for the liability of the fuel suppliers to reimburse the company for the payment of the FuelEU penalties.

10. The Commission is empowered to adopt delegated acts in accordance with Article 28 to amend Annex IV in order to adapt the factor indicated in cell 7 and, where applicable, cell 14 of the table in Part B of that Annex and used in the formula referred to in paragraph 1 of this Article, based on the developments in the cost of energy, and to amend the multiplication factor laid down in paragraph 5 of this Article, based on the indexation of the average cost of electricity in the Union.

11. Member States shall endeavour to ensure that the revenue generated from the FuelEU penalties, or its equivalent financial value, is used to support the rapid deployment and the use of renewable and low-carbon fuels in the maritime sector, by stimulating the production of greater quantities of renewable and low-carbon fuels for the maritime sector, facilitating the construction of appropriate bunkering facilities or OPS infrastructure in ports, and supporting the development, testing and deployment of the most innovative technologies in the fleet to achieve significant emission reductions.

By 30 June 2030, and every five years thereafter, Member States shall make public a report on the use of revenue generated from the FuelEU penalties over the five-year period preceding the year of every such report, including information on the beneficiaries and the level of expenditure concerning the objectives listed in the first subparagraph.

**Article 24**

**Obligation to hold a valid FuelEU document of compliance**

1. By 30 June of the verification period, ships calling at a port under the jurisdiction of a Member State, arriving at, staying within or departing from a port under the jurisdiction of a Member State, or which have carried out voyages during the corresponding reporting period, shall hold a valid FuelEU document of compliance.
2. The FuelEU document of compliance issued for the ship concerned in accordance with Article 22 shall constitute evidence of compliance with this Regulation.

### Article 25

#### Enforcement

1. Member States shall lay down the rules on sanctions applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The sanctions provided for shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

2. Each Member State shall ensure that any inspection of a ship in a port under its jurisdiction carried out in accordance with Directive 2009/16/EC includes checking that the ship holds a valid FuelEU document of compliance.

3. Where a ship fails to comply with the obligation set out in Article 24 for two or more consecutive reporting periods, and where other enforcement measures have failed to ensure compliance with this Regulation, the competent authority of the Member State of the port of call may, in respect of a ship not flying the flag of that Member State and after giving the opportunity to the company concerned to submit its observations, issue an expulsion order. Where the competent authority of the Member State of the port of call decides to issue an expulsion order, it shall notify that order to the Commission, the other Member States and the flag State concerned through the FuelEU database. Every Member State, with the exception of the Member State whose flag the ship is flying, shall refuse entry of the ship which is subject to the expulsion order into any of its ports until the company fulfils its obligations. Where a ship fails to comply with the obligation set out in Article 24 for two or more consecutive reporting periods and enters into a port of the Member State whose flag it flies, the Member State concerned shall, while that ship is in one of its ports, after giving the opportunity to the company concerned to submit its observations, order a flag detention until the company fulfils its obligations.

4. The company concerned shall confirm compliance with the obligation to hold a valid FuelEU document of compliance by notifying a valid FuelEU document of compliance to the competent national authority which issued the expulsion order. This paragraph shall be without prejudice to the provisions of international law applicable in the case of ships in distress.

5. Sanctions against a specific ship by any Member State shall be notified to the Commission, to the other Member States and to the flag State concerned through the FuelEU database.

### Article 26

#### Right to review

1. Companies shall be entitled to apply for a review of the calculations and measures addressed to them by the verifier under this Regulation, including the refusal to issue a FuelEU document of compliance in accordance with Article 22(1).

The application for a review shall be lodged with the competent authority of the Member State in which the verifier is accredited within one month of the notification of the result of the calculation or of the measure by the verifier.

2. The decisions taken under this Regulation by the competent authority of a Member State shall be subject to review by a court of the Member State of that competent authority.

### Article 27

#### Competent authorities

Member States shall designate one or more competent authorities to be responsible for the application and enforcement of this Regulation (‘competent authorities’) and communicate their names and contact information to the Commission. The Commission shall publish on its website the list of competent authorities.
Chapter VI
Delegated and implementing powers and final provisions

Article 28

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 4(4), 5(7), 6(6), 14(5) and 23(10) shall be conferred on the Commission for an indeterminate period of time from 12 October 2023.

3. The delegation of power referred to in Articles 4(4), 5(7), 6(6), 14(5) and 23(10) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 4(4), 5(7), 6(6), 14(5) and 23(10) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 29

Committee procedure

1. The Commission shall be assisted by the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) established by Regulation (EC) No 2099/2002 of the European Parliament and of the Council (25). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.

Article 30

Reports and review

1. By 23 September 2024, the Commission shall present a report to the European Parliament and to the Council examining the interaction and convergence between this Regulation and Regulation (EU) 2015/757 or any other sectoral legal acts. Where appropriate, that report may be accompanied by a legislative proposal.

2. By 31 December 2027, and every five years thereafter at the latest, the Commission shall report to the European Parliament and the Council the results of an evaluation as regards the functioning of this Regulation, including possible impacts of market distortions or port evasion; as regards the evolution of the zero-emission technologies in maritime transport and their market, as well as the evolution of the technologies and market for renewable and low-carbon fuels and for OPS, including at anchorage; as regards the use of revenue generated by the FuelEU penalties; and as regards the impact of this Regulation on the competitiveness of the maritime sector in the Union.

In that report, the Commission shall consider, inter alia:

(a) the material and geographical scope of this Regulation, as regards decreasing the gross tonnage threshold referred to in Article 2(1) or expanding the share of energy used by ships in voyages to and from third countries referred to in Article 2(1), point (d);

(b) the limit referred to in Article 4(2), with a view to achieving the objectives set out in Regulation (EU) 2021/1119;

(c) the ship types and size to which Article 6(1) applies and an extension of the obligations referred to in Article 6(1) to ships at anchorage;

(d) the exceptions provided for in Article 6(5);

(e) the counting of the electricity delivered through OPS in Annex I and the well-to-tank emission factor associated with that electricity defined in Annex II;

(f) the possibility to include in the scope of this Regulation dedicated mechanisms for the most sustainable and innovative fuel technologies with a significant decarbonisation potential, in order to create a clear and predictable legal framework and encourage the market development and deployment of such fuel technologies;

(g) the calculation of the compliance balance for ships requesting to exclude the additional energy used due to sailing in ice conditions set out in Annexes IV and V, and the possible extension of the validity of those provisions after 31 December 2034;

(h) the possibility to include energy provided by wind in the calculation of the GHG intensity of the energy used on board set out in Annex I, subject to the availability of a verifiable method for monitoring and accounting of wind propulsion energy;

(i) the possibility to include new GHG abatement technologies, such as onboard carbon capture, in the calculation of the GHG intensity of the energy used on board and of the compliance balance as set out in Annexes I and IV respectively, subject to the availability of a verifiable method for monitoring and accounting of the captured carbon;

(j) the possibility to include additional elements in this Regulation, in particular black carbon emissions;

(k) the need for measures to address attempts by companies to evade the requirements set out in this Regulation.

The Commission shall consider, if appropriate, whether to accompany that report by a proposal to amend this Regulation.

3. The Commission shall include in the report provided for in paragraph 2 an evaluation of the social impacts of this Regulation in the maritime sector, including on its workforce.

4. In preparing its report referred to in paragraph 2 the Commission shall consider the extent to which the implementation of this Regulation has met its objectives and the extent to which it has impacted the competitiveness of the maritime sector. In that report, the Commission shall also consider the interaction of this Regulation with other relevant Union legal acts and identify any provisions that could be updated and simplified, as well as actions and measures that have been or could be taken to reduce the total cost pressure on the maritime sector. As part of the Commission’s analysis of the efficiency of this Regulation, the report shall also include an assessment of the burden this Regulation imposes on businesses.
The Commission shall consider, if appropriate, whether to accompany that report by a proposal to amend this Regulation, in view of the conclusions of the report referred to in the first subparagraph.

5. In the event of the adoption by the IMO of a global GHG fuel standard or global GHG intensity limits for the energy used on board by ships, the Commission shall, without delay, present a report to the European Parliament and to the Council. In that report, the Commission shall examine that global measure as regards its ambition in light of the objectives of the Paris Agreement and its overall environmental integrity. It shall also examine any issue related to the possible articulation or alignment of this Regulation with that global measure, including the need to avoid duplicating regulation of GHG emissions from maritime transport at Union as well as international level.

Where appropriate, that report may be accompanied by a legislative proposal to amend this Regulation, consistent with the Union economy-wide GHG emission commitments, and with the aim of preserving the environmental integrity and effectiveness of the Union climate action.

6. The Commission shall monitor the implementation of this Regulation in relation to maritime transport, in particular to detect evasive behaviour in order to prevent such behaviour at an early stage, and including with regard to outermost regions.

The monitoring results shall be reflected in the report to be made every two years referred to in Article 3gg(3) of Directive 2003/87/EC.

Article 31

Amendment to Directive 2009/16/EC

The following point shall be added to the list set out in Annex IV to Directive 2009/16/EC:


Article 32

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 1 January 2025, with the exception of Articles 8 and 9 which shall apply from 31 August 2024.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 13 September 2023.

For the European Parliament

The President

R. METSOLA

For the Council

The President

J. M. ALBARES BUENO
ANNEX I

Methodology for establishing the greenhouse gas intensity of the energy used on board by a ship

For the purpose of calculating the GHG intensity of the energy used on board by a ship, the following formula, referred to as Equation (1) shall apply:

\[
\text{GHG intensity } \left( \frac{\text{gCO}_2\text{eq}}{\text{MJ}} \right) = f_{\text{wind}} \times (\text{WtT} + \text{TrW}) \quad \text{Equation (1)}
\]

\[
\text{WtT} = \sum_{i}^{n_{\text{fuel}}} \frac{M_{i,j} \times \text{CO}_{2\text{eq WtT, } i} + \sum_{k} E_{k} \times \text{CO}_{2\text{eq electricity, } k}}{\sum_{i} M_{i,j} \times \text{LCV}_{i} \times \text{RWD}_{i} + \sum_{k} E_{k}}
\]

\[
\text{TrW} = \sum_{i}^{n_{\text{fuel}}} \sum_{j}^{m_{\text{engine}}} \left( \frac{1}{\text{CO}_{2\text{eq TrW, i, j}}} \times \left( \frac{\text{RWD}_{i,j}}{\text{CO}_{2\text{eq WtT, i, j}}} + \sum_{k} E_{k} \right) \right)
\]

\[
f_{\text{wind}} \quad \text{Reward factor for wind-assisted propulsion}
\]

For the purposes of Equation (1), the different terms and notations used are presented in the following table:

<table>
<thead>
<tr>
<th>Term</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>i</td>
<td>Index corresponding to the fuel types delivered to the ship in the reporting period</td>
</tr>
<tr>
<td>j</td>
<td>Index corresponding to the fuel consumer units on board the ship. For the purpose of this Regulation the fuel consumer units considered are the main engine(s), auxiliary engine(s), boilers, fuel cells and waste incinerators</td>
</tr>
<tr>
<td>k</td>
<td>Index corresponding to the OPS connection points</td>
</tr>
<tr>
<td>n</td>
<td>Total number of fuel types delivered to the ship in the reporting period</td>
</tr>
<tr>
<td>c</td>
<td>Total number of OPS connection points</td>
</tr>
<tr>
<td>m</td>
<td>Total number of fuel consumer units</td>
</tr>
<tr>
<td>M_{i,j}</td>
<td>Mass of fuel i consumed by fuel consumer unit j [gFuel]</td>
</tr>
<tr>
<td>E_{k}</td>
<td>Electricity delivered to the ship per OPS connection point k [MJ]</td>
</tr>
<tr>
<td>CO_{2eqWtT, i}</td>
<td>WtT GHG emission factor of fuel i [gCO_{2eq}/MJ]</td>
</tr>
<tr>
<td>CO_{2eqelectricity, k}</td>
<td>WtT GHG emission factor associated with the electricity delivered to the ship at berth per OPS connection point k [gCO_{2eq}/MJ]</td>
</tr>
<tr>
<td>LCV_{i}</td>
<td>Lower calorific value of fuel i [MJ/gFuel]</td>
</tr>
<tr>
<td>RWD_{i}</td>
<td>Where the fuel is of non-biological origin, a reward factor of 2 from 1 January 2025 to 31 December 2033 can be applied. Otherwise RWD_{i} = 1.</td>
</tr>
</tbody>
</table>
Non-combusted fuel coefficient as a percentage of the mass of the fuel consumed by fuel consumer unit \( j \) [%]. \( C_{\text{slip}} \) includes fugitive and slipped emissions.

\[
C_{\text{sf CO}_2}^{i,j}, \quad C_{\text{sf CH}_4}^{i,j}, \quad C_{\text{sf N}_2O}^{i,j}
\]

TTW GHG emission factors by combusted fuel \( i \) to consumer unit \( j \) [gGHG/gFuel]

\[
C_{\text{CO}_2eq,TTW}^{i,j} = \left( C_{\text{CO}_2}^{i,j} \times \text{GWP}_{\text{CO}_2} + C_{\text{CH}_4}^{i,j} \times \text{GWP}_{\text{CH}_4} + C_{\text{N}_2O}^{i,j} \times \text{GWP}_{\text{N}_2O} \right)
\]

Equation (2)

\[
C_{\text{CO}_2eq,TTWslip}^{i,j}
\]

TTW GHG emission factors by slipped fuel \( i \) to consumer unit \( j \) [gGHG/gFuel]

\[
C_{\text{CO}_2eq,TTWslip}^{i,j}
\]

TTW CO\(_2\) equivalent emissions of combusted fuel \( i \) to consumer unit \( j \) [gCO\(_2\)eq/gFuel]

\[
C_{\text{CO}_2eq,TTW}^{i,j} = \left( C_{\text{CO}_2}^{i,j} \times \text{GWP}_{\text{CO}_2} + C_{\text{CH}_4}^{i,j} \times \text{GWP}_{\text{CH}_4} + C_{\text{N}_2O}^{i,j} \times \text{GWP}_{\text{N}_2O} \right)
\]

Where: \( C_{\text{CO}_2} \) and \( C_{\text{N}_2O} \) are 0.

\[
C_{\text{CH}_4} = 1.
\]

For the purposes of this Regulation, the term \( \sum_{k} E_{k} \times \text{CO}_2\text{eq,electricity}_k \) in the numerator of Equation (1) shall be set to zero.

Method for determining \([M]\) mass of fuel

The \([M]\) mass of fuel shall be determined using the amount reported in accordance with the framework of the reporting under Regulation (EU) 2015/757 for voyages within the scope of this Regulation based on the monitoring methodology chosen by the company.

Method for determining WtT GHG emission factors

The WtT emissions are determined on the basis of the methodology contained in this Annex as provided in Equation (1).

The WtT GHG emission factors (CO\(_{2eq,WtT}\)) default values are contained in Annex II.

In the case of fossil fuels, only the default values contained in Annex II shall be used.

Actual values may be used provided that they are certified under a scheme that is recognised by the Commission in accordance with Article 30(5) and (6) of Directive (EU) 2018/2001 for biofuels, biogas, RFNBO and recycled carbon fuels, or, where applicable, in accordance with the relevant provisions of Union legal acts for the internal markets in renewable and natural gases and in hydrogen, in application of Article 10(4) of this Regulation.

Fuel Bunker Delivery Note (BDN)

Under existing MARPOL Annex VI regulations, the BDN is mandatory and information to be included in the BDN is specified.
For the purposes of this Regulation:

1. BDNs including fuels other than fossil fuels used on board shall be complemented with the following information regarding those fuels:
   
   — Lower calorific value [MJ/g],
   
   — For biofuels, E values as established in accordance with the methodologies laid down in Directive (EU) 2018/2001, Part C of Annex V and Part B of Annex VI [gCO$_2$eq/MJ] and related evidence of compliance with the rules set out in that Directive for those fuels, identifying the fuel production pathway,
   
   — For fuels other than fossil fuels and biofuels, WtT GHG emission factor [gCO$_2$eq/MJ] and related certificate identifying the fuel production pathway.

2. Where there is product blending, information required by this Regulation shall be given for each product.

Electricity Delivery Note (EDN)

For the purposes of this Regulation, relevant EDNs for electricity delivered to the ship shall contain at least the following information:

1. supplier: name, address, telephone number, email address, representative;

2. receiving ship: IMO number (MMSI), ship name, ship type, flag, ship representative;

3. port: name, location (LOCODE), terminal/berth;

4. OPS connection point: connection point details;

5. OPS time: date/time of commencement/finalisation;

6. energy supplied: power fraction allocated to supply point (if applicable) [kW], electricity consumption (kWh) for the billing period, peak power information (if available);

7. metering.

Method for determining TtW GHG emission factors

The TtW emissions are determined on the basis of the methodology contained in this Annex as provided in Equation (1) and Equation (2).

The TtW GHG emission factors (CO$_2$eq,TtW, j) default values are contained in Annex II.

In accordance with its monitoring plan referred to in Article 8 and upon assessment by the verifier, a company may use other methods, such as direct CO$_2$eq measurement or laboratory testing, if they enhance the overall accuracy of the calculation, in application of Article 10(5).

Method for determining TtW fugitive and slipped emissions

Fugitive and slipped emissions are emissions caused by the amount of fuel that does not reach the combustion chamber of the combustion unit or that is not consumed by the fuel consumer unit because they are uncombusted, vented, or leaked from the system. For the purposes of this Regulation, fugitive and slipped emissions are taken into account as a percentage of the mass of the fuel used by the fuel consumer unit. The default values are contained in Annex II.

Methods for determining the reward factors linked to wind-assisted propulsion
Where wind-assisted propulsion is installed on board, a reward factor can be applied, determined as follows:

<table>
<thead>
<tr>
<th>Reward factor for wind-assisted propulsion – WIND (f_{wind})</th>
<th>$\frac{P_{Wind}}{P_{Prop}}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.99</td>
<td>0.05</td>
</tr>
<tr>
<td>0.97</td>
<td>0.1</td>
</tr>
<tr>
<td>0.95</td>
<td>$\geq 0.15$</td>
</tr>
</tbody>
</table>

Where:
- $P_{Wind}$ is the available effective power of the wind-assisted propulsion systems and corresponds to $f_{eff} \cdot P_{eff}$ as calculated in accordance with the 2021 guidance on treatment of innovative energy efficiency technologies for calculation and verification of the attained energy efficiency design index (EEDI) and energy efficiency existing ships index (EEXI) (MEPC.1/Circ.896);
- $P_{Prop}$ is the propulsion power of the ship and corresponds to $P_{ME}$ as defined in the 2018 guidelines on the method of calculation of the attained EEDI for new ships (IMO resolution MEPC.364(79)) and the 2021 guidelines on the method of calculation of the attained EEXI (IMO resolution MEPC.333(76)). Where shaft motor(s) are installed, $P_{Prop} = P_{ME} + P_{PTI(i),shaft}$.

The GHG intensity index of the ship is then calculated by multiplying the result of Equation (1) by the reward factor.
**ANNEX II**

**Default emission factors**

The default emission factors contained in the table below shall be used for the determination of the GHG intensity index referred to in Annex I of this Regulation, except where companies diverge from those default emission factors in application of Article 10(4) and (5) of this Regulation.

In the table below:

— TBM stands for To Be Measured,

— N/A stands for Not Available,

— The dash means not applicable,

— E is established in accordance with the methodologies laid down in Directive (EU) 2018/2001, Part C of Annex V and Part B of Annex VI.

Where a cell indicates either TBM or N/A, unless a value is demonstrated in accordance with Article 10, the highest default value of the fuel class in the same column shall be used.

Where, for a particular fuel class, all cells in the same column indicate either TBM or N/A, unless a value is demonstrated in accordance with Article 10, the default value of the least favourable fossil fuel pathway shall be used. This rule does not apply to column 9, where TBM or N/A refers to non-available values for the fuel consumer. In case of no default value, a certified value in accordance with Article 10(5) should be used.

<table>
<thead>
<tr>
<th>Fuel Class</th>
<th>Pathway name</th>
<th>LCV [MJ]</th>
<th>CO(_{2eq}) [g/kWh]</th>
<th>Fuel Consumer Unit Class</th>
<th>C(_{\text{CO}_2}) [g/kWh]</th>
<th>C(_{\text{CH}_4}) [g/kWh]</th>
<th>C(_{\text{N}_2\text{O}}) [g/kWh]</th>
<th>C(_{\text{slip}}) As % of the mass of the fuel used by the engine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fossil</td>
<td>HFO ISO 8217 Grades RME to RMK</td>
<td>0.0405</td>
<td>13.5</td>
<td>ALL ICEs</td>
<td>3.114</td>
<td>0.00005</td>
<td>0.00018</td>
<td>-</td>
</tr>
<tr>
<td>Fossil</td>
<td>LFO ISO 8217 Grades RMA to RMD</td>
<td>0.041</td>
<td>13.2</td>
<td>ALL ICEs</td>
<td>3.151</td>
<td>0.00005</td>
<td>0.00018</td>
<td>-</td>
</tr>
<tr>
<td>Fossil</td>
<td>MDO MGO ISO 8217 Grades DMX to DMB</td>
<td>0.0427</td>
<td>14.4</td>
<td>ALL ICEs</td>
<td>3.206</td>
<td>0.00005</td>
<td>0.00018</td>
<td>-</td>
</tr>
<tr>
<td>Fuel Class</td>
<td>Pathway name</td>
<td>LCV</td>
<td>CO\text{eq} \text{Wt}</td>
<td>Fuel Consumer Unit Class</td>
<td>( \frac{C_{\text{CO}_2}}{\text{fuel}} )</td>
<td>( \frac{C_{\text{CH}_4}}{\text{fuel}} )</td>
<td>( \frac{C_{\text{N}_2 \text{O}}}{\text{fuel}} )</td>
<td>C_{\text{cap}} % of the mass of the fuel used by the engine</td>
</tr>
<tr>
<td>------------</td>
<td>--------------</td>
<td>-----</td>
<td>---------------------</td>
<td>--------------------------</td>
<td>------------------</td>
<td>------------------</td>
<td>------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Fossil</td>
<td>LNG</td>
<td>0,0491</td>
<td>18.5</td>
<td>LNG Otto (dual fuel slow speed)</td>
<td>2,750</td>
<td>0</td>
<td>0,00011</td>
<td>3,1</td>
</tr>
<tr>
<td></td>
<td>LNG</td>
<td>0,0491</td>
<td>18.5</td>
<td>LNG Otto (dual fuel medium speed)</td>
<td>3,1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LPG</td>
<td>0,046</td>
<td>7,8</td>
<td>ALL ICEs 3,030 Butane 3,000 Propane</td>
<td>TBM</td>
<td>TBM</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H2 (natural gas)</td>
<td>0,12</td>
<td>132</td>
<td>Fuel Cells 0 0 -</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NH3 (natural gas)</td>
<td>0,0186</td>
<td>121</td>
<td>Fuel Cells 0 N/A TBM</td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methanol (natural gas)</td>
<td>0,0199</td>
<td>31,3</td>
<td>ALL ICEs 1,375 TBM TBM</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
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</tr>
<tr>
<td></td>
<td>WtT</td>
<td></td>
<td></td>
<td></td>
<td>TtW</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fuel Class</td>
<td>Pathway name</td>
<td>LCV</td>
<td>CO$_{2\text{eq WtT}}$</td>
<td>Fuel Consumer Unit Class</td>
<td>C$_{f CO_2}$</td>
<td>C$_{f CH_4}$</td>
<td>C$_{f N_2O}$</td>
<td>C$_{slip}$ As % of the mass of the fuel used by the engine</td>
</tr>
<tr>
<td>Ethanol Production Pathways of Directive (EU) 2018/2001</td>
<td>ALL ICEs</td>
<td>1,913</td>
<td>TBM</td>
<td>TBM</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bio-diesel Production Pathways of Directive (EU) 2018/2001</td>
<td>ALL ICEs</td>
<td>2,834</td>
<td>TBM</td>
<td>TBM</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biofuels</td>
<td>Hydrotreated Vegetable Oil (HVO) Production Pathways of Directive (EU) 2018/2001</td>
<td>ALL ICEs</td>
<td>3,115</td>
<td>0.00005</td>
<td>0.00018</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Liquefied Biogas Methane as transport fuel (Bio-LNG) Production Pathways of Directive (EU) 2018/2001</td>
<td>LNG Otto (dual fuel medium speed)</td>
<td>2,750</td>
<td>0</td>
<td>0.00011</td>
<td>3.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LNG Otto (dual fuel slow speed)</td>
<td>1,7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LNG Diesel (dual fuels)</td>
<td>0.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LBSI</td>
<td>2.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
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<td>---------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WtT</td>
<td>TtW</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fuel Class</td>
<td>Pathway name</td>
<td>LCV</td>
<td>CO_{eq} Wt</td>
<td>Fuel Consumer Unit Class</td>
<td>C_{eq} CO</td>
<td>C_{eq} CH</td>
<td>C_{eq} N</td>
<td>C_{eq} As % of the mass of the fuel used by the engine</td>
</tr>
<tr>
<td>Bio-methanol Production Pathways of Directive (EU) 2018/2001</td>
<td>ALL ICEs</td>
<td>1,375</td>
<td>TBM</td>
<td>TBM</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Production Pathways of Directive (EU) 2018/2001</td>
<td>ALL ICEs</td>
<td>3,115</td>
<td>0,00005</td>
<td>0,00018</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biofuels</td>
<td>N/A</td>
<td>ICE</td>
<td>0</td>
<td>0</td>
<td>TBM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e-diesel</td>
<td>Ref. to Directive (EU) 2018/2001</td>
<td>ALL ICEs</td>
<td>3,206</td>
<td>0,00005</td>
<td>0,00018</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e-methanol</td>
<td>Ref. to Directive (EU) 2018/2001</td>
<td>All ICEs</td>
<td>1,375</td>
<td>TBM</td>
<td>TBM</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renewable Fuels of Non-Biological Origin (RFNBO)</td>
<td>LNG Otto (dual fuel medium speed)</td>
<td>LBSI</td>
<td>2,750</td>
<td>0</td>
<td>0,00011</td>
<td>3.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- e-Fuels</td>
<td>LNG Otto (dual fuel slow speed)</td>
<td>1,7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e-LNG</td>
<td>Ref. To Directive (EU) 2018/2001</td>
<td>LNG Diesel (dual fuels)</td>
<td>0,2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2,6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fuel Class</td>
<td>Pathway name</td>
<td>LCV [MJ/g]</td>
<td>CO$_{eq}$ WtT [gCO$_2eq$/MJ]</td>
<td>Fuel Consumer Unit Class</td>
<td>C$_{eq}$ CO$_2$ [gCO$_2$/MJ]</td>
<td>C$_{eq}$ CH$_4$ [gCH$_4$/MJ]</td>
<td>C$_{eq}$ N$_2$O [gN$_2$O$/MJ]</td>
<td>CO slip As % of the mass of the fuel used by the engine</td>
</tr>
<tr>
<td>------------</td>
<td>--------------</td>
<td>-------------</td>
<td>-------------------------------</td>
<td>--------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------</td>
<td>----------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>e-H2</td>
<td>Ref. to Directive (EU) 2018/2001</td>
<td>0.12</td>
<td>Fuel Cells</td>
<td>ICE</td>
<td>0</td>
<td>0</td>
<td>TBM</td>
<td>N/A</td>
</tr>
<tr>
<td>e-NH3</td>
<td>N/A</td>
<td>0.0186</td>
<td>N/A</td>
<td>N/A</td>
<td>TBM</td>
<td>N/A</td>
<td>N/A</td>
<td>-</td>
</tr>
<tr>
<td>e-LPG</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>-</td>
</tr>
<tr>
<td>e-DME</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>-</td>
</tr>
<tr>
<td>Others</td>
<td>Electricity</td>
<td>-</td>
<td>EU ENERGY MIX</td>
<td>On-shore power supply (OPS)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Column 1 identifies the class of the fuels, namely fossil fuels, liquid biofuels, gaseous biofuels and e-fuels.

Column 2 identifies the name or the pathways of the relevant fuels within the class.

Column 3 contains the lower calorific value of the fuels in [MJ/g]. For liquid biofuels, values of energy content by weight (lower calorific value, MJ/kg) as set out in Annex III to Directive (EU) 2018/2001 shall be converted in [MJ/g] and used.

Column 4 contains the WtT GHG emission factors in [gCO$_{2eq}$/MJ]:

(a) For liquid biofuels, the default values shall be calculated by using the values of E established in accordance with the methodologies laid down in Directive (EU) 2018/2001, Part C of Annex V to that Directive for all liquid biofuels except bio-LNG and Part B of Annex VI to that Directive for bio-LNG, and on the basis of default values related to the particular biofuel used as a transport fuel and its production pathway, laid down in that Directive, Parts D and E of Annex V to that Directive for all liquid biofuels except bio-LNG and in Part D of Annex VI to that Directive for bio-LNG. However, the values of E need to be adjusted by subtracting the ratio of the values contained in column 6 ($C_{f CO_2}$) and column 3 (LCV). This is required under this Regulation, which separates the WtT and the TtW calculations, to avoid double counting of emissions;

(b) For RFNBO and other fuels not referred to in point (a) to be taken into account for the purpose referred to in Article 4(1) of this Regulation, default values are to be either calculated by using the methodology of the delegated act referred to in Article 28(5) of Directive (EU) 2018/2001, or, if applicable, a similar methodology if defined under a Union legal act concerning the internal markets in renewable and natural gases and in hydrogen, pursuant to Article 10(1) and (2) of this Regulation.
Column 5 identifies the main types/classes of fuel consumer units such as 2 and 4 strokes Internal Combustion Engines (ICE) Diesel or Otto cycle, Lean-Burn Spark-Ignited (LBSI) engines, fuel cells, etc.

Column 6 contains the emission factor $C_f$ for CO$_2$ in [gCO$_2$/gfuel]. Emission factors values as specified in Regulation (EU) 2015/757 shall be used. For all those fuels not contained in Regulation (EU) 2015/757, the default values are specified in the table.

Column 7 contains the emission factor $C_f$ for methane in [gCH$_4$/gfuel]. For LNG fuels, $C_f$ for methane are set to zero.

Column 8 contains the emission factor $C_f$ for nitrous oxide in [gN$_2$O/gfuel].

Column 9 identifies the part of fuel lost as fugitive and slipped emissions ($C_{slip}$) measured as % of the mass of fuel used by the specific fuel consumer unit. For fuels such as LNG for which the fugitive and slipped emissions exist, the amount of fugitive and slipped emissions as presented in the table is expressed in % of the mass of fuel used (Column 9). The values of $C_{slip}$ in the table are calculated at 50 % of the full engine load.
### ANNEX III

**General requirements for zero-emission technologies**

The following non-exhaustive table identifies types of technologies as well as general requirements for their operation to be considered as zero-emission technologies within the meaning of Article 3, point (7).

<table>
<thead>
<tr>
<th>Types of technology</th>
<th>General requirements for operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fuel cells</td>
<td>Power supplied by onboard fuel cells with a fuel or a system ensuring that, when used to provide energy, it does not release any emissions referred to in Article 3, point (7), into the atmosphere</td>
</tr>
<tr>
<td>On-board electrical energy storage</td>
<td>Power supplied by on-board electrical energy storage systems previously charged via:</td>
</tr>
<tr>
<td></td>
<td>— onboard power generation at sea</td>
</tr>
<tr>
<td></td>
<td>— shore side battery charging</td>
</tr>
<tr>
<td></td>
<td>— battery swapping</td>
</tr>
<tr>
<td>On-board power generation from wind and solar energy</td>
<td>Power supplied by on-board renewable energy sources, either directly supplying to the ship grid or via charging of on-board intermediate electrical energy storage</td>
</tr>
</tbody>
</table>

Power supplied by on-board technologies not identified in this table that achieve zero emissions, within the meaning of Article 3, point (7), can be added to this table by means of delegated acts in accordance with Article 6(6).

The fulfilling of the general requirements indicated above and in Article 6(6) for other technologies as well as of the detailed criteria for acceptance specified in the implementing acts referred to in Article 6(7), is to be proved by relevant documentation.
ANNEX IV

Formulas for calculating the compliance balance and FuelEU penalties laid down in Article 23(2)

A. Formulas for calculating the ship's compliance balance

(a) For the purpose of calculating the compliance balance of a ship for GHG intensity as referred to in Article 4(2), the following formula shall apply:

\[
\text{Compliance balance } [\text{gCO}_2\text{eq}] = (\text{GHGIE}_{\text{target}} - \text{GHGIE}_{\text{actual}}) \times \left[\sum_{i} M_i \times \text{LCV}_i + \sum_{k} E_k \right]
\]

Where:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>\text{gCO}_2\text{eq}</td>
<td>Grams of CO$_2$ equivalent</td>
</tr>
<tr>
<td>\text{GHGIE}_{\text{target}}</td>
<td>GHG intensity limit of the energy used on-board a ship according to Article 4(2)</td>
</tr>
<tr>
<td>\text{GHGIE}_{\text{actual}}</td>
<td>Yearly average of the GHG intensity of the energy used on-board a ship calculated for the relevant reporting period</td>
</tr>
</tbody>
</table>

For any ship having the ice class IC, IB, IA or IA Super or an equivalent ice class, the company may request, until 31 December 2034, to exclude the additional energy consumption, due to sailing in ice conditions.

For any ship having the ice class IA or IA Super or an equivalent ice class, the company may request to exclude the additional energy consumption, due to the technical characteristics of the ship.

For both cases in which additional energy consumption is excluded, the calculation of the compliance balance above, the values of $M_i$ shall be replaced by the adjusted mass of fuel $M_{iA}$ defined in Annex V and the value of $\text{GHGIE}_{\text{actual}}$ to be used for calculating the compliance balance shall be recalculated with the corresponding values of $M_{iA}$.

(b) For the purpose of calculating the compliance balance of a ship with respect to the subtarget for RFNBO according to Article 5(3), the following formula shall apply:

\[
\text{CB}_{\text{RFNBO}}[\text{MJ}] = \left(0.02 \times \left(\sum_{i} M_i \times \text{LCV}_i\right)\right) - \left(\sum_{i}^{\text{RFNBO}} M_i \times \text{LCV}_i\right)
\]

Where:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>\text{CB}_{\text{RFNBO}}</td>
<td>Compliance balance in MJ of RFNBO subtarget referred to in Article 5(3)</td>
</tr>
<tr>
<td>$\sum_{i}^{\text{RFNBO}} M_i \times \text{LCV}_i$</td>
<td>Annual sum of energy used from RFNBO and/or from fuels providing equivalent GHG emissions savings referred to in Article 5</td>
</tr>
</tbody>
</table>
B. Formula for calculating the FuelEU Penalties laid down in Article 23(2)

The amount of the FuelEU penalties laid down in Article 23(2) shall be calculated as follows:

(a) FuelEU penalty with respect to compliance balance for GHG intensity of the ship according to Article 4(2)

\[
\text{FuelEU Penalty} = \frac{|\text{Compliance Balance}| \times 41000 \times 2400}{\text{GHGIE}_{\text{actual}}} 
\]

1. FuelEU Penalty
2. Is in EUR
3. |Compliance Balance|
4. Is the absolute value of the compliance balance
5. 41 000
6. Is 1 metric ton of VLSFO that is equivalent to 41 000 MJ
7. 2 400
8. Is the amount to be paid in EUR per equivalent metric ton of VLSFO

(b) FuelEU penalty with respect to the subtarget for RFNBO according to Article 5(3)

If \( CB_{RFNBO} > 0 \), the amount of the FuelEU penalty as referred to in Article 23(2) shall be calculated as follows:

\[
\text{FuelEU Penalty (RFNBO)} = \frac{CB_{RFNBO} \times P_d}{41000} 
\]

9. FuelEU Penalty
10. Is in EUR
11. \( CB_{RFNBO} \)
12. Is the value of the compliance balance for RFNBO
13. \( P_d \)
14. Price difference between RFNBO and fossil fuel compatible with ship installation
15. 41 000
16. Is 1 metric ton of VLSFO that is equivalent to 41 000 MJ
ANNEX V

Calculation of adjusted mass of fuel for ice navigation

This Annex describes how to calculate:
— the additional energy consumption due to technical characteristics of a ship having the ice class IA or IA Super or an equivalent ice class
— the additional energy consumption of a ship having the ice class IC, IB, IA or IA Super or an equivalent ice class due to sailing in ice conditions
— the adjusted mass \( M_{iA} \) after the deduction of the additional energy, allocated to each fuel \( i \)

Additional energy due to ice class

The additional energy consumption due to the technical characteristics of a ship having the ice class IA or IA Super or an equivalent ice class is calculated as follows:

\[
E_{\text{additional due to ice class}} = 0.05 \times (E_{\text{voyages, total}} - E_{\text{additional due to ice conditions}})
\]

Where:
- \( E_{\text{voyages, total}} \) denotes the total energy consumed for all voyages and;
- \( E_{\text{additional due to ice conditions}} \) denotes the additional energy consumption due to sailing in ice conditions.

The total energy consumed for all voyages is calculated as follows:

\[
E_{\text{voyages, total}} = \sum M_{i,\text{voyages, total}} \times LCV_i
\]

Where:
- \( M_{i,\text{voyages, total}} \) denotes the mass of fuel \( i \) consumed for all voyages within the scope of this Regulation and;
- \( LCV_i \) the lower calorific value of fuel \( i \).

Additional energy due to sailing in ice conditions

The additional energy consumption of a ship having the ice class IC, IB, IA or IA Super or an equivalent ice class due to sailing in ice conditions is calculated as follows:

\[
E_{\text{additional due to ice conditions}} = E_{\text{voyages, total}} - E_{\text{voyages, open water}} - E_{\text{voyages, ice conditions, adjusted}}
\]

Where:
- \( E_{\text{voyages, open water}} \) denotes the energy consumed on voyages in open water and;
- \( E_{\text{voyages, ice conditions, adjusted}} \) denotes the adjusted energy consumed in ice conditions.
- \( E_{\text{additional due to ice conditions}} \) cannot be higher than \( 1.3 \times E_{\text{voyages, open water}} \)

The energy consumed for voyages that include sailing in open water only is calculated as follows:

\[
E_{\text{voyages, open water}} = E_{\text{voyages, total}} - E_{\text{voyages, ice conditions}}
\]

Where:
- \( E_{\text{voyages, ice conditions}} \) denotes energy consumed for sailing in ice conditions, which is calculated as follows:

\[
E_{\text{voyages, ice conditions}} = \sum M_{i,\text{voyages, ice conditions}} \times LCV_i
\]
Where:

\[ M_{i,\text{voyages,ice conditions}} \] denotes the mass of fuel \( i \) consumed for sailing in ice conditions, within the scope of this Regulation.

The adjusted energy consumed in ice conditions is calculated as follows:

\[ E_{\text{voyages, ice conditions, adjusted}} = D_{\text{ice conditions}} \times \frac{E}{D_{\text{open water}}} \]

Where:

\( D_{\text{ice conditions}} \) denotes the aggregated distance travelled when sailing in ice conditions within the scope of this Regulation.

\( \frac{E}{D_{\text{open water}}} \) is the energy consumption per distance travelled in open water calculated as follows:

\[ \frac{E}{D_{\text{open water}}} = \frac{(E_{\text{voyages, total}} - E_{\text{voyages, ice conditions}})}{(D_{\text{total}} - D_{\text{ice conditions}})} \]

Where:

\( E_{\text{voyages, ice conditions}} \) denotes the energy consumption when sailing in ice conditions and;

\( D_{\text{total}} \) is the aggregated annual distance travelled within the scope of this Regulation.

Total additional ice energy due to ice class and sailing in ice conditions

\[ E_{\text{additional, ice}} = E_{\text{additional due to ice class}} + E_{\text{additional due to ice conditions}} \]

Adjusted mass \([M_{i,A}]\)

The company shall allocate the total additional ice energy \( E_{i,\text{additional ice}} \) to the different fuels \( i \) used during the year, with the following conditions:

\[ \sum E_{i,\text{additional ice}} = E_{\text{additional, ice}} \]

For each fuel \( i \),

\[ E_{i,\text{additional ice}} \leq M_i \times LCV_i \]

The \([M_{i,A}]\) adjusted mass of fuel is calculated as follows:

\[ M_{i,A} = M_i - \frac{E_{i,\text{additional ice}}}{LCV_i} \]
II
(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1806
of 20 September 2023
amending Implementing Regulation (EU) 2019/73 imposing a definitive anti-dumping duty and definitively collecting the provisional duty imposed on imports of electric bicycles originating in the People’s Republic of China

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union (1), and in particular Article 14(1) thereof,

Whereas:

(1) Imports of electric bicycles originating in the People’s Republic of China are subject to definitive anti-dumping duties imposed by Commission Implementing Regulation (EU) 2019/73 (2).

(2) Jinhua Enjoycare Motive Technology Co., Ltd., TARIC (3) additional code C419, a company subject to an anti-dumping duty rate of 24.2 % for ‘Other cooperating companies in the anti-dumping investigation (with the exception of the companies subject to the parallel countervailing duty rate for all other companies Implementing Regulation (EU) 2019/72)’, informed the Commission on 21 November 2022 that it had changed its name to Enjoycare Technology (Zhejiang) Co., Ltd.

(3) The company requested the Commission to confirm that the change of name does not affect the right of the company to benefit from the anti-dumping duty rate applied to it under its previous name.

(4) The Commission examined the information supplied and concluded that the change of name was properly registered with the relevant authorities and did not result in any new relationship with other groups of companies which were not investigated by the Commission.

(5) Accordingly, this change of name does not affect the findings of Implementing Regulation (EU) 2019/73 and in particular the anti-dumping duty rate applicable to it.

(6) The name change should take effect as of the date on which the company changed its name, i.e. 22 September 2022. The Commission requested the applicant to confirm whether this date was appropriate.

(3) The Integrated Tariff of the European Union.
(7) Given the considerations in the recitals above, the Commission considered it appropriate to amend Implementing Regulation (EU) 2019/73 to reflect the changed name of the company previously attributed to additional TARIC code C419.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 15(1) of Regulation (EU) 2016/1036,

HAS ADOPTED THIS REGULATION:

Article 1

1. Annex I of Implementing Regulation (EU) 2019/73 is amended as follows:

<table>
<thead>
<tr>
<th>Jinhua Enjoycare Motive Technology Co., Ltd.</th>
<th>Zhejiang</th>
<th>C419</th>
</tr>
</thead>
</table>

is replaced by

<table>
<thead>
<tr>
<th>Enjoycare Technology (Zhejiang) Co., Ltd.</th>
<th>Zhejiang</th>
<th>C419</th>
</tr>
</thead>
</table>

2. TARIC additional code C419 previously attributed to Jinhua Enjoycare Motive Technology Co., Ltd. shall apply to Enjoycare Technology (Zhejiang) Co., Ltd. as of 22 September 2022. Any definitive duty paid on imports of products manufactured by Enjoycare Technology (Zhejiang) Co., Ltd. in excess of the anti-dumping duty established in Article 1(2) of Implementing Regulation (EU) 2019/73 as regards Jinhua Enjoycare Motive Technology Co., Ltd. shall be repaid or remitted in accordance with the applicable customs legislation.

Article 2

This Regulation shall enter into force on the day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 September 2023.

For the Commission
The President
Ursula VON DER LEYEN
COMMISSION IMPLEMENTING REGULATION (EU) 2023/1807
of 21 September 2023
amending Implementing Regulation (EU) 2019/72 imposing a definitive countervailing duty on imports of electric bicycles originating in the People’s Republic of China

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/1037 of the European Parliament and of the Council of 8 June 2016 on protection against subsidised imports from countries not members of the European Union (1), and in particular Article 24(1) thereof,

Whereas:

(1) Imports of electric bicycles originating in the People’s Republic of China are subject to definitive countervailing duties imposed by Commission Implementing Regulation (EU) 2019/72 (2).

(2) Jinhua Enjoycare Motive Technology Co., Ltd., TARIC (3) additional code C419, a company subject to a countervailing duty rate of 9.2%, informed the Commission on 21 November 2022 that it had changed its name to Enjoycare Technology (Zhejiang) Co., Ltd.

(3) The company requested the Commission to confirm that the change of name does not affect the right of the company to benefit from the duty rate for ‘Other cooperating companies listed in Annex I’ applied to it under its previous name.

(4) The Commission examined the information supplied and concluded that the change of name was properly registered with the relevant authorities, and did not result in any new relationship with other groups of companies which were not investigated by the Commission.

(5) Accordingly, this change of name does not affect the findings of Implementing Regulation (EU) 2019/72 and in particular the countervailing duty rate applicable to it.

(6) The name change should take effect as of the date on which the company changed its name, i.e. 22 September 2022. The Commission requested the applicant to confirm whether this date was appropriate.

(7) Given the considerations in the recitals above, the Commission considered it appropriate to amend Commission Implementing Regulation (EU) 2019/72 to reflect the changed name of the company previously attributed to additional TARIC code C419.

(8) According to Article 25 of Regulation (EU) 2016/1037, the measures provided for in this Regulation are in accordance with the opinion of the Committee established by Regulation (EU) 2016/1036 of the European Parliament and of the Council (4),

(3) The Integrated Tariff of the European Union.
HAS ADOPTED THIS REGULATION:

Article 1

1. Annex I to Implementing Regulation (EU) 2019/72 is amended as follows:

| Jinhua Enjoycare Motive Technology Co., Ltd. | Zhejiang | C419’ |

is replaced by

| Enjoycare Technology (Zhejiang) Co., Ltd. | Zhejiang | C419’ |

2. TARIC additional code C419 previously attributed to Jinhua Enjoycare Motive Technology Co., Ltd. shall apply to Enjoycare Technology (Zhejiang) Co., Ltd. as of 22 September 2022. Any definitive duty paid on imports of products manufactured by Enjoycare Technology (Zhejiang) Co., Ltd. in excess of the countervailing duty established in Article 1(2) of Implementing Regulation (EU) 2019/72 as regards Jinhua Enjoycare Motive Technology Co., Ltd. shall be repaid or remitted in accordance with the applicable customs legislation.

Article 2

This Regulation shall enter into force on the day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 September 2023.

For the Commission
The President
Ursula VON DER LEYEN
COMMISSION IMPLEMENTING REGULATION (EU) 2023/1808
of 21 September 2023

setting out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (1), and in particular Article 7(3) thereof,

Whereas:

(1) Regulation (EU) 2022/2371 lays down mechanisms and structures for coordinating preparedness for and response to serious cross-border threats to health, including reporting on prevention, preparedness and response planning.

(2) Pursuant to Article 7(1), first subparagraph, of Regulation (EU) 2022/2371, Member States are to provide the Commission and relevant Union agencies and bodies an updated report on prevention, preparedness and response planning and implementation at national level, and where appropriate, cross-border interregional levels by 27 December 2023 and every 3 years thereafter.

(3) Article 7(1), second and third subparagraphs, of Regulation (EU) 2022/2371 lay down the information on prevention, preparedness and response planning which Member States are to provide to the Commission and relevant Union agencies and bodies.

(4) Pursuant to Article 7(2), first subparagraph, of Regulation (EU) 2022/2371, every 3 years the Commission is to make the information received available to the Health Security Committee (HSC) in a report prepared in collaboration with the European Centre for Disease Prevention and Control (ECDC) and other relevant Union agencies and bodies. That report is to include country profiles for monitoring progress and developing action plans to address gaps identified at national level for which the Commission may issue general recommendations considering the outcomes of the assessment of Article 8 of that Regulation.

(5) Pursuant to Article 7(2), second and third subparagraphs, of Regulation (EU) 2022/2371, based on that report, the Commission is to initiate discussion in the HSC on the progress and gaps in preparedness. An overview of recommendations of the report is to be published on the websites of the Commission and the ECDC.

(6) The template of the questionnaire to be used by Member States when providing the information referred to in Article 7(1) of that Regulation should ensure its relevance to the objectives identified in that paragraph and its comparability, while avoiding any duplication of information requested and submitted. The template was elaborated in close collaboration with the Working Group on Preparedness of the HSC with active participation of majority of Member States, the relevant Commission Directorates-General, the ECDC, and the World Health Organisation (WHO). The template was aligned, where possible, with the International Health Regulations (2005) State Party Self-Assessment Report (SPAR).

(7) The measures provided for in this Regulation are in accordance with the opinion of the Committee on serious cross-border threats to health,

HAS ADOPTED THIS REGULATION:

Article 1

The template to be used by Member States when providing information on their prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Article 7(1) of Regulation (EU) 2022/2371, as is set out in the Annex to this Regulation, is adopted.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 September 2023.

For the Commission
The President
Ursula VON DER LEYEN
ANNEX

Table of contents

A. International Health Regulations (IHR) 2005 capacities .................................................. 108
   1. Policy, legal and normative Instruments to implement the International Health Regulations (IHR) 2005 ................................................................. 108
   2. Financing ...................................................................................................................... 109
   3. Laboratory .................................................................................................................. 110
   4. Surveillance ............................................................................................................... 113
   5. Human resources ...................................................................................................... 114
   6. Health emergency management ............................................................................... 115
      Management of health emergency response ............................................................. 115
      Emergency logistic and supply chain management .................................................. 118
   7. Health services provision ....................................................................................... 121
   8. Risk communication ............................................................................................... 124
   9. Points of entry (PoEs) and border health ................................................................. 125
  10. Zoonotic diseases and threats of environmental origin, including those due to the climate ................................................................. 126
  11. Chemical events ...................................................................................................... 127

B. Additional capacities as per Regulation (EU) 2022/2371 .................................................. 129
  12. Antimicrobial resistance (AMR) and Healthcare associated infections .......... 129
     AMR .............................................................................................................................. 129
     Healthcare associated infections (HAIs) .................................................................. 134
  13. Union level coordination and support functions .................................................... 135
  14. Research development and evaluations to inform and accelerate emergency preparedness ................................................................. 137
  15. Recovery elements ................................................................................................. 139
  16. Actions taken to improve gaps found in the implementation of prevention, preparedness, and response plans ................................................................. 139

C. Other ............................................................................................................................ 141
<table>
<thead>
<tr>
<th>A.1.1</th>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.1.1</td>
<td>Regarding your Member State’s legal instruments for preparedness and response planning, please indicate your Member State’s corresponding level:</td>
<td>1-5</td>
</tr>
<tr>
<td></td>
<td>Legal instruments do not incorporate coordination across national, regional, and local levels of government during a public health emergency</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Legal instruments incorporate coordination across national, regional, and local levels of government during a public health emergency</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Legal instruments incorporate coordination across national, regional, and local levels of government during a public health emergency. In addition, legal instruments also incorporate coordination with sectors responsible for critical infrastructure during a public health emergency</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Legal instruments incorporate coordination across national, regional, and local levels of government during a public health emergency. In addition, legal instruments also incorporate coordination with sectors responsible for critical infrastructure during a public health emergency. Moreover, the operational readiness of these legal instruments has been tested in the last 3 years</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>As per level 4 and, in addition, there is a mechanism for reviewing and revising legal instruments (if needed based on recommendations from testing)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>— If level 5: has your country revised the legal instruments in the last 3 years? (yes/no)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>— If yes, please upload relevant links (optional for Member States):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>— Additional comments:</td>
<td></td>
</tr>
<tr>
<td>A.1.2</td>
<td>In the event of a public health emergency, do your country’s legal instruments for IHR 2005 implementation assign a clear decision-making process, which may comprise one or more authorities? (yes/no/other)</td>
<td>Not applicable (N/A)</td>
</tr>
<tr>
<td></td>
<td>— If other, please describe:</td>
<td></td>
</tr>
</tbody>
</table>
### Financing

<table>
<thead>
<tr>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A.2.1</strong> Regarding Member States's planning to test the financial resources for contingency funding to respond to health threats, please indicate your Member State's corresponding level:</td>
<td>1-5 or N/A</td>
</tr>
<tr>
<td>Member State cannot answer the question [at central state level]</td>
<td>N/A</td>
</tr>
<tr>
<td>There are no plans to conduct tests of financial resources for contingency funding for response to health threats in the next 3 years</td>
<td>1</td>
</tr>
<tr>
<td>There are plans to conduct tests of financial resources for contingency funding for response to health threats in the next 3 years but this is on an ad hoc basis</td>
<td>2</td>
</tr>
<tr>
<td>There are plans to conduct tests of financial resources for contingency funding for response to health threats and this is to be conducted on a regular basis</td>
<td>3</td>
</tr>
<tr>
<td>Tests of financial resources for contingency funding for response to health threats have been and continue to be conducted on a regular basis</td>
<td>4</td>
</tr>
<tr>
<td>As per level 4, and, in addition, recommendations from the tests have been implemented and corresponding plans have been reviewed and revised</td>
<td>5</td>
</tr>
</tbody>
</table>

— **Additional comments:**

Your Member State cannot answer this question at the central state level, due to governance and legislative frameworks? (yes)

In this case, please indicate if national level recommendations/guidelines are sent to regional authorities (yes/no)

If yes, please advise if at central level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges

If not, please explain:

<table>
<thead>
<tr>
<th><strong>A.2.2</strong> Does the Ministry of Health and Ministry of Finance of your Member State have dedicated procedures for the coordination of policies and activities in the case of a public health emergency? (yes/no/other)</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>— If yes, please elaborate: (e.g., regular meetings, joint task force or working group, guidelines, and regulatory measures, etc.)</td>
<td></td>
</tr>
<tr>
<td>— If other, please describe:</td>
<td></td>
</tr>
</tbody>
</table>
### A.3.1

**Question:** Please indicate your Member State’s corresponding level in relation to the scaling up the laboratory testing capacity in the event of a public health emergency:

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>There is no plan and organisation (*) for scaling up the laboratory testing capacity in the event of a public health emergency</td>
</tr>
<tr>
<td>2</td>
<td>A plan and organisation for scaling up the laboratory testing capacity in the event of a public health emergency is being developed</td>
</tr>
<tr>
<td>3</td>
<td>There is a plan and organisation for scaling up the laboratory testing capacity in the event of a public health emergency, but the plan has not been tested in the last 3 years</td>
</tr>
<tr>
<td>4</td>
<td>There is a plan and organisation for scaling up the laboratory testing capacity in the event of a public health emergency and this plan has been tested in a stress test in the last 3 years</td>
</tr>
<tr>
<td>5</td>
<td>As per level 4 and, in addition, the system has been revised accordingly</td>
</tr>
</tbody>
</table>

---

(*) Here, in this question an organisation refers to an officially mandated group responsible for implementing the emergency plan.

### A.3.2

**Question:** Please indicate your Member State’s corresponding level regarding implementation of new nucleic acid amplification-based tests (NAATs) and adapted associated laboratory systems in the event of a novel pathogen emergence with pandemic potential:

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>In the context of my Member State, it would not be possible to implement new NAATs and adapt associated laboratory systems within 6 months.</td>
</tr>
<tr>
<td>2</td>
<td>&gt; 3 – 6 months</td>
</tr>
<tr>
<td>3</td>
<td>&gt; 1 – 3 months</td>
</tr>
<tr>
<td>4</td>
<td>2 – 4 weeks</td>
</tr>
<tr>
<td>5</td>
<td>&lt; 2 weeks</td>
</tr>
</tbody>
</table>

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---
A.3.3 Please indicate your Member State’s corresponding level, in an event of a public health emergency with pandemic potential requiring large-scale testing

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>In an event of a public health emergency and where a validated NAAT is available, it would be possible to scale up diagnostic NAAT testing services to a weekly sample testing capacity corresponding to up to 0.01% of the population in my Member State</td>
</tr>
<tr>
<td>2</td>
<td>In an event of a health emergency and where a validated NAAT is available, it would be possible to scale up diagnostic NAAT testing services to a weekly sample testing capacity corresponding to 0.01-0.1% of the population in my Member State</td>
</tr>
<tr>
<td>3</td>
<td>In an event of a health emergency and where a validated NAAT is available, it would be possible to scale up diagnostic NAAT testing services to a weekly sample testing capacity corresponding to 0.1-1% of the population in my Member State</td>
</tr>
<tr>
<td>4</td>
<td>In an event of a health emergency and where a validated NAAT is available, it would be possible to scale up diagnostic NAAT testing services to a weekly sample testing capacity corresponding to 1-2% of the population in my Member State</td>
</tr>
<tr>
<td>5</td>
<td>In an event of a health emergency and where a validated NAAT is available, it would be possible to scale up diagnostic NAAT testing services to a weekly sample testing capacity corresponding to &gt;2% of the population in my Member State</td>
</tr>
</tbody>
</table>

— If N/A, please quantify NAAT capacity according to your own proposal:
— Additional comments:

A.3.4 Does your Member State have access to additional sources of laboratory capacity for diagnostic services in an event where an increased capacity is needed (e.g. research or veterinary laboratories, etc.)? (yes/no/other)
— If yes, please advise if this is by formal agreement or on an ad hoc basis.
— If other, please describe:

N/A
| A.3.5 | Does your Member State have the capacity for reporting laboratory testing results for national surveillance via an electronic reporting system? (yes/no/other)  
|       | — If yes, is this reporting system capable of managing scaled up testing information? (yes/no)  
|       | — If yes, is this reporting system capable of integrating input from different sources of laboratory capacities (e.g., research, hospitals, commercial or veterinary laboratories, etc.)? (yes/no)  
|       | — If other, please describe: | N/A |
| A.3.6 | Please indicate if your Member State has access to high-containment laboratories i.e. biosafety level 3 or 4 laboratories:  
|       | Does your Member State have access to a biosafety level 3 laboratory? (yes/no/other)  
|       | — If no, does your Member State have a formal agreement with another EU/EEA country for this service? (yes/no)  
|       | — If other, please describe:  
|       | Does your Member State have access to a biosafety level 4 laboratory (yes/no/other)  
|       | — If no, does your country have a formal agreement with another EU/EEA Member State for this service? (yes/no)  
|       | — If other, please describe:  
|       | *In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security*
|       | N/A |
| A.3.7 | Does your Member State have the capacity for characterization of a novel pathogen by Next Generation Sequencing (NGS)? (yes/no/other)  
|       | — If yes, are NGS data for national surveillance reported via an electronic reporting system? (yes/no)  
|       | — If no, does your country have an arrangement with another Member State? (yes/no).  
|       | — If yes, please indicate the Member State:  
|       | — If other, please describe: | N/A |
| A.3.8 | Does your Member State have a facility dedicated to validating newly introduced devices for the diagnosis of the novel pathogen? (yes/no/other)  
|       | — If other, please describe: | N/A |
4. Surveillance

<table>
<thead>
<tr>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.4.1 Does your Member State’s surveillance system for acute respiratory infections cover all healthcare levels? (yes/no/other)</td>
<td>N/A</td>
</tr>
<tr>
<td>— If other, please describe:</td>
<td></td>
</tr>
<tr>
<td>A.4.2 Are the surveillance systems for Acute Respiratory Infection (ARI), Influenza-Like Illness (ILI) and Severe Acute Respiratory Infections (SARI) automated (†) in your Member State? (yes/no/other)</td>
<td>N/A</td>
</tr>
<tr>
<td>— If other, please describe:</td>
<td></td>
</tr>
<tr>
<td>A.4.3 Would your Member State’s surveillance system for respiratory infections be able to scale up during a pandemic (i.e., to increase the number of reporting sites, the breath of data collected, the timeliness of reporting, etc.)? (yes/no/other)</td>
<td>N/A</td>
</tr>
<tr>
<td>— If other, please describe:</td>
<td></td>
</tr>
<tr>
<td>A.4.4 Is your Member State able to monitor the following indicators on an ongoing basis and for the whole country’s territory, during a public health emergency (i.e. taking into account expanded capacities and/or new settings)?</td>
<td>N/A</td>
</tr>
<tr>
<td>Hospital bed capacity</td>
<td>yes/no</td>
</tr>
<tr>
<td>Hospital intensive care units' capacity</td>
<td></td>
</tr>
<tr>
<td>Hospital emergency rooms capacity</td>
<td></td>
</tr>
<tr>
<td>Hospital utilisation</td>
<td></td>
</tr>
<tr>
<td>Testing capacity</td>
<td></td>
</tr>
<tr>
<td>Contact tracing capacity</td>
<td></td>
</tr>
<tr>
<td>Other, please describe</td>
<td></td>
</tr>
<tr>
<td>— Additional comments:</td>
<td></td>
</tr>
<tr>
<td>A.4.5 Does your country have a wastewater monitoring system in place for respiratory pathogens? (yes/no/other)</td>
<td>N/A</td>
</tr>
<tr>
<td>— If other, please describe:</td>
<td></td>
</tr>
<tr>
<td>A.4.6 Does your country have plans and infrastructures for timely and ongoing assessment of a pandemic threat, i.e., for assessing:</td>
<td>N/A</td>
</tr>
<tr>
<td>— Transmissibility, route of transmission, effective reproduction number</td>
<td>yes/no</td>
</tr>
<tr>
<td>Severity</td>
<td></td>
</tr>
</tbody>
</table>

(†) Automation refers to the surveillance process being embedded in the healthcare provision system with automatic extraction and sharing of relevant information, or other type of automation that reduces the dependency on human resources.
### Human resources

<table>
<thead>
<tr>
<th>A.5.1</th>
<th>In the event of a public health emergency regarding a potential surge in demand of human resources, please indicate your Member State's level:</th>
<th>Indicator 1-5 or N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Member State cannot answer the question at central state level</td>
<td></td>
</tr>
<tr>
<td>Level 1</td>
<td>There is no mechanism to ensure a surge in human resources in the event of a public health emergency</td>
<td></td>
</tr>
<tr>
<td>Level 2</td>
<td>There is no mechanism to ensure a surge in human resources in the event of a public health emergency but there is a plan to work on a strategy to have it in the coming 3 years</td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td>There is a mechanism to ensure a surge in human resource in the event of a public health emergency, but it is not a structured operational instrument nor is it routinely updated</td>
<td></td>
</tr>
<tr>
<td>Level 4</td>
<td>There is a mechanism to ensure a surge in human resource in the event of a public health emergency which comprises a structured operational instrument that is routinely updated and participants are periodically trained</td>
<td></td>
</tr>
<tr>
<td>Level 5</td>
<td>As per level 4 and, in addition, this mechanism is tested to ensure its functioning</td>
<td></td>
</tr>
</tbody>
</table>
— Additional comments:
Your country cannot answer this question at the central state level due to governance and legislative frameworks? (yes)
— In this case, please indicate whether national level recommendations/guidelines are sent to regional authorities (yes/no)
— If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:
— If not, please explain

A.5.2 Please advise if regions within your Member State have agreements to receive/exchange human resource support in the health sector in case of need? (yes/no/other)
— If other, please describe:

N/A

6. Health emergency management

Management of health emergency response

<table>
<thead>
<tr>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.6.1 Regarding your Member State's prevention, preparedness, and response planning for public health emergencies, please indicate if your country uses:</td>
<td>N/A</td>
</tr>
<tr>
<td>— A generic [prevention, preparedness and response plan? (yes/no)</td>
<td></td>
</tr>
<tr>
<td>— Equivalent documents? (yes/no)</td>
<td></td>
</tr>
<tr>
<td>— If yes, please describe:</td>
<td></td>
</tr>
<tr>
<td>— Other, please describe:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>A.6.2 Regarding health emergency risk profiling and specific epidemic response plans, please indicate your Member State's level:</th>
<th>Indicator 1-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level</td>
<td>Level</td>
</tr>
<tr>
<td>There is no routine health emergency risk profiling for serious cross-border threats to health</td>
<td>1</td>
</tr>
<tr>
<td>There is routine health emergency risk profiling for serious cross-border threats to health</td>
<td>2</td>
</tr>
<tr>
<td>There is routine health emergency risk profiling for serious cross-border threats to health and this is undertaken at least once every 3 years</td>
<td>3</td>
</tr>
<tr>
<td>There is routine health emergency risk profiling for serious cross-border threats to health, this is undertaken at least once every 3 years and specific plan(s) to these threats have been developed</td>
<td>4</td>
</tr>
<tr>
<td>As per level 4 and, in addition, these plan(s) have been tested and revised as needed</td>
<td>5</td>
</tr>
</tbody>
</table>
— Additional comments:
— If level 2 or above, please advise if your Member State has a plan in place which addresses the availability and use (i.e. development, manufacturing, procurement, stockpiling, and distribution) of threat-specific medical countermeasures (MCMs) in relation to:

<table>
<thead>
<tr>
<th></th>
<th>Development (yes/no)</th>
<th>Manufacturing (yes/no)</th>
<th>Procurement (yes/no)</th>
<th>Stockpiling (yes/no)</th>
<th>Distribution (yes/no)</th>
<th>Other:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicable diseases with epidemic or pandemic potential</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemical and biological-related threats</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multi-drug resistant agents in a crisis situation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

— If yes to any of the above, please specify the agents of concern and related MCMs:

In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security

A.6.3 Regarding your Member State's specific epidemic response plan(s), please indicate which plan(s) have been developed and, where possible, provide link to the specific epidemic response plan(s):

N/A

A.6.4 Regarding the national level Incident Management System (IMS) or equivalent structure, please indicate your Member State's corresponding level:

<table>
<thead>
<tr>
<th>Level</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1-5</td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

— Additional comments:
### A.6.5 Regarding the implementation and evaluation of public health and social measures (PHSMs) and in the case of a public health emergency, please indicate your Member State's corresponding level:

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>There is no mechanism for decision-making for the implementation of PHSMs during a public health emergency</td>
</tr>
<tr>
<td>2</td>
<td>There is a mechanism in place to support decision-making for the implementation of PHSMs during a public health emergency, but the multi-disciplinary and cross-sectoral nature is not fully defined</td>
</tr>
<tr>
<td>3</td>
<td>There is a mechanism for the implementation of PHSMs during a public health emergency and the multi-disciplinary and cross-sectoral nature is fully defined</td>
</tr>
<tr>
<td>4</td>
<td>There is a mechanism for the implementation of PHSMs during a public health emergency, which is multi-disciplinary and cross-sectoral and includes provisions for evaluating the timeliness and effectiveness of Non Pharmaceutical Interventions (NPIs)</td>
</tr>
<tr>
<td>5</td>
<td>As per level 4 and, in addition, this mechanism has been tested in the last 3 years</td>
</tr>
</tbody>
</table>

---

### A.6.6 Regarding provisions for cross-border mutual aid in the preparedness and response plan or equivalent document(s), please indicate your Member State's corresponding level:

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Cannot answer question as Member State does not have a preparedness and response plan or equivalent document(s)</td>
</tr>
<tr>
<td>1</td>
<td>The preparedness and response plan or equivalent document(s) does not include cross-border mutual aid</td>
</tr>
<tr>
<td>2</td>
<td>The preparedness and response plan or equivalent document(s) includes cross-border mutual aid</td>
</tr>
<tr>
<td>3</td>
<td>The preparedness and response plan or equivalent document(s) includes cross-border mutual aid, and this has been tested with at least one Member State</td>
</tr>
<tr>
<td>4</td>
<td>The preparedness and response plan or equivalent document(s) includes cross-border mutual aid, and this has been tested with at least one Member State and updated where relevant</td>
</tr>
<tr>
<td>5</td>
<td>As per level 4 and, in addition, information related to the cross-border mutual aid as well as results of the testing have been shared within the Health Security Committee (HSC)</td>
</tr>
</tbody>
</table>

---

**Additional comments:**

- If level 2 or higher, please list the type of cross-border mutual aid included and with which Member State:

<table>
<thead>
<tr>
<th>Country/Grouping of Member State (please specify):</th>
<th>Type of cross-border mutual aid (please specify):</th>
</tr>
</thead>
</table>

- If level 3 or higher, please list the Member States and type of cross-border mutual aid that has been tested:

| Country/Grouping of countries (please specify): | Type of cross-border mutual aid (please specify): |
Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)
   — In this case, please indicate if national level recommendations/guidelines are sent to regional authorities (yes/no)
   — If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:
   — If not, please explain:

<table>
<thead>
<tr>
<th>A.6.7</th>
<th>Does your Member State’s preparedness and response plan or equivalent document(s) ensure specific national coordination mechanisms (1) for preparedness and response in case of an intentional release scenario? (yes/no/other)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>— If yes, is the governance structure for response – between the health sector and other critical sectors for the management of the response – clear and defined? (yes/no)</td>
</tr>
<tr>
<td></td>
<td>— If yes, please advise which sector leads the response:</td>
</tr>
<tr>
<td></td>
<td>— If other, please describe:</td>
</tr>
</tbody>
</table>

In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security

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**Emergency logistic and supply chain management**

<table>
<thead>
<tr>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical MCMs demand and supply</strong></td>
<td></td>
</tr>
<tr>
<td>A.6.8</td>
<td>Has your Member State identified critical MCMs for preparedness and response to serious cross-border threats to health? (yes/no/other)</td>
</tr>
<tr>
<td></td>
<td>— If yes, is there a list? (yes/no)</td>
</tr>
<tr>
<td></td>
<td>— If yes, please provide a hyperlink or the list itself. <em>(Please include a hyperlink of these MCMs categorized by specific threats, if applicable.)</em></td>
</tr>
<tr>
<td></td>
<td>— If other, please describe:</td>
</tr>
</tbody>
</table>

In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security

| A.6.9    | Regarding national policies or plans for the monitoring of supply and estimating demand of critical MCMs, please indicate your Member State’s corresponding level: |
|          | Indicator 1-5 |

There are no foreseen national policies or plans for the monitoring of supply and estimating demand of critical MCMs

---

(1) Here this refers to coordination between sectors such as security, justice, defence and civil protection that allows a specific mechanism for preparing and responding to an intentional release.
National policies or plans for the monitoring of supply and estimating demand of critical MCMs are under consideration

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>There are no foreseen provisions in the preparedness and response plan or equivalent document(s) or mechanisms to mitigate supply chain vulnerabilities of critical MCMs</td>
</tr>
<tr>
<td>2</td>
<td>Provisions in the preparedness and response plan or equivalent document(s) or mechanism to mitigate supply chain vulnerabilities of critical MCMs are under consideration</td>
</tr>
<tr>
<td>3</td>
<td>There are provisions in the preparedness and response plan or equivalent document(s) or mechanism to mitigate supply chain vulnerabilities of critical MCMs. However, these provisions are not yet implemented</td>
</tr>
<tr>
<td>4</td>
<td>There are provisions in the preparedness and response plan or equivalent document(s) or mechanism to mitigate supply chain vulnerabilities of critical MCMs. However, only some of them are implemented or under implementation</td>
</tr>
<tr>
<td>5</td>
<td>There are provisions in the preparedness and response plan or equivalent document(s) or mechanism to mitigate supply chain vulnerabilities of critical MCMs. These provisions are all implemented</td>
</tr>
</tbody>
</table>

— If yes, please provide details of how the national policies and plans monitor supply and estimate demand:
— Additional comments:
### Production of MCMs

**A.6.11**

Please indicate the critical MCMs referred in question A.6.8 that are currently produced in your Member State as follows:

<table>
<thead>
<tr>
<th>Type of production</th>
<th>Product information (if raw materials or components please also add information on the MCMs for which the products are needed)</th>
<th>Economic operator information including address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full production including raw materials/components/active pharmaceutical ingredients (APIs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finished products, please identify the MCM, the producer of the finished product and critical suppliers (including location) on which the production relies on</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Production of critical raw materials/components/APIs of MCMs: please identify the producer and relevant MCMs that need these materials for its manufacturing process.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— Additional comments:</td>
<td></td>
<td>In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security</td>
</tr>
</tbody>
</table>

**A.6.12**

Does your Member State have existing or planned arrangements to ensure that manufacturing of crisis-relevant MCMs can be scaled-up in a timely manner in times of crisis, for example through product or capacity reservation contracts or other mechanism? (yes/no/other)

- If yes, provide a list of specific MCMs and of type of arrangement:
  - In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security

### Strategic stockpiles (*')

**A.6.13**

Does your Member State have national strategic stockpiles of MCMs? (yes/no/other)

- If yes, please advise:
  - which MCMs are covered by this stockpile:
  - type of stockpile (virtual/physical):
  - size of the stock
  - If yes, please indicate how you manage your stockpile and if there are requirements for the deployment of the MCMs held within the stockpile:
  - If other, please describe:

- In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security

(*) Stock of pharmaceuticals and medical equipment held by Member States to save lives in crisis.
### 7. Health services provision

<table>
<thead>
<tr>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.7.1 Does your Member State's prevention, preparedness and response plan or equivalent document(s) provide for foresight assessment of the potential impact of a health emergency on continuity of healthcare services? (yes/no/other) — If other, please describe:</td>
<td>N/A</td>
</tr>
<tr>
<td>A.7.2 In the case of a public health emergency where there is an increase in demand for healthcare provision and potential decrease in healthcare staff, please indicate your Member State's corresponding level:</td>
<td>Indicator 1-5 or N/A</td>
</tr>
<tr>
<td></td>
<td>Hospital services</td>
</tr>
<tr>
<td>N/A</td>
<td>Member State cannot answer the question at central state level</td>
</tr>
<tr>
<td>Level 1</td>
<td>Your Member State does not have a dedicated operational plan for continuity of healthcare service</td>
</tr>
<tr>
<td>Level 2</td>
<td>Your Member State has a dedicated operational plan for continuity of healthcare service</td>
</tr>
<tr>
<td>Level 3</td>
<td>Your Member State has a dedicated operational plan for continuity of healthcare service, but it has not been tested in the last 3 years</td>
</tr>
<tr>
<td>Level 4</td>
<td>Your Member State has a dedicated operational plan for continuity of healthcare service, and it has been tested in the last 3 years</td>
</tr>
<tr>
<td>Level 5</td>
<td>As per level 4 and, in addition, recommendations from the testing have been implemented and the operational plan has been reviewed and revised</td>
</tr>
</tbody>
</table>

— If level 2 or above, please advise if this includes a mechanism for prioritisation/flexibility of health service provision to ensure sufficient continuity of care? (yes/no/other) — If yes, is this a permanent or an ad hoc mechanism? — If yes, has the mechanism been tested in the last 3 years and is there a provision for regular testing? — If no, please describe why: — If other, please describe:
### A.7.3
Please advise if your Member State ensures interdisciplinary crisis management coordination between all actors of the health care system (e.g., hospital services, rescue services, other public health services, outpatient primary care services, pharmacies, laboratory services, nursing/rehabilitation services)? (yes/no/other)
- If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:
- If not please explain

- Additional comments:
  Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)
- In this case, please indicate if national level recommendations/guidelines are sent to regional authorities (yes/no)
- If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:
- If no, please explain

### A.7.4
Regarding your Member State's business continuity plans for healthcare providers in case of a disruptive event, please indicate your country's corresponding level:

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Member State cannot answer the question [at central state level]</td>
</tr>
<tr>
<td>1</td>
<td>There is/are no national guidance/recommendations for business continuity plans (or equivalents such as contingency plans) to ensure the continuity of healthcare services</td>
</tr>
<tr>
<td>2</td>
<td>There is/are national guidance/recommendations for business continuity plans (or equivalents such as contingency plans) to ensure the continuity of healthcare services</td>
</tr>
<tr>
<td>3</td>
<td>There is/are national guidance/recommendations for business continuity plans (or equivalents such as contingency plans) to ensure the continuity of healthcare services and guidance/recommendations have been reviewed and revised in the past 3 years</td>
</tr>
<tr>
<td>4</td>
<td>There is/are national guidance/recommendations for business continuity plans (or equivalents such as contingency plans) to ensure the continuity of healthcare services and guidance/recommendations have been reviewed and revised in the past 3 years using a multi-sectoral approach</td>
</tr>
<tr>
<td>5</td>
<td>As per level 4 and, in addition, all healthcare services implement the national guidance/recommendations for business continuity plans</td>
</tr>
</tbody>
</table>

- Additional comments:
  Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)
- In this case, please indicate if national level recommendations/guidelines are sent to regional authorities (yes/no)
- If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:
- If no, please explain
| A.7.5 | Please advise if your Member State requires hospitals to have a hospital alert and response plan or equivalent document(s) (*) in order to be prepared for public health emergencies that may affect a hospital's capacity and function? (yes/no/other)  
— If yes, please advise if the plans include instructions on how to sustain patient care in the event of a shortage (medical personnel, medical stockpile, treatment facilities) or a technical breakdown (e.g., energy, water, IT):  
— If yes, please advise if these plans or equivalent document(s) are tested on a regular basis:  
— If other, please describe:  
Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)  
— In this case, please advise if national level recommendations/guidelines are sent to regional authorities (yes/no)  
— If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:  
— If not, please explain: | N/A |
| A.7.6 | Does your Member State have the capacity to map immediately available health services in the case of a public health emergency? (yes/no/other)  
— If other, please describe: | N/A |
| A.7.7 | Does your Member State’s prevention, preparedness and response plan or equivalent document(s) include agreements and/or provisions for the medical transfer of patients and/or mobile medical teams with other countries? (yes/no/other)  
— If yes, please list countries involved:  
— If other, please describe: | N/A |

(*) Such as the hospital response and operational plan
8. **Risk communication**

<table>
<thead>
<tr>
<th>A.8.1</th>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regarding risk communication, please indicate your country’s corresponding level:</td>
<td></td>
<td>1-5 or N/A</td>
</tr>
<tr>
<td>Member State cannot answer the question at central state level</td>
<td>level</td>
<td>N/A</td>
</tr>
<tr>
<td>There is no separate national risk communication plan or risk communication section as part of a preparedness and response plan or equivalent document(s) is not in place and mechanisms for public communication are on an ad-hoc basis and only includes conventional media focus</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>A separate national risk communication plan or section in a preparedness and response plan or equivalent document(s) is being developed and mechanisms for public communication are on an ad-hoc basis and includes conventional media with minimal online and social media focus</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>National risk communication is in place as a defined section within a preparedness and response plan or equivalent document(s) and includes conventional media and online and social media focus. In addition, there is analysis of target audiences and preferred communication channels to inform risk communication interventions</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>A separate, dedicated national risk communication plan is in place and includes conventional media and online and social media focus. In addition, there is analysis of target audiences and preferred communication channels to inform risk communication interventions. Moreover, there is proactive outreach through a variety of channels (e.g. hotline, complaint systems, social listening), online and offline media are monitored daily for feedback and insights and data are used to adjust and improve risk communication strategies</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>As per level 4 and, in addition, the national risk communication plan has been tested in the last 3 years</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>— Additional comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— In this case, please advise if national level recommendations/guidelines are sent to regional authorities (yes/no)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— If not, please explain:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A.8.2</td>
<td>Does your Member State’s risk communication plan include a dedicated step to coordinate in liaison with the HSC the risk and crisis communication related to a serious cross-border threat to health? (yes/no/other)</td>
<td>N/A</td>
</tr>
<tr>
<td>— If other, please describe:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Points of entry (PoEs) and border health

<table>
<thead>
<tr>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.9.1 Regarding your Member State’s nationally designated POEs public health emergency contingency plans, please indicate your Member State's corresponding level:</td>
<td>1-5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>The nationally designated POEs’ public health emergency contingency plan has no operational instruments to facilitate sharing of travel related health data/information and reporting to the national level</td>
</tr>
<tr>
<td>Level 2</td>
<td>The nationally designated POEs’ public health emergency contingency plan has operational instruments to facilitate sharing of travel related health data/information and reporting to the national level</td>
</tr>
<tr>
<td>Level 3</td>
<td>The nationally designated POEs’ public health emergency contingency plan has operational instruments to facilitate sharing of travel related health data/information and reporting to the national level and this has been tested in the last 3 years</td>
</tr>
<tr>
<td>Level 4</td>
<td>The nationally designated POEs’ public health emergency contingency plan has operational instruments to facilitate sharing of travel related health data/information and reporting to the national level and this has been tested in the last 3 years. In addition, the national level also has operational instruments to then facilitate the sharing of this information to other national sectors (†) and third parties e.g. WHO and Early Warning Response System (EWRS)</td>
</tr>
<tr>
<td>Level 5</td>
<td>As per level 4 and, in addition, this has been tested in the last 3 years</td>
</tr>
</tbody>
</table>

† This may include the health, civil protection and border control sectors for implementation, if needed, of dedicated measures such as quarantine, screening, NPIs, etc.
### A.9.2
Regarding the implementation and evaluation of international travel-related measures please advise:
- If the implementation of international-travel related measures has been tested in at least one nationally designated POE in the last 3 years (yes/no/other)
- If other, please describe:
- If there is a dedicated step to discuss with the HSC prior to implementation of international travel related measures? (yes/no/other)
- If other, please describe:

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

### 10. Zoonotic diseases and threats of environmental origin, including those due to the climate

<table>
<thead>
<tr>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.10.1 Regarding your country's implementation of One Health as referred to in Article 3(7) of the Regulation (EU) 2022/2371, please indicate your Member State’s corresponding level:</td>
<td>1-5 or N/A</td>
</tr>
<tr>
<td>Member State cannot answer question as Member State does not have a prevention, preparedness and response plan or equivalent document(s)</td>
<td>N/A</td>
</tr>
<tr>
<td>There is no One Health approach in the preparedness and response plan or equivalent document(s)</td>
<td>1</td>
</tr>
<tr>
<td>A One Health approach in the preparedness and response plan or equivalent document(s) is being developed but coordination of surveillance between animal health, public health, and environmental sectors and mechanisms for information sharing have not been established</td>
<td>2</td>
</tr>
<tr>
<td>A One Health approach in the preparedness and response plan or equivalent document(s) is in place and coordination of surveillance between animal health, public health, and environmental sectors and mechanisms for information sharing has been established</td>
<td>3</td>
</tr>
<tr>
<td>A One Health approach in the preparedness and response plan or equivalent document(s) is in place and coordination of surveillance between animal health, public health, and environmental sectors and mechanisms for information sharing has been established. In addition, this has been tested in the last 3 years</td>
<td>4</td>
</tr>
<tr>
<td>As per level 4 and, in addition, its implementation is monitored and revised on a regular basis</td>
<td>5</td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
<tr>
<td>If at level 2 or above:</td>
<td></td>
</tr>
<tr>
<td>please advise if there is in the preparedness and response plan or equivalent document(s), coordination of surveillance between two out of the three sectors (animal health, public health, and environmental) and mechanisms for information sharing? (yes/no/other)</td>
<td></td>
</tr>
<tr>
<td>If yes, please indicate the sectors involved:</td>
<td></td>
</tr>
<tr>
<td>If other, please describe:</td>
<td></td>
</tr>
</tbody>
</table>
— please indicate if you have developed any joint training programmes for One Health professionals (animal health, public health and environmental sectors) on zoonoses prevention, detection, and response? (yes/no/other)
  — If other, please describe:
— please indicate if you have developed a guideline on the procedures to follow for the public on finding sick and/or dead wild birds and other animals? (yes/no/other)
  — If other, please describe:
— please advise if there is a list of prioritised zoonotic diseases for surveillance purposes? (yes/no/other)
  — If yes, please list the prioritised zoonotic disease:
  — If other, please describe:

A.10.2
— Does your Member States integrate provisions about the actual or projected effects of climate change on zoonotic diseases (yes/no/other)
If yes, please elaborate on the potential effects and any dedicated provisions for health preparedness and response
If other, please describe:

A.10.3
— Does your Member State integrate provisions about the actual or projected impacts of extreme weather events (like heatwaves, floods or – indirectly – wildfires) on public health (yes/no/other)
If yes, please elaborate on the potential impacts and any dedicated provisions for health preparedness and response:
If other, please describe:

11. Chemical events

<table>
<thead>
<tr>
<th>A.11.1</th>
<th>Regarding the management of a health threat from chemical origin, please indicate your country's corresponding level:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level</td>
<td>Indicator 1-5 or N/A</td>
</tr>
<tr>
<td>Member State cannot answer the question at central state level</td>
<td>N/A</td>
</tr>
<tr>
<td>There is no separate chemical preparedness and response plan or equivalent document(s), nor is it included in the preparedness and response plan or equivalent document(s)</td>
<td>1</td>
</tr>
<tr>
<td>There is a chemical preparedness and response plan or equivalent document(s) and/or it is included in the preparedness and response plan or equivalent document(s)</td>
<td>2</td>
</tr>
<tr>
<td>The chemical preparedness and response plan or equivalent document(s) is in place and roles and responsibilities as well as major hazard sites are considered and identified</td>
<td>3</td>
</tr>
</tbody>
</table>
The chemical preparedness and response plan or equivalent document(s) is in place and roles and responsibilities as well as major hazard sites are considered and identified. In addition, the chemical response plan or chapter in the preparedness and response plan or equivalent document(s) has been tested through a simulation exercise in the last 3 years

| 4 |

As per level 4 and, in addition, recommendations from the test(s) have been implemented and corresponding plans reviewed and revised

| 5 |

— Additional comments:

Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)

— In this case, please advise if national level recommendations/guidelines are sent to regional authorities (yes/no)
  — If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:
  — If not, please explain

| 4 |

A.11.2 Does your Member State have procedures for a health risk assessment in case of a health threat from chemical origin? (yes/no/other)

— If yes, please describe:
— If no, please describe:
— If other, please describe:

| N/A |

A.11.3 Does your Member State have available guidelines on:

— Surveillance of chemical events and poisoning/intoxication? (yes/no/other)
  — If yes, please describe:
  — If no, please describe:
  — If other, please describe:

— Assessment of chemical events and poisoning/intoxication? (yes/no/other)
  — If yes, please describe:
  — If no, please describe:
  — If other, please describe:

— Management of chemical events and poisoning/intoxication? (yes/no/other)
  — If yes, please describe:
  — If no, please describe:
  — If other, please describe:

| N/A |
12. Antimicrobial resistance (AMR) and Healthcare associated infections (HAIs)

AMR

<table>
<thead>
<tr>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>National One Health Action Plans on AMR</strong></td>
<td>N/A</td>
</tr>
<tr>
<td>In order to avoid duplication of efforts, the Commission and the European Center For Disease Prevention and Control (ECDC) will be relying on inputs made to WHO Tracking Antimicrobial Resistance Country Self-Assessment Survey (TrACSS) (7). Thus, national reporting to TrACSS will be considered as part of the assessment under Article 8 of Regulation (EU) 2022/2371. Please upload in pdf format your Member State's most recent TrACSS submission to WHO. Regarding the national action plan (NAP) on AMR, have there been any updates since your country's last reporting to TrACSS?</td>
<td></td>
</tr>
<tr>
<td>— No</td>
<td></td>
</tr>
<tr>
<td>— Yes (please detail in the open text)</td>
<td></td>
</tr>
</tbody>
</table>

**Resources**

What resources are allocated to the implementation of the NAP on AMR?

<table>
<thead>
<tr>
<th>Level</th>
<th>No or very few resources (budget and human resources) are available for the implementation of the NAP.</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No specific resources are available, and implementation is entrusted to the resources (budget and human resources) of national/regional stakeholders (e.g. relevant competent authorities responsible for health, agriculture, environment, etc.) involved in the implementation of the NAP</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Non-earmarked funding can be accessed for AMR activities from national/regional funds and can be used for implementation of the NAP</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Specific earmarked funding for AMR activities is available from national/regional funds and is used for implementation of the NAP</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Implementation of the NAP is fully costed and funded through dedicated budget lines from national/regional funds.</td>
<td>5</td>
</tr>
</tbody>
</table>

— Additional comments:

(7) https://www.who.int/publications/m/item/tripartite-amr-country-self-assessment-survey—tracss-(6.0)-2022
### Monitoring and evaluation of progress

Does your Member State have national indicators or targets to measure national progress on AMR (including antimicrobial consumption/use) and/or HAIs? Please, provide a description of the indicators/targets or a hyperlink to where they can be found in the comments section.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>No, there are neither national indicators, nor national targets to measure progress on AMR (including antimicrobial consumption/use) and/or HAIs in the country</td>
<td>1</td>
</tr>
<tr>
<td>There are plans to set up national indicators and/or national targets, and these will be in place in the near future</td>
<td>2</td>
</tr>
<tr>
<td>There are national indicators, similar to the globally available indicators (e.g. Sustainable Development Goals and WHO, etc.), but without targets</td>
<td>3</td>
</tr>
<tr>
<td>Yes, there are national indicators that cover AMR (including antimicrobial consumption/use) and/or HAIs with concrete national targets to be reached by a certain timeframe, and progress is reviewed regularly but this is not linked to the objectives of the NAP on AMR</td>
<td>4</td>
</tr>
<tr>
<td>Yes, there are national indicators and national targets that cover both AMR (including antimicrobial consumption/use) and HAIs, which are linked to the NAP on AMR, and progress is reviewed regularly</td>
<td>5</td>
</tr>
</tbody>
</table>

— Additional comments:

### Main challenges

Currently, what are the biggest challenges that your Member State faces in addressing AMR? Please choose three challenges, then rank them from 3 – the most important to 1 – the least important):

- Implementation of prevention and control measures in routine practice
- Budget limitations
- Ensuring One-health coordination across the different sectors
- Absence of or insufficient legal framework
- Lack of human resources
- Infrastructure limitations (e.g. lack of single rooms, old hospital buildings, etc.)
- Insufficient awareness among stakeholders such as healthcare professionals, e.g. doctors, nurses, pharmacists, etc., animal keepers and farmers and the general public
- Limited access to certain antimicrobials, e.g. narrow-spectrum antibiotics and novel antimicrobials

— Additional comments:
**Prevention of priority multidrug-resistant organisms (MDROs)**

Regarding the prevention of multidrug resistant organism, please indicate your Member State’s level below.

Note: the below levels have been adapted based on the wording of the Joint External Evaluation (JEE) (1), question P4.3 referring to the prevention of multidrug resistant organism.

The MDROs considered under this indicator are listed below, as they are considered critical at Union level. If a Member State considers that its replies cannot cover all MDROs, this can be specified in the comments section below.

<table>
<thead>
<tr>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
</tbody>
</table>

**Indicator 1-5**

<table>
<thead>
<tr>
<th>These MDROs (phenotypes and genotypes) have not been identified as priority by national authorities, and they are not detected</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>National strategy or guidance for MDRO containment exists and includes colonization screening for priority MDROs</td>
</tr>
<tr>
<td>(phenotypes and genotypes) that have been identified by national authorities. Some health facilities can detect</td>
</tr>
<tr>
<td>priority MDROs based on laboratory data.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Selected health facilities have access to MDRO phenotype confirmation. Facilities notify national levels when</td>
</tr>
<tr>
<td>priority MDROs are detected</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>All health facilities have access to MDRO phenotype confirmation. Facilities notify national levels when</td>
</tr>
<tr>
<td>priority MDROs are detected in a timely manner. Responses are tracked and supported at the national level</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Functional system is in place to rapidly communicate and track the detection, confirmation and notification of</td>
</tr>
<tr>
<td>novel or priority MDROs within hospitals and to national levels. All hospitals are able to launch response</td>
</tr>
<tr>
<td>activities to priority MDROs in a timely manner. Facilities regularly communicate pertinent MDRO data to local</td>
</tr>
<tr>
<td>referral networks to inform prevention/containment efforts</td>
</tr>
</tbody>
</table>

— Additional comments:

**Priority MDROs in hospitals and cross-border patient transfers**

Regarding national activities related to screening patients for MDRO carriage at hospital admission, as a means to reduce the spread of priority MDROs among hospitals, please indicate your Member States’ corresponding level below.

Note: the MDROs considered under the indicator are listed below, as they are considered critical at Union level.

If a Member State considers that its replies cannot cover all MDROs, this can be specified in the comments section below.

<table>
<thead>
<tr>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

**Indicator 1-5**

<table>
<thead>
<tr>
<th>There are no national procedures and protocols in place for screening patients for MDRO carriage at hospital admission</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>There are national procedures and protocols in place for screening for MDRO carriage only for patients being</td>
</tr>
<tr>
<td>directly transferred from a hospital in another country</td>
</tr>
</tbody>
</table>

(1) Joint External Evaluation tool developed by the World Health Organization third edition, 2022
There are national procedures and protocols in place for screening for MDRO carriage only for patients being directly transferred from a hospital in another country or who have recently been hospitalised in another country

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>National policy and regulations promoting appropriate antimicrobial use/antimicrobial stewardship activities are developed for the community and health care settings</td>
</tr>
</tbody>
</table>

- Additional comments:
  - Yes, in case of cross-border transfer as well as transfer to a hospital (or healthcare facility) within the country
  - Yes, only in case of cross-border transfer
  - No (please explain why)
  - If other, please describe:

**Antimicrobial stewardship/prudent use of antimicrobials in primary and secondary care:**

Regarding the optimal use of antimicrobial medicines in human health, please indicate your Member State’s corresponding level below.

Note: the below indicator levels have been adapted based on the wording of the Joint External Evaluation (JEE) (Ibid), question P4.4 referring to the optimal use of antimicrobial medicines in human health

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No or weak national policy and/or regulations on appropriate use, availability, quality and use of antimicrobials in human health</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>National policy and regulations promoting appropriate antimicrobial use/antimicrobial stewardship activities are developed for the community and health care settings</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Guidelines for appropriate use of antimicrobials are available and antimicrobial stewardship programmes are established in some health care facilities. The latest WHO “Access, Watch and Reserve” (AWaRe) classification of antibiotics is adopted in the national essential medicines list</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Guidelines and practices to enable appropriate use of antimicrobials are implemented in health care facilities nationwide. Functioning AMR stewardship programs in all major health care facilities. Monitoring of antibiotic consumption is being performed and based on the latest AWaRe classification of antibiotics</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Guidelines on optimizing antibiotic use are implemented for all major syndromes and data on use is systematically fed back to prescribers. The AWaRe classification of antibiotics is incorporated into antimicrobial stewardship strategies. Robust national monitoring of antibiotic consumption is being performed</td>
</tr>
</tbody>
</table>

— Additional comments:

(Ibid)
**AMR surveillance**

Regarding the surveillance of AMR, please indicate your Member State’s corresponding level below.

Note: the below indicator levels have been adapted based on the wording of the Joint External Evaluation (JEE) (10), question P4.2 referring to the surveillance of AMR

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No or limited capacity for generating, collating, and reporting data (antibiotic susceptibility testing and accompanying clinical and epidemiological data)</td>
</tr>
<tr>
<td>2</td>
<td>AMR data are collated locally for common pathogens in hospitalized and community patients, but data collection may not use a standard approach and lacks national coordination and/or quality management</td>
</tr>
<tr>
<td>3</td>
<td>AMR data are collated nationally for common pathogens, but national coordination and standardization are lacking</td>
</tr>
<tr>
<td>4</td>
<td>There is a standardized national AMR surveillance system collecting data on common pathogens in hospitalized and community patients, with an established network of surveillance sites, designated national reference laboratory for AMR and a national coordinating centre producing reports on AMR</td>
</tr>
<tr>
<td>5</td>
<td>In addition to the above, the national AMR surveillance system’s data is analysed, interpreted and reported together with antimicrobial consumption and/or use data for human health, and analysis of similar data across sectors (human and animal health and agriculture) is attempted</td>
</tr>
</tbody>
</table>

---

Additional comments:

---

(10) Ibid
### Healthcare associated infections (HAIs)

<table>
<thead>
<tr>
<th>B.12.9</th>
<th><strong>Main challenges</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Question</td>
<td>Currently, what are the biggest challenges that your country faces in addressing healthcare associated infections (HAIs)? Please choose three challenges, then rank them from 3 – the most important to 1 - the least important):</td>
</tr>
<tr>
<td>Indicator</td>
<td>N/A</td>
</tr>
<tr>
<td>Implementation of prevention and control measures in routine practice</td>
<td></td>
</tr>
<tr>
<td>Budget limitations</td>
<td></td>
</tr>
<tr>
<td>Absence of or insufficient legal framework</td>
<td></td>
</tr>
<tr>
<td>Lack of human resources</td>
<td></td>
</tr>
<tr>
<td>Infrastructure limitations (e.g. lack of single rooms, old hospital buildings, etc.)</td>
<td></td>
</tr>
<tr>
<td>Insufficient awareness among healthcare professionals, e.g. doctors, nurses, pharmacists, etc. and the general public</td>
<td></td>
</tr>
<tr>
<td>Limited access to certain antimicrobials, e.g. narrow-spectrum antibiotics and novel antimicrobials</td>
<td></td>
</tr>
<tr>
<td>— Additional comments:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B.12.10</th>
<th><strong>HAI surveillance</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question</strong></td>
<td>Regarding the surveillance of HAI, please indicate your Member State’s corresponding level below. Note: the below indicator levels have been adapted based on the wording of the Joint External Evaluation (JEE) (11), question R4.2 referring to the surveillance of HAI</td>
</tr>
<tr>
<td><strong>Indicator</strong></td>
<td>1-5</td>
</tr>
<tr>
<td><strong>Level</strong></td>
<td></td>
</tr>
<tr>
<td>No national HAI surveillance programme or national strategic plan for HAI surveillance, including pathogens that are antimicrobial resistant and/or prone to outbreaks is available or under development</td>
<td>1</td>
</tr>
<tr>
<td>A national strategic plan for HAI surveillance (including pathogens that are antimicrobial resistant and/or prone to outbreaks) is available but not implemented</td>
<td>2</td>
</tr>
<tr>
<td>A national strategic plan for HAI surveillance (including pathogens that are antimicrobial resistant and/or prone to outbreaks) is available and implemented through a national programme and system for data collection, analysis, and feedback. Selected secondary and tertiary health care facilities are conducting HAI surveillance (as specified above) and provide timely and regular feedback to senior management and health workers</td>
<td>3</td>
</tr>
</tbody>
</table>

(11) Ibid
A national strategic plan for HAI surveillance (including pathogens that are antimicrobial resistant and/or prone to outbreaks) is available and implemented nationwide in all secondary and tertiary health care facilities through a national system according to the WHO recommendations on Infection Prevention and Control (IPC) core components. Regular reports are available for providing feedback.

A national strategic plan for HAI surveillance (including pathogens that are antimicrobial resistant and/or prone to outbreaks) are available and implemented nationwide in all secondary and tertiary health care facilities through a national programme and system according to the WHO recommendations on IPC core components. Data are shared and being used continuously and in a timely manner to inform prevention efforts. The quality and impact of the system are regularly evaluated, and improvement actions are taken accordingly.

— Additional comments:

<table>
<thead>
<tr>
<th>13. Union level coordination and support functions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question</strong></td>
</tr>
<tr>
<td>B.13.1 Do your Member State's legal instruments for health response to a public health emergency incorporate coordination and cooperation at national-Union interface during a public health emergency? (yes/no/other)</td>
</tr>
<tr>
<td>— If other, please describe:</td>
</tr>
<tr>
<td>N/A</td>
</tr>
<tr>
<td>B.13.2 During a health emergency, is your Member State's HSC representative incorporated into national level coordination structures, notably to support the flow of information between your Member State and the HSC? (yes/no/other)</td>
</tr>
<tr>
<td>— If no, what is the role of the HSC representative in the national emergency response and if they do not act as the liaison with the HSC during public health emergencies, who does?</td>
</tr>
<tr>
<td>— If other, please describe:</td>
</tr>
<tr>
<td>N/A</td>
</tr>
<tr>
<td>B.13.3 Is your Member State's Public Health Emergency Operation Center or IMS interoperable with the Early Warning and Response System module for incident and/or crisis management? (yes/no/other)</td>
</tr>
<tr>
<td>— If other, please describe:</td>
</tr>
<tr>
<td>N/A</td>
</tr>
<tr>
<td>B.13.4 Over the last 3 years, has your Member State incorporated or factored in opinions and guidance from HSC for the prevention and control of serious cross-border threats to health? (yes/no/other/partial)</td>
</tr>
<tr>
<td>— If yes, please describe how</td>
</tr>
<tr>
<td>— If no, why</td>
</tr>
<tr>
<td>— If other, please describe:</td>
</tr>
<tr>
<td>— If partial, please describe:</td>
</tr>
<tr>
<td>N/A</td>
</tr>
<tr>
<td>B.13.5 Over the last 3 years, has your Member State incorporated or factored in Commission's recommendations on common temporary public health measures? (yes/no/other/partial)</td>
</tr>
<tr>
<td>— If yes, please describe how</td>
</tr>
<tr>
<td>— If no, why</td>
</tr>
<tr>
<td>— If other, please describe:</td>
</tr>
<tr>
<td>— If partial, please describe:</td>
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<tr>
<td>N/A</td>
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<tr>
<td>B.13.6</td>
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</table>

<table>
<thead>
<tr>
<th>B.13.7</th>
<th>Please indicate if the following support roles, functions and instruments of the Commission and relevant Union agencies and bodies are considered in your Member State's preparedness and response planning process:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medical Evacuation Support via EWRS</td>
</tr>
<tr>
<td></td>
<td>European External Action Service (EEAS) for consular and repatriation support</td>
</tr>
<tr>
<td></td>
<td>Directorate-General for European Civil Protection and Humanitarian Aid Operations (DG ECHO) and its support capacities, including those in the ResEU reserve as well as the union Civil Protection Mechanism Prevention and Preparedness Projects (e.g. tenders and grants on developing cross-border health projects)</td>
</tr>
<tr>
<td></td>
<td>Directorate-General for Health Emergency and Response to support to medical countermeasures research and development, manufacturing, production, stockpiling and deployment (DG HERA)</td>
</tr>
<tr>
<td></td>
<td>DG HERA's Emergency Office</td>
</tr>
<tr>
<td></td>
<td>Instruments for the mobilisation of EU funding for rapid research</td>
</tr>
<tr>
<td></td>
<td>Risk Assessment of the ECDC</td>
</tr>
<tr>
<td></td>
<td>Risk Assessment of the European Medicines Agency (EMA)</td>
</tr>
<tr>
<td></td>
<td>Risk Assessment of the European Food Safety Authority (EFSA)</td>
</tr>
<tr>
<td></td>
<td>Risk Assessment of the European Chemicals Agency (ECHA)</td>
</tr>
<tr>
<td></td>
<td>Risk Assessment of the European Environment Agency (EEA)</td>
</tr>
<tr>
<td></td>
<td>Risk Assessment of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)</td>
</tr>
<tr>
<td></td>
<td>Risk assessments carried out in cooperation with the European Union Agency for Law Enforcement Cooperation (Europol) where the threat is emanating from terrorist or criminal activity</td>
</tr>
<tr>
<td></td>
<td>Technical reports and guidance of the ECDC</td>
</tr>
<tr>
<td></td>
<td>Risk Assessment of the European Agency for occupational safety and health</td>
</tr>
<tr>
<td></td>
<td>ECDC's ad-hoc support in preparedness and outbreak response (e.g. EU Health Task Force)</td>
</tr>
<tr>
<td></td>
<td>EU reference laboratories</td>
</tr>
<tr>
<td></td>
<td>Other, please specify:</td>
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<tr>
<td></td>
<td>— Additional comments:</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
</tr>
</tbody>
</table>
— Does your Member State take into account the Union prevention, preparedness and response plan established in accordance with Article 5 of Regulation (EU) 2022/2371, by including also cross-border interregional preparedness elements into your Member’s State preparedness and response plan or equivalent document(s)? If yes, please describe how
— If no, why
— If other, please describe:

N/A

14. Research development and evaluations to inform and accelerate emergency preparedness

<table>
<thead>
<tr>
<th>B.14.1</th>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Regarding the role of research in the preparedness and response plan or equivalent document(s), please indicate your Member State’s corresponding level:</td>
<td>1-5 or N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Member State cannot answer question as the Member State does not have preparedness and response plan or equivalent document(s)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>A preparedness and response plan or equivalent document(s) is in place, but it does not include a strategy for emergency research and innovation</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>A preparedness and response plan or equivalent document(s) that includes a strategy for emergency research and innovation is in place, but no funding has been set aside for conducting research during health emergencies</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>A preparedness and response plan or equivalent document(s) that includes a strategy for emergency research and innovation is in place, and funding has been set aside for conducting research during health emergencies</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>A preparedness and response plan or equivalent document(s) that includes a strategy for emergency research and innovation is in place, funds have been set aside for conducting research during health emergencies and a process is in place for their swift mobilisation</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>A preparedness and response plan or equivalent document(s) that includes a strategy for emergency research and innovation is in place, funds have been set aside for health emergencies, a process is in place for their swift mobilisation and research and innovation capacities have been strengthened</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>— If level 2 or above: does the strategy for emergency research and innovation (in the preparedness and response plan or equivalent document(s)) include a process to link public health needs with research priorities and needs? (yes/no/other)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>— If yes, please describe this process</td>
<td></td>
</tr>
<tr>
<td></td>
<td>— If other, please describe:</td>
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<tr>
<td></td>
<td>— Additional comments:</td>
<td></td>
</tr>
</tbody>
</table>
B.14.2 | Is your Member State part of a i) national, ii) Union-wide or iii) international network of clinical trial sites or cohorts to promote the participation in large-scale trials that have more chance to reach meaningful results in limited timeframes? (yes/no/other)  
| — If yes, please specify (name and level)  
<table>
<thead>
<tr>
<th>National</th>
<th>Union-wide</th>
<th>International</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>International network of cohorts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— If other, please describe:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B.14.3 | Does your Member State have processes in place for the establishment of harmonised protocols and data collection within these networks? (yes/no/other)  
| — If yes, please specify which ones:  
| — If other, please describe: |

B.14.4 | Does your Member State have procedures in place for rapid site accreditation and for expedited coordinated (between the national competent authorities and ethics committees) clinical trial assessment and authorisation in the case of a public health emergency? (yes/no/other)  
| — If yes, please specify, including cooperation with ethics committees:  
| — If other, please describe: |

B.14.5 | Please advise if your Member State has an approach to operational (e.g. in action) research which includes:  
| Research preparedness, including predesigned protocols, partnerships, roles, and responsibilities in place in advance of a health emergency |
| In case of a public health emergency, operational instruments in place so needed resources are available with means for rapid funding |
| In case of a public health emergency, operational instruments in place for rapid ethical clearance and data sharing |
| — Additional comments: |
### 15. Recovery elements

<table>
<thead>
<tr>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.15.1 Regarding your Member State's recovery plan or the recovery section in your prevention preparedness and response plan or equivalent document(s), please indicate your Member State's level:</td>
<td>Level</td>
</tr>
<tr>
<td>No recovery plan or recovery section in the preparedness and response plan or equivalent document(s) available</td>
<td>1</td>
</tr>
<tr>
<td>Recovery plan or section available</td>
<td>2</td>
</tr>
<tr>
<td>Recovery plan or section includes or links to a process of capturing lessons using After Actions Reviews (AARs) or Inter Action Reviews (IARs), and embedding them in practice through an action plan</td>
<td>3</td>
</tr>
<tr>
<td>Recovery plan includes or links to a process of capturing lessons using AARs or IARs and embedding them in practice under an overarching framework such as the National Action Planning for Health Security (NAPHS) or equivalent. This process is implemented and regularly monitored at national level</td>
<td>4</td>
</tr>
<tr>
<td>Recovery includes or links to a process of capturing lessons using AARs or IARs and embedding them in practice through NAPHS or equivalent. This process is implemented and regularly monitored at national and regional (sub-national) level</td>
<td>5</td>
</tr>
<tr>
<td>— Additional comments:</td>
<td></td>
</tr>
</tbody>
</table>

### 16. Actions taken to improve gaps found in the implementation of prevention, preparedness and response plans

<table>
<thead>
<tr>
<th>Question</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.16.1 Please upload your Member State's most recent IHR State Party Annual Report as submitted by the National IHR Focal Point to WHO in pdf format</td>
<td>Indicators IHR</td>
</tr>
<tr>
<td>B.16.2 Please indicate whether your Member State has used any of the following complementary mechanisms to assess the implementation of IHR capacities and prevention, preparedness, and response planning in the last 3 years: Tick where appropriate:</td>
<td>N/A</td>
</tr>
<tr>
<td>Completed in the last 3 years? (Yes/No) (If published, please provide link)</td>
<td></td>
</tr>
<tr>
<td>Joint External Evaluation</td>
<td></td>
</tr>
<tr>
<td>In-action reviews</td>
<td></td>
</tr>
<tr>
<td>After action reviews</td>
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<tr>
<td>SimEx</td>
<td></td>
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<tr>
<td>Joint Assessment and Detection of Events</td>
<td></td>
</tr>
<tr>
<td>Other: please specify</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B.16.3</th>
<th>Please indicate your Member State’s corresponding level regarding the NAPHS proposed by WHO or equivalent system:</th>
<th>Indicator 1-5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>level</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NAPHS or equivalent system is not developed or under development</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>NAPHS or equivalent system developed but not yet whole of government and one health for all hazards approach aligned</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>NAPHS or equivalent system is developed and aligned with whole of government and one health for all hazards approach including defined roles, responsibilities, and collaborative mechanism</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>NAPHS or equivalent system is developed and aligned with whole of government and one health for all hazards approach including definitions of roles, responsibilities, and collaborative mechanisms. In addition, the National Action Planning for Health Security or equivalent system has been costed</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>As per level 4 and, in addition, at least one activity planned is being implemented</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Additional comments:</td>
</tr>
<tr>
<td></td>
<td>— If level 1: please advise if your Member State is planning to start a National Action Plan for Health Security or equivalent system:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>— All levels: if your Member State does not use the National Action Planning for Health Security, please describe the equivalent system:</td>
<td></td>
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<td>---</td>
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<td></td>
</tr>
<tr>
<td>C.1</td>
<td>Please describe your ideas on what further actions the Commission could undertake to support the implementation of prevention, preparedness, response, and recovery planning to serious cross-border threats to health:</td>
<td></td>
</tr>
<tr>
<td>C.2</td>
<td>Please provide any comments or clarifications in relation to the questions above and, if considered necessary, list any relevant activities that your country has conducted or provide additional information which is relevant to the topic of this questionnaire:</td>
<td></td>
</tr>
</tbody>
</table>
COMMISSION DECISION (EU) 2023/1809
of 14 September 2023
establishing the EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups
(notified under document C(2023) 6024)
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (1), and in particular Article 8(2) thereof,

After consulting the European Union Ecolabelling Board,

Whereas:

(1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to those products with a reduced environmental impact during their entire life cycle.

(2) Regulation (EC) No 66/2010 provides that specific EU Ecolabel criteria are to be established according to product groups.

(3) Commission Decision 2014/763/EU (2) established EU Ecolabel criteria and related assessment and verification requirements for the product group ‘absorbent hygiene products’. The period of validity of those criteria and requirements has been extended to 31 December 2023 by Commission Decision (EU) 2018/1590 (3).

(4) In order to better reflect best practice in the market for the product group and to take account of policy developments, potential future windows of opportunity for increased uptake and the market’s demand for sustainable products, it is appropriate to establish a new set of criteria for absorbent hygiene products. As a sustainable alternative with a potential growing market, it is also appropriate to establish a set of criteria for reusable menstrual cups.

(5) The EU Ecolabel Fitness Check Report (4) of 30 June 2017, reviewing the implementation of Regulation (EC) No 66/2010, concluded on the need to develop a more strategic approach for the EU Ecolabel, including the bundling of closely related product groups where appropriate.

(6) In line with those conclusions and after consulting the EU Ecolabelling Board, it is appropriate to bundle the product group ‘absorbent hygiene products’ with the product group ‘reusable menstrual cups’ in the same Decision, as the two product groups fulfil the same function.

In line with Regulation (EC) No 66/2010, the EU Ecolabel shall not be awarded to any type of medical device, including those defined in Regulation (EU) 2017/745 of the European Parliament and of the Council (\(^1\)).

The new Circular Economy Action Plan for a cleaner and more competitive Europe (\(^2\)) adopted on 11 March 2020 stipulates that the durability, recyclability and recycled content requirements are to be more systematically included in the EU Ecolabel criteria.

The revised EU Ecolabel criteria for absorbent hygiene products and reusable menstrual cups should aim to promote products that have limited environmental impact along their life cycle, and that are produced using material-efficient and energy-efficient processes. In particular, the revised EU Ecolabel criteria promote products that have limited impacts in terms of emissions to water and to air during production, that use raw materials sourced from sustainably managed forests, and that fulfil strict requirements on harmful substances. Moreover, in order to contribute towards the transition to a more circular economy, the criteria promote the use of paper and/or cardboard packaging, when possible, as an alternative to plastic packaging, and promote packaging with recycled content which can be easily recycled.

Reusable products made of textiles are appearing on the market as an alternative to single-use products. The revised EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups do not apply to these reusable textile alternatives, whose environmental hotspots and ecological criteria are planned to be specifically investigated for the purposes of the revision of EU Ecolabel criteria for textile products established by Commission Decision 2014/350/EU (\(^3\)).

The new criteria and related assessment and verification requirements should remain valid until 31 December 2029, taking into account the innovation cycle for the product groups.

For reasons of legal certainty, Decision 2014/763/EU should be repealed.

A transitional period should be available to producers whose products have been awarded the EU Ecolabel for absorbent hygiene products on the basis of the criteria set out in Decision 2014/763/EU, so that they have sufficient time to adapt their products to comply with the new criteria and requirements. For a limited period after adoption of this Decision, producers of absorbent hygiene products should be allowed to submit applications based either on the criteria established by Decision 2014/763/EU or on the new criteria established by this Decision. It should also be allowed to use EU Ecolabels awarded in accordance with the criteria established by Decision 2014/763/EU for a transitional period.

The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010.

HAS ADOPTED THIS DECISION:

**Article 1**

1. The product group ‘absorbent hygiene products’ shall comprise any article whose function is to absorb and retain human fluids such as urine, faeces, sweat, menstrual fluid or milk, excluding textile products. The product group ‘absorbent hygiene products’ shall include products for both private and professional use.

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2. The product group ‘absorbent hygiene products’ shall not include products falling under the scope of Regulation (EU) 2017/745.

Article 2

1. The product group ‘reusable menstrual cups’ shall comprise reusable flexible cups or barriers worn inside the body whose function is to retain and collect menstrual fluid, and which are made of silicone or other elastomers.

2. The product group ‘reusable menstrual cups’ shall not include products falling under the scope of Regulation (EU) 2017/745.

Article 3

1. In order for a product to be awarded the EU Ecolabel under Regulation (EC) No 66/2010 for the product group ‘absorbent hygiene products’, it shall fall within the definition of that product group as specified in Article 1 of this Decision, and shall comply with the respective criteria and related assessment and verification requirements set out in Annex I to this Decision.

2. In order for a product to be awarded the EU Ecolabel under Regulation (EC) No 66/2010 for the product group ‘reusable menstrual cups’, it shall fall within the definition of that product group as specified in Article 2 of this Decision and shall comply with the respective criteria and related assessment and verification requirements set out in Annex II to this Decision.

Article 4

The EU Ecolabel criteria for the product group ‘absorbent hygiene products’ and for the product group ‘reusable menstrual cups’ and the related assessment and verification requirements shall be valid until 31 December 2029.

Article 5

1. For administrative purposes, the code number assigned to the product group ‘absorbent hygiene products’ shall be ‘047’.

2. For administrative purposes, the code number assigned to the product group ‘reusable menstrual cups’ shall be ‘055’.

Article 6

Decision 2014/763/EU is repealed.

Article 7

1. Applications for the EU Ecolabel for the product group ‘absorbent hygiene products’, as defined in Decision 2014/763/EU, submitted before the date of application of this Decision shall be evaluated in accordance with the criteria set out in Decision 2014/763/EU.

2. Applications for the EU Ecolabel for products falling within the product group ‘absorbent hygiene products’ submitted on or within two months from the date of application of this Decision may be based, by the applicant, on, and evaluated in accordance with, either the criteria set out in this Decision, or on the criteria set out in Decision 2014/763/EU.

3. EU Ecolabel licences awarded on the basis of an application evaluated in accordance with the criteria set out in Decision 2014/763/EU may be used for 12 months from the date of application of this Decision.
Article 8

This Decision is addressed to the Member States.

It shall apply from 21 September 2023.

Done at Brussels, 14 September 2023.

For the Commission
Virginijus SINKEVIČIUS
Member of the Commission
EU Ecolabel criteria for awarding the EU Ecolabel to absorbent hygiene products

The EU Ecolabel criteria target the best absorbent hygiene products on the market, in terms of environmental performance. The criteria focus on the main environmental impacts associated with the life cycle of these products and promote circular economy aspects.

Assessment and verification requirements

For the EU Ecolabel to be awarded to a specific product, the product shall comply with each requirement. The applicant shall provide a written confirmation stating that all the criteria are fulfilled.

Specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or their supplier(s) as appropriate.

Competent bodies shall preferentially recognise attestations that are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories, and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes, and services.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

Changes in suppliers and production sites pertaining to products to which the EU Ecolabel has been awarded shall be notified to competent bodies, together with supporting information to enable verification of continued compliance with the criteria.

As pre-requisite, the product shall meet all respective legal requirements of the country or countries in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.

The following information shall be provided together with the application for the EU Ecolabel:

(a) a description of the product, together with the weight of the individual product units and the total weight of the product;

(b) a description of the sales packaging, together with its total weight, if applicable;

(c) a description of the grouped packaging, together with its total weight, if applicable;

(d) a description of the separate components, together with their individual weight;

(e) the components, materials and all substances used in the product with their respective weights and, whenever applicable, their respective CAS numbers.

For the purposes of this Annex, the following definitions shall apply:

(1) ‘additives’ means substances added to components, materials or the final product in order to improve or preserve some of its characteristics;

(2) ‘biobased plastic’ means a plastic manufactured from biobased raw materials as feedstock for its production. While conventional plastics are made from fossil resources (oil and natural gas), biobased plastics are made from biomass. The biomass currently originates mainly from plants grown specifically to be used as feedstock to substitute fossil resources, such as sugarcane, cereal crops, oil crops or non-food sources like wood. Other sources are organic waste and by-products, such as used cooking oil, bagasse and tall oil. Plastics can be fully or partially made from biobased feedstock. Biobased plastics can be both biodegradable and non-biodegradable;

(3) ‘cellulose pulp’ means a fibrous material mainly composed of cellulose and obtained from the treatment of lignocellulosic materials with one or more aqueous solutions of pulping and/or bleaching chemicals;
(4) ‘component’ means one or several materials and chemical products that together fulfil a desirable function in the absorbent hygiene product, such as an absorbent core, adhesives, or an outer barrier film;

(5) ‘composite packaging’ means a unit of packaging made of two or more different materials, excluding materials used for labels, closures and sealing, which cannot be separated manually and therefore form a single integral unit;

(6) ‘grouped packaging’, also known as secondary packaging, means packaging conceived so as to constitute a grouping of a certain number of sales units at the point of sale whether the latter is sold as such to the end user or it serves only as a means to replenish the shelves at the point of sale or create a stock-keeping or distribution unit, and which can be removed from the product without affecting its characteristics;

(7) ‘impurities’ means residuals, pollutants, contaminants etc. from production, including the production of raw materials, that remain in the raw material/ingredient and/or in the chemical product (used in the final product and any component therein) in concentrations less than 100 ppm (0,0100 % w/w, 100 mg/kg);

(8) ‘ingoing substance’ means all substances included in the chemical product (used in the final product and any component therein), including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances in stabilized manufacturing conditions (e.g. formaldehyde and arylamine) are also considered as ingoing substances;

(9) ‘man-made cellulose fibres’, also known as regenerated fibres, means fibres produced from the raw material cellulose which include viscose, modal, lyocell, cupro and triacetate;

(10) ‘materials’ mean the materials constituting different components of an absorbent hygiene product, such as fluff pulp, cotton or polypropylene (PP);

(11) ‘packaging’ means items of any materials that are intended to be used for the containment, protection, handling, delivery or presentation of products and that can be differentiated into packaging formats based on their function, material and design, including:

(a) items that are necessary to contain, support or preserve the product throughout its lifetime without being an integral part of the product which is intended to be used, consumed or disposed of together with the product;

(b) components of, and ancillary elements to, an item referred to in point (a) that are integrated into the item;

(c) ancillary elements to an item referred to in point (a) that are hung directly on, or attached to, the product and that perform a packaging function without being an integral part of the product which is intended to be used, consumed or disposed of together with the product; etc.;

(12) ‘plastic materials’, also referred to as ‘plastics’, means polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (1), to which additives or other substances may have been added, and which are capable of functioning as main structural components of final products and/or packaging, with the exception of natural polymers that have not been chemically modified;

(13) ‘polymer’ means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition, a ‘monomer unit’ means the reacted form of a monomer substance in a polymer, as defined in Regulation (EC) No 1907/2006;

(14) ‘product unit’ means the smallest item that can be used by the consumer and that fulfils the product’s function;

(15) ‘recyclability’ means the amount (mass or percentage) of an item available for recycling;

(16) ‘recycled content’ means the amount of an item (by area, length, volume or mass) that is sourced from post-consumer and/or post-industrial recycled material. Item can refer to the product or to the packaging in this case;

(17) ‘recycling’ means, in accordance with Article 3 of Directive 2008/98/EC of the European Parliament and of the Council (1), any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and the reprocessing into materials that are to be used as fuels or for backfilling operations;

(18) ‘sales packaging’, also known as primary packaging, means packaging conceived so as to constitute a sales unit consisting of products and packaging to the final user or consumer at the point of sale;

(19) ‘separate component’, also known as additional component, means a packaging component that is distinct from the main body of the packaging unit, which may be of a different material, that needs to be disassembled completely and permanently from the main packaging unit in order to access the product, and that is typically discarded prior to and separately from the packaging unit. In the case of absorbent hygiene products, it is any component with protective or hygienic function that is removed before the use of the product, e.g. the individual wrapping or film where some absorbent hygiene products are contained within the sales packaging (mainly for tampons and sanitary pads), the release liner and paper in baby diapers and sanitary pads, or the applicator for tampons;

(20) ‘substances identified to have endocrine disrupting properties’, also referred to as endocrine disruptors, means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 (candidate list of substances of very high concern for authorisation), or Regulation (EU) No 528/2012 of the European Parliament and of the Council (2) or Regulation (EC) No 1107/2009 of the European Parliament and of the Council (3), or Regulation (EC) No 1272/2008 of the European Parliament and of the Council (4);

(21) ‘super absorbent polymers’ means synthetic polymers designed for absorbing and retaining large amounts of liquid compared to their own mass;

(22) ‘synthetic polymers’ means macromolecular substances other than cellulose pulp intentionally obtained either by:

(a) a polymerisation process such as poly-addition or poly-condensation or by any other similar process of combination of monomers and other starting substances;

(b) chemical modification of natural or synthetic macromolecules;

(c) microbial fermentation.

Criterion 1. Fluff Pulp

This criterion applies to fluff pulp that represents ≥ 1 % w/w of the final product.

1.1. Sourcing of fluff pulp

All (100 %) fluff pulp suppliers shall hold valid chain of custody certificate issued by an independent third-party certification scheme such as FSC, PEFC or equivalent.


A minimum of 70% of the wood raw materials used for the production of the fluff pulp shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The remaining proportion of the wood raw materials, including any virgin wood material, shall be controlled wood covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

The certification bodies issuing the chain of custody and/or the Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

**Assessment and verification:**

The applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificates for the suppliers of all (100%) fluff pulp used in the product. FSC, PEFC or equivalent schemes shall be accepted as independent third-party certification.

In addition, the applicant shall provide audited accounting documents that demonstrate that at least 70% of the wood raw materials used for the production of the fluff pulp is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel licence. Competent bodies shall check the accounting documents again 12 months after the awarding of the EU Ecolabel licence.

If the fluff pulp is used in an air-laid material, then the air-laid material supplier shall allocate credits to the air-laid delivered to the product, providing invoices to support the number of credits allocated.

For the remaining proportion of wood raw materials, proof shall be provided that the content of uncertified virgin material does not exceed 30% and that it is controlled wood covered by a verification system that ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material. In case the certification scheme does not specifically require that all virgin material is sourced from non-GMO species, additional evidence shall be provided to demonstrate this.

### 1.2. Bleaching of fluff pulp

The pulp used in the product shall not be bleached with the use of elemental chlorine (Cl$_2$) gas.

In the case of elemental chlorine free (ECF) pulp, the average annual adsorbable organically bound halogens (AOX) emissions, expressed in kg/air dried tonne (ADt), from the production of each pulp used in EU Ecolabel products shall not exceed 0.140 kg/ADt.

**Assessment and verification:**

The applicant shall provide a declaration of compliance with this criterion, supported by a test report performed using the ISO 9562:2004 test method, including the AOX emissions relative to the ECF bleached pulp, expressed as kg AOX/ADt pulp. In case different pulp quality grades are used, the applicant shall provide the individual AOX emission corresponding to each pulp. Equivalent methods may be accepted as test methods if considered equivalent by a third-party, and shall be accompanied by detailed calculations showing compliance with this requirement and related supporting documentation.

Measurements of AOX emissions shall be taken on unfiltered and unsettled samples at the effluent discharge point of the mills’ wastewater treatment plant. In cases where the mill effluent is sent to a municipal or other third-party wastewater treatment plant, unfiltered and unsettled samples from the mill effluent sewer discharge point shall be analysed and the results multiplied by a standard removal efficiency factor for the municipal or third-party wastewater treatment plant. The removal efficiency factor shall be based on information provided by the operator of the municipal or other third-party wastewater treatment plant.

Information on the AOX emissions shall be expressed as the annual average from at least 12 measurements taken at least every month. In case of a new or rebuilt production plant, measurements shall be based on at least 45 subsequent days of stable running of the plant. The supporting documentation shall include an indication of the measurement frequency.

AOX shall only be measured in processes where chlorine compounds are used for bleaching the pulp (ECF bleaching). AOX does not need to be measured in the effluent from pulp production without bleaching or where bleaching is performed with chlorine-free substances.
The applicant shall also provide a declaration from the pulp manufacturer that elemental chlorine (Cl₂) gas was not used.

In case the applicant does not use any ECF pulp, a corresponding declaration is sufficient.

### 1.3. Emissions from fluff pulp production to water (chemical oxygen demand – COD and phosphorus (P)), and to air (sulphur compounds (S) and NOₓ)

The emissions to water and to air from the pulp production shall be expressed in terms of points \( P_{\text{COD}}, P_{\text{P}}, P_{\text{S}}, P_{\text{NOx}} \). Points are calculated by dividing the actual emission value by the reference values reported in Table 1.

- None of the individual points \( P_{\text{COD}}, P_{\text{P}}, P_{\text{S}}, \text{ and } P_{\text{NOx}} \) shall exceed 1.5.
- The sum of the points \( P_{\text{total}} = P_{\text{COD}} + P_{\text{P}} + P_{\text{S}} + P_{\text{NOx}} \) shall not exceed 4.0.

For each pulp ‘i’ sourced, the related measured emissions (expressed in kg/ADt) shall be weighted according to the proportion of pulp sourced (pulp ‘i’ with respect to air dried tonne of pulp ‘i’) and summed together. The reference values for each pulp type used are given in the Table 1. Finally, the total emissions shall be divided by the total reference value as shown in the following formula for COD:

\[
P_{\text{COD}} = \frac{\text{COD}_{\text{total}}}{\text{COD}_{\text{ref, total}}} = \frac{\sum_{i=1}^{n}[\text{COD}_{\text{pulp, i}} \times \text{COD}_{\text{ref, pulp, i}}]}{\sum_{i=1}^{n}[\text{COD}_{\text{pulp, i}} \times \text{COD}_{\text{ref, pulp, i}}]}
\]

#### Table 1

Reference values for emissions from different pulp types. CTMP = chemi-thermomechanical pulp; NSSC = neutral sulphite semi-chemical pulp

<table>
<thead>
<tr>
<th>Pulp Type</th>
<th>COD ref</th>
<th>P ref</th>
<th>S ref</th>
<th>NOX ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated mills</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleached chemical pulp (others than sulphite)</td>
<td>16,0</td>
<td>0,030</td>
<td>0,05</td>
<td>0,6</td>
</tr>
<tr>
<td>Bleached chemical pulp (sulphite)</td>
<td>24,0</td>
<td>0,03</td>
<td></td>
<td>0,6</td>
</tr>
<tr>
<td>Unbleached chemical pulp</td>
<td>6,5</td>
<td>0,02</td>
<td></td>
<td>0,6</td>
</tr>
<tr>
<td>Unbleached chemical pulp (only UKP-E quality)</td>
<td>6,5</td>
<td>0,035</td>
<td></td>
<td>0,6</td>
</tr>
<tr>
<td>CTMP</td>
<td>15,0</td>
<td>0,01</td>
<td></td>
<td>0,2</td>
</tr>
<tr>
<td>NSSC</td>
<td>11</td>
<td>0,02</td>
<td></td>
<td>0,4</td>
</tr>
<tr>
<td>Non-integrated mills (')</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Converting process</td>
<td>1</td>
<td>0,001</td>
<td>0,15</td>
<td>0,6</td>
</tr>
</tbody>
</table>

(’) Net emissions of P are considered in the calculation. The P naturally contained in wood raw materials and in water can be subtracted from the total emissions of P. Reductions up to 0.010 kg/ADt shall be accepted.

(’) The higher value refers to mills using eucalyptus and southern U.S. pine species from regions with higher levels of phosphorus and applies until 31 December 2026. From 1 January 2027, the limit of 0.03 kg P/ADt shall apply also to mills using eucalyptus and southern US pine species from regions with higher levels of phosphorus.

(’) For non-integrated mills, the raw material pulp(s) shall comply with the values listed for integrated mills, to which the emissions resulting from the conversion process should be added.

### Assessment and verification:

The applicant shall provide detailed calculations and test data showing compliance with this criterion, together with related supporting documentation that include test reports using the following continuous or periodical monitoring standard test methods: COD: ISO 15705 or ISO 6060; Total P: EN ISO 6878; NOX: EN 14792, ISO 11564, or EPA Method 7e; S (sulphur oxides): EN 14791, EPA Method No 6C or 8; S(reduced sulphur): EPA No 15A, 16A, 16B or 16c; S content in oil:
ISO 8754; S content in coal: ISO 19579; S content in biomass: EN 15289. Test methods whose scope and requirement standards are considered equivalent to the one of the named national and international standards and whose equivalency has been confirmed by an independent third-party shall be accepted. Rapid tests can also be used to monitor emissions as long as they are done regularly (e.g. monthly) against the relevant aforementioned standards or suitable equivalents.

In the case of COD measurements, continuous monitoring based on analysis of total organic carbon (TOC) shall be accepted as long as a correlation between TOC and COD results has been established for the site in question.

The minimum measurement frequency for COD measurements and for total P emissions shall be weekly. Emissions of S and NOx shall be measured at least twice per calendar year (separated by four to six months).

Data shall be reported as annual averages except in cases where:

— the production campaign is for a limited time period only,

— the production plant is new or has been rebuilt, in which case the measurements shall be based on at least 45 subsequent days of stable running of the plant.

Measurement results shall be representative of the respective campaign and a sufficient number of measurements shall have been taken place for each emission parameter. The supporting documentation shall include the measurement frequency and the calculation of the points for COD, Total P, S and NOx.

Measurements of emissions to water shall be taken on unfiltered and unsettled samples at the effluent discharge point of the mills' wastewater treatment plant. In cases where the mill effluent is sent to a municipal or other third-party wastewater treatment plant, unfiltered and unsettled samples from the mill effluent sewer discharge point shall be analysed and the results multiplied by a standard removal efficiency factor for the municipal or third-party wastewater treatment plant. The removal efficiency factor shall be based on information provided by the operator of the municipal or other third-party wastewater treatment plant.

Emissions to air shall include all emissions of S and NOx that occur during the production of pulp, including steam generated outside the production site, minus any emissions allocated to the production of electricity. In cases where co-generation of heat and electricity occur at the same plant, the emissions of S compounds and NOx resulting from on-site electricity generation shall be subtracted from the total amount. The proportion of the emissions resulting from electricity generation shall be calculated as:

\[ 2 \times \frac{\text{MWh(electricity)}}{2 \times \text{MWh(electricity)} + \text{MWh(heat)}} \]

In this calculation, 'electricity' is the electricity produced at the co-generation plant, and 'heat' is the net heat delivered from the co-generation plant to the pulp production.

Measurements of S compounds and NOx shall include recovery boilers, lime kilns, steam boilers and destructor furnaces for strong smelling gases. Diffuse emissions shall also be taken into account.

Reported emission values for S compounds shall include both oxidised and reduced S emissions (SO₂ and total reduced sulfur (TRS) – measured as S). The S emissions related to the heat energy generation from oil, coal and other external fuels with known S content may be calculated instead of being measured, and shall be taken into account.

1.4. Emissions of CO₂ from fluff pulp production

CO₂ emissions from the production of fluff pulp shall not exceed the values presented in Table 2, including emissions from the production of electricity (whether on-site or off-site). CO₂ emissions shall include all sources of energy used during the production of pulp.

Reference emission values according to Table 3 shall be used in the calculation of CO₂ emission from energy sources. If needed, CO₂ emission factors for other energy sources can be found in Annex VI to Commission Implementing Regulation (EU) 2018/2066 (*), whereas the CO₂ emission factors for grid electricity should be in line with Commission Delegated Regulation (EU) 2019/331 (**).


Table 2

Limit values for different types of pulp. CTMP: chemical thermomechanical pulp

<table>
<thead>
<tr>
<th>Integrated mills</th>
<th>Non-integrated mills</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical and semi-chemical pulp</td>
<td></td>
</tr>
<tr>
<td>400 kg CO$_2$/ADt</td>
<td></td>
</tr>
<tr>
<td>CTMP</td>
<td>900 kg CO$_2$/ADt</td>
</tr>
</tbody>
</table>

| Non-integrated mills                  |                       |
| Converting process (*)               | 95 kg CO$_2$/ADt      |

(*) The raw material pulp(s) for non-integrated mills shall comply with the values listed for integrated mills, to which the emissions resulting from the conversion process should be added.

Table 3

Reference values for CO$_2$ emissions from different energy sources

<table>
<thead>
<tr>
<th>Fuel</th>
<th>CO$_2$ emissions</th>
<th>Unit</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coal</td>
<td>94,6</td>
<td>g CO$_2$ fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>Crude oil</td>
<td>73,3</td>
<td>g CO$_2$ fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>Fuel oil 1</td>
<td>74,1</td>
<td>g CO$_2$ fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>Fuel oil 2-5</td>
<td>77,4</td>
<td>g CO$_2$ fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>LPG</td>
<td>63,1</td>
<td>g CO$_2$ fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>Natural Gas</td>
<td>56,1</td>
<td>g CO$_2$ fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>Grid Electricity</td>
<td>376</td>
<td>g CO$_2$ fossil/kWh</td>
<td>Regulation (EU) 2019/331</td>
</tr>
</tbody>
</table>

Assessment and verification:

The applicant shall provide data and detailed calculations showing compliance with this criterion, together with related supporting documentation.

For each pulp used, the pulp manufacturer shall provide the applicant with a single CO$_2$ emission value in kg CO$_2$/ADt.

The CO$_2$ emission data shall include all sources of energy sources used during the production of pulp, including the emissions from the production of electricity (whether on-site or off-site).

When calculating CO$_2$ emissions, the amount of energy from renewable sources purchased and used for the production processes shall count as zero CO$_2$ emission. For biomass combustion, this means that the biomass needs to fulfil the relevant sustainability and greenhouse gas savings criteria as specified in the Directive (EU) 2018/2001 of the European Parliament and of the Council (8). The applicant shall provide appropriate documentation that this kind of energy is actually used at the mill or has been externally purchased (copy of the contract and an invoice indicating the renewable share of the purchased electricity).

The period for the calculations and/or mass balances shall be based on the production over 12 months. The calculations shall be repeated on a yearly basis. In case of a new or a rebuilt production plant, the calculations shall be based on at least 45 subsequent days of stable running of the plant. The calculations shall be representative of the respective campaign.

For the grid electricity, the value provided above (the European average) shall be used unless the applicant presents documentation establishing the specific value for its suppliers of electricity (contract for specified electricity or certified electricity). In this case, the applicant may use this value instead of the value quoted. The documentation used as proof of compliance shall include technical specifications that indicate the average value (e.g. copy of a contract).

1.5. Energy consumption for fluff pulp production

The energy consumption for the pulp production shall include both the electricity consumption and the fuel consumption for heat production and shall be expressed in terms of points ($P_{\text{electricity}}$ and $P_{\text{fuel}}$). The following limits and reference values shall apply:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Calculation of electricity consumption points:

$$P_{\text{electricity}} = \frac{\sum_{i=1}^{n} |E_{\text{pulp},i}| \times E_{\text{pulp},i}}{\sum_{i=1}^{n} |E_{\text{pulp},i}| \times E_{\text{ref},\text{pulp},i}}$$

Where:

$E_{\text{pulp},i}$ = internally produced electricity + purchased electricity – sold electricity;

$E_{\text{ref},\text{pulp},i}$ as in Table 4.

$E_{\text{pulp},i}$ shall be expressed in kWh/ADt and calculated for each pulp $i$ used in the final product.

Calculation of fuel consumption points:

$$P_{\text{fuel}} = \frac{\sum_{i=1}^{n} |F_{\text{pulp},i}| \times F_{\text{pulp},i}}{\sum_{i=1}^{n} |F_{\text{pulp},i}| \times F_{\text{ref},\text{pulp},i}}$$

Where:

$F_{\text{pulp},i}$ = internally produced fuel + purchased fuel – sold fuel – 1.25 × internally produced electricity;

$F_{\text{ref},\text{pulp},i}$ as in Table 4.

$F_{\text{pulp},i}$ shall be expressed in kWh/ADt and calculated for each pulp $i$ used in the final product.

The amount of fuel used to produce the sold heat shall be added to the term ‘sold fuel’ in the equation above.

In case of a mix of pulps, the reference value for electricity and fuel consumption for heat production shall be weighted according to the proportion of each pulp used (pulp ‘$i$’ with respect to air dry tonne of pulp), and added together. The energy consumed when mixing the pulps as well as the energy used in the converting process shall be added as well.

Table 4

Reference values for electricity and fuel

<table>
<thead>
<tr>
<th>Pulp grade</th>
<th>$E_{\text{ref},\text{pulp}}$ kWh/ADt</th>
<th>$F_{\text{ref},\text{pulp}}$ kWh/ADt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated mills</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemical and semi-chemical pulp</td>
<td>800</td>
<td>5 400</td>
</tr>
</tbody>
</table>
Non-integrated mills (\(^1\))

<table>
<thead>
<tr>
<th></th>
<th>1 800</th>
<th>900</th>
</tr>
</thead>
<tbody>
<tr>
<td>Converting process</td>
<td>250</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) For non-integrated mills, the raw material pulp(s) shall comply with the values listed for integrated mills, to which the energy used during the conversion process should be added.

**Assessment and verification:**

The applicant shall provide the total electricity and fuel consumption, together with the calculations and related supporting documentation showing compliance with this criterion.

The applicant shall calculate all energy inputs, divided into heat/fuels and electricity used during the production of the pulp. If a mix of fluff pulps is used, the energy must be proportionally calculated to each fluff pulp. Energy used in the transportation of the raw materials is not included in the energy consumption calculations. The period for the calculations or mass balances shall be based on the production over 12 months. The calculations shall be repeated on a yearly basis. In case of a new or a rebuilt production plant, the calculations shall be based on at least 45 subsequent days of stable running of the plant. The calculations shall be representative of the respective campaign.

Total electricity consumption \(E_{\text{pulp}}\) includes the net imported electricity coming from the grid and the internal generation of electricity measured as electric power. Electricity used for wastewater treatment shall not be included.

Total fuel consumption \(F_{\text{pulp}}\) includes all purchased fuels, the heat energy recovered by incinerating liquors and waste from on-site processes (e.g. wood waste, sawdust, liquors, etc.), as well as the heat recovered from the internal generation of electricity. However, the applicant only needs to count 80 % of the heat energy from such sources when calculating the total heat energy.

Where steam is generated using electricity as the heat source, the heat value of the steam shall be calculated, then divided by 0.8 and added to the total fuel consumption.

**Criterion 2. Man-made cellulose fibres**

This criterion applies to man-made cellulose fibres that represent ≥ 1 % w/w of the final product.

2.1. **Sourcing of man-made cellulose fibres**

All (100 %) dissolving pulp suppliers shall hold valid chain of custody certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent.

A minimum of 70 % of the raw materials used for the production of the dissolving pulp shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The remaining proportion of raw materials used for the production of the dissolving pulp shall be controlled wood covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

The certification bodies issuing the chain of custody and/or Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

Dissolving pulp produced from cotton linters shall meet criterion 3.1 for cotton (sourcing and traceability).

**Assessment and verification:**

The applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificate for the suppliers of all (100 %) dissolving pulp used in the product. FSC, PEFC or equivalent schemes shall be accepted as independent third-party certification.
In addition, the applicant shall provide audited accounting documents that demonstrate that at least 70% of the raw materials used for the production of the dissolving pulp is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel licence. Competent bodies shall check the accounting documents again 12 months after the awarding of the EU Ecolabel licence.

If man-made cellulose fibres are used in an air-laid or other nonwoven materials, the air-laid or other nonwoven material supplier or the air-laid or other nonwoven material producer shall allocate credits to the air-laid or other nonwoven materials delivered to the product, providing invoices to support the number of credits allocated.

For the remaining proportion of raw materials, proof shall be provided that the content of uncertified virgin material does not exceed 30% and that it is controlled material covered by a verification system that ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

In case the certification scheme does not specifically require that all virgin material is sourced from non-GMO species, additional evidence shall be provided to demonstrate this.

2.2. **Bleaching of man-made cellulose fibres**

This sub-criterion does not apply to totally chlorine free (TCF) bleached pulp.

The pulp used to manufacture man-made cellulose fibres shall not be bleached with the use of elemental chlorine (Cl₂) gas.

The resulting total amount of AOX and organically bound chlorine (OCl) shall not exceed the following:

- 0.140 kg/ADt, measured in the wastewater from pulp manufacturing (AOX), and
- 150 ppm, measured in the finished man-made cellulose fibres (OCl).

**Assessment and verification:**

The applicant shall provide a declaration from the pulp supplier that chlorine gas is not used and a test report (if possible) showing compliance with both the AOX and the OCl requirements, using the appropriate test method:

- For AOX: ISO 9562 or the equivalent EPA 1650C,
- For OCl: ISO 11480.

Frequency of measurement for AOX shall be set in accordance with the criterion 1.2 for fluff pulp.

In case the applicant could not provide the actual value of AOX level measured in the wastewater from pulp manufacturing, a corresponding declaration of compliance signed by the pulp manufacturer, in accordance with the exposed requirement, shall be provided.

In case the applicant does not use any ECF pulp, a corresponding declaration is sufficient.

2.3. **Production of man-made cellulose fibres**

(a) More than 50% of dissolving pulp used to manufacture man-made cellulose fibres shall be obtained from dissolving pulp mills that recover value from their spent process liquor either by:

(i) generating on-site electricity and/or steam; or

(ii) manufacturing chemical co-products.
(b) The following limit values for the emission of several compounds to air and water shall be respected in the viscose and in the modal fibres production process:

Table 5

<table>
<thead>
<tr>
<th>Fibre type</th>
<th>Sulphur emissions to air – Limit value (g/kg)</th>
<th>Zinc emissions to water – Limit value (g/kg)</th>
<th>COD measurements in water – Limit value (g/kg)</th>
<th>SO$_4^{2-}$ emissions to water – Limit value (g/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staple fibre</td>
<td>20</td>
<td>0,05</td>
<td>5</td>
<td>300</td>
</tr>
<tr>
<td>Filament fibre</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>— Batch washing</td>
<td>40</td>
<td>0,10</td>
<td>5</td>
<td>200</td>
</tr>
<tr>
<td>— Integrated washing</td>
<td>170</td>
<td>0,50</td>
<td>6</td>
<td>250</td>
</tr>
</tbody>
</table>

Note: Limit values are expressed as annual average. All values are expressed as g of pollutant/kg of product.

Assessment and verification:

(a) The applicant shall provide supporting documentation and evidence that the required proportion of dissolving pulp suppliers has the appropriate energy generating equipment or co-product recovery and manufacturing systems installed at the related production sites. The list of such dissolving pulp suppliers shall also be provided.

(b) In relation to test methods:

(i) The applicant shall provide detailed documentation and test reports showing compliance with this criterion, together with a declaration of compliance.

(ii) Sulphur emissions to air: use method defined in EN 14791, EPA No 8, 15A, 16A or 16B or DIN 38405-D27.

(iii) Zinc emissions to water: use method defined in EN ISO 11885.

(iv) COD measurements in water: use method defined in ISO 6060, DIN ISO 15705, DIN 38409-01 or DIN 38409-44.

(v) SO$_4^{2-}$ (sulphates) emissions to water: use method defined in ISO 22743.

(vi) Test methods whose scope and requirement standards are considered equivalent to the one of the named national and international standards and whose equivalency has been confirmed by an independent third-party shall be accepted.

(vii) The detailed documentation and test reports shall include an indication of the measurement frequency for S, Zn, COD and SO$_4^{2-}$. The minimum measurement frequency, shall be weekly for COD, S, Zn and SO$_4^{2-}$, in addition to any measurements stipulated in the regulatory requirements.

Criterion 3. Cotton and other natural cellulosic seed fibres

3.1. Sourcing and traceability of cotton and other natural cellulosic seed fibres

This criterion applies to cotton and other natural cellulosic seed fibres that represents ≥ 1 % w/w of the final product.
(a) All cotton and other natural cellulosic seed fibres shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007 (9) and Regulation (EU) 2018/848 of the European Parliament and of the Council (10), the US National Organic Programme (NOP (11)) or equivalent legal obligations set by trade partners of the European Union. The organic cotton content may include organically grown cotton and transitional organic cotton.

(b) Cotton and other natural cellulosic seed fibres grown according to criterion 3.1(a) and used to manufacture absorbent hygiene product shall be traceable.

Tampon strings are exempted from complying with this requirement.

**Assessment and verification:**

(a) The organic content of cotton and/or other natural cellulosic seed fibres shall be certified by an independent control body to have been produced in conformity with the production and inspection requirements laid down in Regulation (EC) No 834/2007 and Regulation (EU) 2018/848, the US NOP or equivalent legal obligations set by other trade partners of the European Union. Verification shall be provided on an annual basis and for each country of origin.

(b) The applicant shall demonstrate compliance with the material content requirement for the annual volume of cotton and/or other natural cellulosic seed fibres purchased to manufacture the final product(s) and according to each product line, on an annualised basis. Transaction records or invoices documenting the quantity of cotton and/or other natural cellulosic seed fibres purchased on an annual basis from farmers or producer groups, and the total weight of certified bales shall be provided.

**3.2. Bleaching of cotton and other natural cellulosic seed fibres**

Cotton and other natural cellulosic seed fibres shall be bleached only using TCF technologies.

This sub-criterion shall not apply to cotton linters used to produce dissolving pulp.

**Assessment and verification:**

The applicant shall provide a declaration from the supplier of cotton and/or other natural cellulosic seed fibres that TCF technologies are used.

**Criterion 4. Production of synthetic polymers and plastic materials**

This criterion applies to each synthetic polymer and plastic material that represents ≥ 5 % w/w of the final product and/or of the packaging.

Manufacturing facilities producing synthetic polymers and plastic materials used in the final product shall have systems for the implementation of:

(a) water-savings. The water management system shall be documented or explained and shall include information on at least the following aspects: monitoring of water flows; proof of circulating water in closed systems; and continuous improvement objectives and targets relating to the reduction of wastewater generation and optimisation rates (if relevant, i.e. if water is used in the plant);

(b) integrated waste management, in form of a plan to prioritise treatment options other than disposal for all the waste generated at the manufacturing facilities and to follow the waste hierarchy in relation to prevention, reuse, recycling, recovery and final disposal of waste. The waste management plan shall be documented or explained and shall include information on at least the following aspects: separation of different waste fractions; handling, collection, separation and use of recyclable materials from the non-hazardous waste stream; recovery of materials for other uses; handling, collection, separation and disposal of hazardous waste, as defined by the relevant local and national regulatory authorities; and continuous improvement objectives and targets relating to waste prevention, reuse, recycling and, recovery of waste fractions that cannot be prevented (including energy recovery);

(c) optimisation of energy efficiency and energy management. The energy management system shall address all energy consuming devices, including machinery, lighting, air conditioning and cooling. The energy management system shall include measures for the improvement of energy efficiency and shall include information on at least the following aspects: establishing and implementing an energy data collection plan in order to identify key energy figures; analysis of energy consumption that includes a list of energy consuming systems, processes and facilities; identification of measures for more efficient use of energy; continuous improvement objectives and targets relating to the reduction of energy consumption.

Assessment and verification:

The applicant shall provide a declaration of compliance with the criterion from the suppliers of synthetic polymers and plastic materials used in the final product and/or the packaging. The declaration shall be supported by a report describing in detail the procedures adopted by the suppliers in order to fulfil the requirements for each of the sites concerned in accordance with standards, such as ISO 14001 and/or ISO 50001 for water, waste and energy plans.

If waste management is outsourced, the sub-contractor shall provide a declaration of compliance with this criterion as well.

 Applicants registered with EU Eco-Management and Audit Scheme (EMAS) and/or certified according to ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme shall be considered as having fulfilled these requirements if:

(a) the inclusion of water, waste and energy management plans for the production site(s) is documented in the company's EMAS environmental statement; or

(b) the inclusion of water, waste and energy management plans for the production site(s) is sufficiently addressed by the ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme.

Criterion 5. Biobased plastic materials

This criterion applies only to the final product, separate components, and/or packaging that contain > 1 % w/w of biobased plastic material.

The applicant may source, on a voluntary basis, a certain percentage of the total synthetic polymers and plastic materials in relation to the total weight of polymers in the final product (including super absorbent polymers (SAP)), the separate components and/or in the packaging, from biobased raw materials. Circular economy principles shall guide the selection of feedstocks (as an example, producers shall prioritise the use of organic waste and by-products as feedstock) (12).

In this case, the following shall apply:

(a) The superior environmental profile of the biobased raw materials used to produce biobased plastics in the final product, separate components, and/or packaging shall be demonstrated in compliance with the latest applicable methodologies to assess the impacts of biobased plastics compared to fossil-based plastics (13).

(b) Biobased raw materials used to produce biobased plastics in the final product, separate components, and/or packaging shall be covered by chain of custody certificates issued by an independent third-party certification scheme officially recognised by the European Commission (14).

(12) In line with the Communication from the European Commission on EU Policy Framework on biobased, biodegradable and compostable plastics. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022DC0682&qid=1680246180511.


(14) In line with the sustainability requirements related to the sourcing of biobased raw material as per the review of the Renewable Energy Directive (RED III). The certification schemes officially recognised by the European Commission are available at: https://ec.europa.eu/energy/topics/renewable-energy/biofuels/voluntary-schemes_en.
The final product, separate components, and/or packaging may be voluntarily labelled as containing biobased plastic. In this case, the claim shall be that 'x % of plastic contained in the product [separate components, and/or packaging] is biobased' (where $x > 1$, and $x$ is the exact and measurable share of biobased plastic content in the product [separate components, and/or packaging]). Generic claims such as ‘bioplastics’, ‘biobased’, ‘plant-based’, ‘natural-based’ and similar shall not be used.

**Assessment and verification:**

(a) To demonstrate the superior environmental profile of the biobased plastic raw materials used in the product, separate components, and/or packaging, the applicant shall provide an independent third-party certification that refers to the methodology currently available (\textsuperscript{15}).

(b) The applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificate for the suppliers of all biobased plastics raw materials used in the product, separate components, and/or packaging. The chain of custody certificates shall be valid for the whole duration of the EU Ecolabel licence. Competent bodies shall check the certificates again 12 months after the awarding of the EU Ecolabel licence.

Where applicable, the applicant shall provide a high resolution photograph of the sales packaging, where information regarding the biobased plastic claim appears clearly. The standards based on radiocarbon methods such as EN 16640 or EN 16785 or ASTM D 6866-12 shall be used to determine the biobased carbon content of the synthetic polymers and plastic materials present in the product, separate component, and/or packaging. When radiocarbon methods cannot be used, the mass balance method is allowed if a high level of transparency and accountability is ensured and supported by agreed standards.

The use of purchased certificates based on the Book & Claim system is excluded so that the traceability of the biobased plastic raw materials is possible. The proofs of purchase for the biobased plastic raw materials shall be based on processes according to the segregation or mass balance systems.

In case the certification scheme does not specifically require that all virgin material is sourced from non-GMO species, additional evidence shall be provided to demonstrate this.

**Criterion 6. Material efficiency in the manufacturing of the final product**

Requirements in this criterion shall apply to the final product assembly site.

The quantity of waste generated during the manufacturing and packaging of the products which is sent to landfill or incineration without energy recovery, shall not exceed:

(a) 8 % by weight of the end products for tampons;

(b) 4 % by weight of the end products for all the other products.

**Assessment and verification:**

The applicant shall confirm compliance with the above requirements.

The applicant shall provide evidence of the quantity of waste that has not been reused within the manufacturing process or that is not converted into materials and/or energy.

The applicant shall present all of the following:

(a) the weight of the product and of the packaging;

(b) all the waste streams generated during the manufacturing;

(c) the respective treatment processing of the fraction of recovered waste and that disposed of to landfill or incineration.

The quantity of waste sent to landfill or to incineration without energy recovery shall be calculated as the difference between the amount of waste produced and the amount of waste recovered (reused, recycled, etc.).

\textsuperscript{15} Methodology currently available as explained before.
Criterion 7. Excluded and restricted substances

7.1. Restrictions on substances classified under Regulation (EC) No 1272/2008

This sub-criterion applies to the final product and any components therein.

Unless derogated in Table 8, the final product and any components therein shall not contain ingoing substances (alone or in mixtures) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 6, in accordance with Regulation (EC) No 1272/2008.

Table 6

Excluded hazard classes, categories and associated hazard statement codes

<table>
<thead>
<tr>
<th>Carcinogenic, mutagenic or toxic for reproduction</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Categories 1A and 1B</td>
<td></td>
</tr>
<tr>
<td>H340 May cause genetic defects</td>
<td>H341 Suspected of causing genetic defects</td>
</tr>
<tr>
<td>H350 May cause cancer</td>
<td>H351 Suspected of causing cancer</td>
</tr>
<tr>
<td>H350i May cause cancer by inhalation</td>
<td>-</td>
</tr>
<tr>
<td>H360F May damage fertility</td>
<td>H361f Suspected of damaging fertility</td>
</tr>
<tr>
<td>H360D May damage the unborn child</td>
<td>H361d Suspected of damaging the unborn child</td>
</tr>
<tr>
<td>H360FD May damage fertility. May damage the unborn child</td>
<td>H361fd Suspected of damaging fertility. Suspected of damaging the unborn child</td>
</tr>
<tr>
<td>H360Fd May damage fertility. Suspected of damaging the unborn child</td>
<td>H362 May cause harm to breast fed children</td>
</tr>
<tr>
<td>H360Df May damage the unborn child. Suspected of damaging fertility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute toxicity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Categories 1 and 2</td>
<td>Category 3</td>
</tr>
<tr>
<td>H300 Fatal if swallowed</td>
<td>H301 Toxic if swallowed</td>
</tr>
<tr>
<td>H310 Fatal in contact with skin</td>
<td>H311 Toxic in contact with skin</td>
</tr>
<tr>
<td>H330 Fatal if inhaled</td>
<td>H331 Toxic if inhaled</td>
</tr>
<tr>
<td>H304 May be fatal if swallowed and enters airways</td>
<td>EUH070 Toxic by eye contact</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specific target organ toxicity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>Category 2</td>
</tr>
<tr>
<td>H370 Causes damage to organs</td>
<td>H371 May cause damage to organs</td>
</tr>
<tr>
<td>H372 Causes damage to organs through prolonged or repeated exposure</td>
<td>H373 May cause damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Respiratory and skin sensitisation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1A</td>
<td>Category 1B</td>
</tr>
<tr>
<td>H317 May cause allergic skin reaction</td>
<td>H317 May cause allergic skin reaction</td>
</tr>
</tbody>
</table>
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

Endocrine disruptors for human health and the environment

<table>
<thead>
<tr>
<th>Category 1</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUH380: May cause endocrine disruption in humans</td>
<td>EUH381: Suspected of causing endocrine disruption in humans</td>
</tr>
<tr>
<td>EUH430: May cause endocrine disruption in the environment</td>
<td>EUH431: Suspected of causing endocrine disruption in the environment</td>
</tr>
</tbody>
</table>

Persistent, Bioaccumulative and Toxic

<table>
<thead>
<tr>
<th>PBT</th>
<th>vPvB</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUH440: Accumulates in the environment and living organisms including in humans</td>
<td>EUH441: Strongly accumulates in the environment and living organisms including in humans</td>
</tr>
</tbody>
</table>

Persistent, Mobile and Toxic

<table>
<thead>
<tr>
<th>PMT</th>
<th>vPvM</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUH450: Can cause long-lasting and diffuse contamination of water resources</td>
<td>EUH451: Can cause very long-lasting and diffuse contamination of water resources</td>
</tr>
</tbody>
</table>

Moreover, the final product and any components therein shall not contain incoming substances (alone or in mixtures) in concentrations greater than 0,010 % (weight by weight) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 7, in accordance with Regulation (EC) No 1272/2008 – unless derogated in Table 8.

Table 7

<table>
<thead>
<tr>
<th>Restricted hazard classes, categories and associated hazard statement codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous to the aquatic environment</td>
</tr>
<tr>
<td>Categories 1 and 2</td>
</tr>
<tr>
<td>H400 Very toxic to aquatic life</td>
</tr>
<tr>
<td>H410 Very toxic to aquatic life with long-lasting effects</td>
</tr>
<tr>
<td>H411 Toxic to aquatic life with long-lasting effects</td>
</tr>
<tr>
<td>Category 3 and 4</td>
</tr>
<tr>
<td>H412 Harmful to aquatic life with long-lasting effects</td>
</tr>
<tr>
<td>H413 May cause long-lasting effects to aquatic life</td>
</tr>
<tr>
<td>Hazardous to the ozone layer</td>
</tr>
<tr>
<td>H420 Harms public health and the environment by destroying ozone in the upper atmosphere</td>
</tr>
</tbody>
</table>
### Table 8

**Derogations to restrictions on substances with a harmonised classification under Regulation (EC) No 1272/2008**

<table>
<thead>
<tr>
<th>Substance type</th>
<th>Derogated hazard class, category and hazard statement code</th>
<th>Derogation conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-methyl-2H-isothiazol-3-one (MIT)</td>
<td>H400, H314, H301, H311, H318, H410, H330 and H317</td>
<td>Only in water-soluble inks and in a concentration lower than 15 ppm in the ink (before application) and lower than 0,1 ppm in the final product. The ink shall comply with sub-criterion 7.3.4</td>
</tr>
<tr>
<td>Dipropylene glycol dibenzoate</td>
<td>H412</td>
<td>Only in hot melt adhesives that are used to indicate wetness</td>
</tr>
<tr>
<td>Substances and mixtures with a harmonised classification as H304</td>
<td>H304</td>
<td>Substances with a viscosity under 20,5 cSt at 40 °C.</td>
</tr>
<tr>
<td>Titanium dioxide (nano-form)</td>
<td>H351</td>
<td>Only when used as pigment. It cannot be used in powder or spray form.</td>
</tr>
</tbody>
</table>

The hazard statement codes generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures shall apply.

The use of substances or mixtures that are chemically modified during the production process, so that any relevant hazard for which the substance or mixture has been classified under Regulation (EC) No 1272/2008 no longer applies, shall be exempted from the above requirement.

This criterion shall not apply to:

— substances not included in the scope of Regulation (EC) No 1907/2006 as defined in Article 2(2) of that Regulation,

— substances covered by Article 2(7)(b) of Regulation (EC) No 1907/2006, which sets out the criteria for exempting substances included in Annex V to that Regulation from the registration, downstream user and evaluation requirements.

**Assessment and verification:**

The applicant shall provide a signed declaration of compliance with sub-criterion 7.1, together with relevant declarations from the producers of the components, a list of all chemicals used, their safety data sheet or chemical supplier declaration and any relevant declarations that demonstrate the compliance with the requirement.

For restricted substances and unavoidable impurities with a restricted classification, the concentration of the restricted substance or impurity and an assumed retention factor of 100 % shall be used to estimate the quantity of the restricted substance or impurity remaining in the final product. Impurities can be present in the chemical product up to 0,0100 % w/w, unless further restricted under criterion 7.3.8. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

Justifications for any deviation from a retention factor of 100 % (e.g. solvent evaporation) or for chemical modification of a restricted impurity shall be provided.

For substances exempted from sub-criterion 7.1 (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to demonstrate compliance.
Since multiple products or potential products using the same process chemicals may be covered by one EU Ecolabel licence, the calculation only needs to be presented for each impurity for the worst-case product or component covered by the licence (e.g. the most heavily printed component article when screening for inks with restricted classifications).

The above evidence can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

7.2. **Substances of Very High Concern (SVHCs)**

This sub-criterion applies to the final product and any components therein.

The final product and any components therein shall not contain ingoing substances (alone or in mixtures) that meet the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of that Regulation and included in the candidate list for substances of very high concern for authorisation.

**Assessment and verification**

The applicant shall provide a signed declaration that the final product and any components therein do not contain any SVHCs. The declaration shall be supported by safety data sheets of all supplied chemicals and materials used to produce the final product and the components therein.

The list of substances identified as SVHCs and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here:


Reference to the list shall be made on the submission date of the EU Ecolabel application.

For unavoidable impurities identified as SVHCs, the concentration of the impurity and an assumed retention factor of 100 %, shall be used to estimate the quantity of the SVHC impurity remaining in the final product. Impurities can be present in the chemical product up to 0,0100 % w/w, unless further restricted under criterion 7.3.8. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

Justifications for any deviation from a retention factor of 100 % (e.g. solvent evaporation) or for chemical modification of a SVHC impurity shall be provided.

7.3. **Other specific restrictions**

7.3.1. Specified excluded substances

This sub-criterion applies to the final product and any components therein.

The following substances shall not be added (alone or in mixtures) to the chemical product used in the final product nor in any components therein:

(a) 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT);
(b) Acrylamide in superabsorbent polymers;
(c) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1]. Sterically hindered phenolic antioxidants with molecular weight (MW) > 600 g/mole are allowed;
(d) Antibacterial agents (e.g. Nanosilver and triclosan);
(e) Formaldehyde and formaldehyde releasers [2];
(f) Nitromusk s and Polycyclic musks;
(g) Organotin compounds used as a catalysts in the production of silicone;
(h) Parabens;
(i) Phthalates [3];
(j) Substances identified to have endocrine disrupting properties;
(k) Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects.
Assessment and verification:

The applicant shall provide a signed declaration of compliance with the sub-criterion, supported by declarations from suppliers, if relevant. The substances listed in this sub-criterion are only allowed as impurities, and nevertheless in concentrations lower than 0,0100 % w/w in the chemical product, unless further restricted under criterion 7.3.8. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

[Notes:


[2] The use of formaldehyde and formaldehyde releasers in adhesives is regulated according to sub-criterion 7.3.5

[3] DINP may be allowed if used in adhesive formulations at a maximum concentration of 0,010 % weight by weight of the adhesive formulation]

7.3.2. Fragrances

This sub-criterion applies to the final product, any components therein, the separate components and the packaging.

Fragrances shall not be added to the final product, to any component thereof, to the separate components nor to the packaging.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the sub-criterion.

7.3.3. Lotions

This sub-criterion applies to the final product and any components therein.

Lotions shall not be used in the product, nor in any component thereof.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the above sub-criterion.

7.3.4. Inks and dyes

This sub-criterion applies to the final product and any components therein. This requirement does not apply to the separate components, the sales packaging and the information sheets.

(a) The final product and any components therein shall not be dyed or printed on.

(b) The following components are exempted and may be dyed or printed on:

(i) tampon strings;

(ii) closing systems;

(iii) materials that are not directly in contact with the skin, if the dye or ink fulfils specific functions (e.g. reducing visibility of the product through white or light-coloured clothes, showing landing zones of tapes, indicating the wetness, indicating the back part of a product) or decorative purposes.
In these cases, the content of antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, primary aromatic amines and polychlorinated biphenyl occurring as impurity in the dying colorants and inks shall be below the limits given in the Council of Europe's Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food (\(^{16}\)).

The dying colorants used shall moreover comply with the following:

(a) if used in plastic materials: BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities (\(^{17}\)) or Swiss Ordinance 817.023.21 Annex 2 (\(^{18}\)) and Annex 10 (\(^{19}\));

(b) if used in cellulosic materials: BfR's recommendation XXXVI. Paper and board for food contact (\(^{20}\)).

The dying colorants and inks used shall also comply with sub-criteria 7.1 and 7.2.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant.

In case dyes and/or inks are used, their presence shall be justified by indicating the specific function provided, and documentation shall be provided to ensure that impurities in the dying colorant or ink comply with the Council of Europe's Resolution AP (89) 1, and that the used dyes are authorised according to the BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities, Swiss Ordinance 817.023.21 Annex 2 and Annex 10, or the BfR's recommendation XXXVI. Paper and board for food contact.

7.3.5. Further restrictions applying to adhesives

The content of free formaldehyde in hardened adhesive (glue) shall not exceed 10 ppm. The threshold for formaldehyde generated during adhesive production shall be 250 ppm, measured in newly produced polymer dispersion. Hotmelt adhesives shall be exempted from this requirement.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant, and safety data sheets (SDS) of any substance/mixture and their concentration in the adhesive.

The applicant shall also provide test results for the content of formaldehyde, according to the test method ISO 14184-1:2011 or equivalent.

7.3.6. Super absorbent polymers (SAP)

Superabsorbent polymers used in the product shall:

(a) contain a maximum of 1 000 ppm residual monomers [4] that are classified with the H-codes reported in sub-criterion 7.1. For sodium polyacrylate this limit applies to the sum of unreacted acrylic acid and cross linking agents;

(b) as a maximum, contain 10 % (weight/weight) of water-soluble extracts [5] and these shall comply with sub-criteria 7.1, 7.2 and 7.3.1. For sodium polycarlate these represent monomers and oligomers of acrylic acid with lower molecular weight than the superabsorbent polymer according to ISO 17190.

(c) Acrylamide shall not be included in superabsorbent polymers.

\(^{16}\) Council of Europe, Committee of Ministers, Resolution AP(89)1 on the use of colorants in plastic materials coming into contact with food. Available at: https://rm.coe.int/168048648.

\(^{17}\) https://www.bfr.bund.de/cm/349/IX-Colorants-for-Plastics-and-other-Polymers-Used-in-Commodities.pdf.


\(^{20}\) https://www.dssmith.com/contentassets/1bbf9877253f458aa0eced26b76f2d705/360-english.pdf.
Assessment and verification:

The applicant shall provide a signed declaration of compliance with this sub-criterion, supported by declarations from suppliers if relevant, and safety data sheets (SDS) of any substance/mixture and their concentration in the final product.

In addition, the applicant shall also provide a declaration from the supplier documenting the composition of the super absorbent polymer(s) used in the product and the quantity of water-soluble extracts in the superabsorbent polymer(s). The declaration shall be supported by safety data sheets or test results specifying the residual monomers contained in the SAP and the quantities thereof. Recommended test methods are ISO 17190 and WSP 210. The tested quantities for residual monomers and soluble extracts shall be averages from repeated measures over a certain period of time. The methods used and the measurement frequency for the analyses shall be described, including the information of the laboratories used for the analysis.

[Notes:]

[4] Residual monomers are intended as the total of unreacted acrylic acid and crosslinkers

[5] Water-soluble extracts in SAP are intended as monomers and oligomers of acrylic acid with a lower molecular weight than the one of SAP, and salts

7.3.7. Silicone

This sub-criterion applies to the release liner.

(a) Solvent-based silicone coatings shall not be used.

(b) Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and dodecamethyl cyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the silicone mixture [6] in concentrations above 800 ppm (0.08 % w/w). The 800 ppm limit is to be applied to each substance separately.

Assessment and verification:

The applicant shall provide a declaration of compliance with this sub-criterion, signed by the manufacturer of the release liner, supported by safety data sheets.

[Note:]

[6] Silicone mixture is intended here as the liquid mixture composed of two or more silicone raw materials that is used as a coating on the protective paper or the protective film used for the release liner on some feminine hygiene products (e.g. panty liners and sanitary towels) or on nappy tapes

7.3.8. Other chemicals of concern

This sub-criterion applies to impurities in the final product. The following chemicals shall not be present in the final product in a concentration higher than what indicated in Table 9.

Table 9

<table>
<thead>
<tr>
<th>Substances</th>
<th>Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>&lt; 16 ppm</td>
</tr>
<tr>
<td>Dibenzo-p-dioxins (PCDDs): 2,3,7,8-TCDD; 1,2,3,7,8-TeCDD; 1,2,3,4,7,8-HxCDF; 1,2,3,4,6,7,8-HpCDD; OCDD</td>
<td></td>
</tr>
<tr>
<td>Dibenzofurans (PCDFs): 2,3,7,8-TCDF; 1,2,3,7,8-TeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-HxCDF; 1,2,3,6,7,8-HeCDF; 1,2,3,7,8-9-HxCDF; 1,2,3,4,6,7,8-HpCDF; 1,2,3,4,7,8,9-HpCDD; OCDF</td>
<td>sum TEQ of the detected congeners of PCDDs, PCDFs and DLPCBs &lt; 2 ng/kg</td>
</tr>
<tr>
<td>DLPCBs: PCB 77; PCB 81; PCB 126; PCB 169; PCB 105; PCB 114; PCB 118; PCB 123; PCB 156; PCB 157; PCB 167; PCB 189</td>
<td></td>
</tr>
</tbody>
</table>
### Substances Restrictions

<table>
<thead>
<tr>
<th>Substances</th>
<th>Restrictions</th>
</tr>
</thead>
</table>
| **PAHs** | Each PAH < 0.2 mg/kg  
Sum PAHs < 1 mg/kg |
| Benzo[a]anthracene; Benzo[a]pyrene; Benzo[e]pyrene; Chrysene; Benzo[b]fluoranthene; Benzo[k]fluoranthene; Dibenzo[a,h] anthracene; Benzo[j]fluoranthene; Benzo[g,h,i]perylene; Indeno [1,2,3.cd]pyrene; Phenanthrene; Pyrene; Anthracene; Fluoranthene; Naphthalene | |
| **Phenols** | <0.02 % |
| Bisphenol A | |
| Nonylphenol-di-ethoxylate | <10 mg/kg |
| Nonylphenol | <10 mg/kg |
| **Phthalates** | <0.01 % each |
| DINP, DEHP, DNOP, DIDP, BBP, DBP, DiBP, DIHP, BMEP, DPP/DIPP, DnPP; DnHP; DMP; DnHUP; DCHP; DnHxP; DIOP; DnPrP; DN| |
| Pesticides | <0.5 mg/kg |
| Glyphosate | |
| AMPA | <0.5 mg/kg |
| Quintozene | <0.5 mg/kg |
| Hexachlorobenzene | <0.5 mg/kg |
| **Organotins** | <2 ppb |
| Tributyltin | |
| Other organotins: Monobutyltin; Dibutyltin; Triphenyltin; D| |
| Dioctyltin; Monooctyltin | Each organotin <10 ppb |
| **Heavy metals** | |
| Antimony | <30 mg/kg |
| Cadmium | <0.1 mg/kg |
| Chromium | <1 mg/kg |
| Lead | <0.2 mg/kg |
| Mercury | <0.02 mg/kg |

### Assessment and verification:

The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant.

In addition, the applicant shall provide the results of the analyses performed on the final product. The tests shall be carried out on a representative product. In the case of identically produced products (e.g. hygiene products of different sizes), it is sufficient to carry out tests on one of the product sizes. Alternatively, the analyses can be performed separately on each of the material composing the final (representative) product. The methods used and the date of the measurement for the analyses shall be described, including the information of the laboratories used for the analysis. Recommended test methods are NWSP 360.1R0 or equivalent for the sample preparation, NWSP 360.2R0 or equivalent for the analyte extraction, and NWSP 360.3R0 or equivalent for the instrumental analysis. The frequency of the measurement shall be at least once a year.
Criterion 8. Packaging

This criterion sets requirements for sales and grouped packaging.

Grouped packaging shall be avoided or made of only cardboard and/or paper.

(a) Cardboard and/or paper used for packaging

Sales packaging made of cardboard and/or paper shall contain a minimum 40% of recycled material.

Grouped packaging made of cardboard and/or paper shall contain a minimum 80% of recycled material.

The remaining share (100% minus recycled content percentage) of cardboard and/or paper used for the sales and grouped packaging shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The certification bodies issuing Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

(b) Plastic used for packaging

— Until 31 December 2026, sales packaging made of plastic shall contain a minimum 20% recycled material.

— From 1 January 2027, sales packaging made of plastic shall contain a minimum 35% recycled material.

(c) Recyclability

The content of the sales packaging (either cardboard and/or paper or plastic) and grouped packaging (cardboard and/or paper) that is available for recycling shall be a minimum of 95% by weight, while 5% residuals shall be compatible with recycling.

(d) Additional requirements

— Utilisation of composite packaging (sales and grouped), mixed plastics or the coating of the cardboard and/or paper with plastics or metals are not allowed.

— Recycled content and recyclability of sales and grouped packaging shall be indicated on the sales packaging.

Assessment and verification:

The applicant shall submit (1) a signed declaration of compliance specifying the percentages of recycled content in the sales and grouped packaging when relevant; (2) a declaration of compliance specifying the recyclability of the sales and grouped packaging; and (3) a high resolution photograph of the sales packaging where information regarding recycled content and recyclability of the sales and grouped packaging appears clearly.

Competent bodies shall check the declaration of compliance specifying the percentages of plastic recycled content for sales packaging again after 1 January 2027.

The applicant shall provide audited accounting documents that demonstrate that the remaining share (100% minus recycled content percentage) of the cardboard and/or paper used for the sales and grouped packaging is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel licence. Competent bodies shall check the accounting documents again 12 months after the awarding of the EU Ecolabel licence.

Recycled content shall be verified by complying with the EN 45557 or ISO 14021 while recyclability shall be verified by complying with the EN 13430 or ISO 18604.

Plastic recycled content in the packaging shall comply with chain of custody standards such as ISO 22095 or EN 15343. Equivalent methods may be accepted if considered equivalent by a third-party, and shall be accompanied by detailed explanations showing compliance with this requirement and related supporting documentation. Invoices demonstrating the purchase of the recycled material shall be provided.
In addition, recyclability (availability and compatibility for recycling) of the packaging shall be tested by means of standard testing protocols. Cardboard and/or paper packaging recyclability shall be assessed through repulpability testing and in this case, the applicant shall demonstrate cardboard and/or paper packaging repulpability supported by the result(s) of test report(s) according to the PTS method PTS-RH 021, the ATICELCA 501 evaluation system or equivalent standard methods that are accepted by the competent body as providing data of equivalent scientific quality. Segregation schemes or controlled blending schemes like RecyClass shall be accepted as independent third-party certification for plastic packaging. Equivalent testing methods may be accepted if considered equivalent by a third-party.

**Criterion 9. Guidance on the use and on the disposal of the product and of the packaging**

Instructions for the use of the final product shall be made available on the packaging or through a printed and/or digital leaflet.

The sales packaging shall contain guidance regarding disposal of the sales packaging, the grouped packaging (if any), the separate components and for the disposal of the used product. The following information shall be written or indicated through visual symbols on the sales packaging:

— that the sales packaging, the grouped packaging (if any), the separate components and the used product shall not be flushed into toilets, and

— how to correctly dispose of the sales packaging, the grouped packaging (if any), the separate components and the used product.

**Assessment and verification:**

The applicant shall provide a high resolution photograph of the instructions for use of the product.

The applicant shall provide a high resolution photograph of the sales packaging, where information regarding disposal appears clearly.

**Criterion 10. Fitness for use and quality of the product**

The effectiveness/quality of the final product shall be satisfactory and at least equivalent to that of products already on the market.

Fitness for use shall be tested with respect to the characteristics and the parameters reported in Table 10. Performance thresholds shall be matched, where these have been identified.

**Table 10**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Testing practice required (performance threshold)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baby diapers</td>
</tr>
<tr>
<td>In-use tests</td>
<td></td>
</tr>
<tr>
<td>U1. Absorption and leakage protection (f)</td>
<td>Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)</td>
</tr>
<tr>
<td>U2. Skin dryness</td>
<td>Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)</td>
</tr>
<tr>
<td>U3. Fit and comfort</td>
<td>Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)</td>
</tr>
<tr>
<td>U4. Overall performance</td>
<td>Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)</td>
</tr>
</tbody>
</table>
### Technical tests

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Testing practice required (performance threshold)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1. Absorption</td>
<td>Baby diapers: Absorption rate and absorption before leakage</td>
</tr>
<tr>
<td>and leakage</td>
<td>Feminine care pads: Syngina method</td>
</tr>
<tr>
<td>protection ()</td>
<td>Tampons: As for baby diapers and feminine care pads</td>
</tr>
<tr>
<td>T2. Skin</td>
<td>Nursing pads: As for baby diapers and feminine care pads</td>
</tr>
<tr>
<td>dryness ()</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

(*) Panty liners intended to protect the feminine lingerie (light panty liners) are derogated from these requirements.

### Assessment and verification:

A test report shall be provided for in-use and technical tests. The test report shall describe, as a minimum, the test methods, test results and data used. Tests shall be carried out by laboratories certified to implement quality management systems.

Tests shall be conducted for all the specific type and size of products for which the EU Ecolabel application is made. Nevertheless, if it can be demonstrated that products have the same performance, only one size or a representative mix of sizes per each product design shall be tested.

Special care shall be taken regarding sampling, transport and storage of the products to guarantee reproducible results. It is recommended not to blind products or repack them in neutral packaging due to the risk of altering the performance of products and/or packaging, unless alteration can be excluded.

Information on testing shall be made available to the competent bodies under the respect of confidentiality. Test results shall be clearly explained and presented in language, units and symbols that are understandable to the data user. The following elements shall be specified: place and date of the tests; criteria used to select the products tested and their representativeness; selected testing characteristics and, if applicable, the reasons why some were not included; test methods used and their limitations if any. Clear guidelines on the use of test results shall be provided.

### Additional guidelines for in-use tests:

- Sampling, test design, panel recruitment and the analysis of test results shall comply with standard statistical practices (AFNOR Q 34-019, ASTM E1958-07e1 or equivalent).

- Each product shall be assessed on the basis of a questionnaire. The test is to last at least 72 hours, a full week when possible, and shall be realised in normal conditions of use of the product.

- The recommended number of testers shall be at least 30 (for products specifically designed or not for one gender). All the individuals participating to the survey shall be current users of the specific type/size of product tested.

- When the product is not designed specifically for a single gender, the ratio of male to female individuals shall be 1:1.

- A mixture of individuals representing proportionally different groups of consumers available on the market shall take part to the survey. Age, countries and genders shall be clearly stated.

- Sick individuals and those with a chronic skin condition shall not participate in the test. In cases where individuals become ill during the user trial, this is to be indicated on the questionnaire and the answers shall not be taken into consideration for the assessment.

- For all in-use tests (absorption and leakage protection, skin dryness, fit and comfort and overall performance), 80 % of the consumers testing the product shall rate the performance as satisfactory, with a rate above 60 assigned by the consumer (on a quantitative scale from 1 to 100). Alternatively, 80 % of the consumers testing the product shall rate it as good or very good (among five qualitative options: very poor, poor, average, good, very good).

- The results shall be statistically evaluated after the user trial has been completed.

- External factors such as branding, market shares and advertising that may have an impact on the perceived performance of the products shall be communicated.
Additional requirements for technical tests:

— Test methods shall be based as much as possible on product-relevant, reproducible and rigorous methods.

— A minimum of five samples shall be tested. Average results shall be reported together with indication of the standard deviation.

— Technical tests recommended for nursing pads are the same as for baby diapers and for feminine care pads.

Weight, dimensions and design features of the product shall be described and provided in accordance with information provided in the application general assessment and verification text.

**Criterion 11. Corporate Social Responsibility with regard to labour aspects**

This criterion sets requirements applying to the final absorbent hygiene product assembly site.

Having regard to the International Labour Organisation’s (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy (**21**), the UN Global Compact (Pillar 2) (**22**), the UN Guiding Principles on Business and Human Rights (**23**) and the OECD Guidelines for Multinational Enterprises (**24**), the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the aforementioned international texts and the supplementary provisions below have been respected at the final assembly site for the product.

Fundamental conventions of the ILO:

(i) Child Labour:

— Minimum Age Convention, 1973 (No 138)

— Worst Forms of Child Labour Convention, 1999 (No 182)

(ii) Forced and Compulsory Labour:

— Forced Labour Convention, 1930 (No 29) and 2014 Protocol to the Forced Labour Convention

— Abolition of Forced Labour Convention, 1957 (No 105)

(iii) Freedom of Association and Right to Collective Bargaining:

— Freedom of Association and Protection of the Right to Organise Convention, 1948 (No 87)

— Right to Organise and Collective Bargaining Convention, 1949 (No 98)

(iv) Discrimination:

— Equal Remuneration Convention, 1951 (No 100)

— Discrimination (Employment and Occupation) Convention, 1958 (No 111)

Supplementary provisions:

(v) Working Hours:

— ILO Hours of Work (Industry) Convention, 1919 (No 1)

— ILO Weekly Rest (Industry) Convention, 1921 (No 14)

(vi) Remuneration:

— ILO Minimum Wage Fixing Convention, 1970 (No 131)

— ILO Holidays with Pay Convention (Revised), 1970 (No 132)

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**Notes:**

(**21**) ILO NORMLEX (http://www.ilo.org/dyn/normlex/en) and supporting guidance.


— Living wage: The applicant shall ensure that wages (excluding any taxes, bonuses, allowances, or overtime wages) paid for a normal work week (not exceeding 48 hours) shall be sufficient to afford basic needs (housing, energy, nutrition, clothing, health care, education, potable water, childcare, and transportation) of worker and of a family of four people, and to provide some discretionary income. Implementation shall be audited with reference to the SA8000 (*) guidance on ‘Remuneration’.

(vii) Health & Safety:

— ILO Safety in the use of chemicals at work Convention, 1981 (No 170)
— ILO Occupational Safety and Health Convention, 1990 (No 155)
— ILO Working Environment (Air Pollution, Noise and Vibration) Convention, 1977 (No 148)

(viii) Social protection and inclusion:

— ILO Medical Care and Sickness Benefits Convention, 1969 (No 130)
— ILO Social Security (Minimum Standards) Convention, 1952 (No 102)
— ILO Employment Injury Benefits Convention, 1964 (No 121)
— ILO Equality of Treatment (Accident Compensation) Convention, 1925 (No 19)
— ILO Maternity Protection Convention, 2000 (No 183)

(ix) Fair dismissal:

— ILO Termination of Employment Convention, 1982 (No 158).

In locations where the right to freedom of association and collective bargaining are restricted under law, the company shall not restrict workers from developing alternative mechanisms to express their grievances and protect their rights regarding working conditions and terms of employment, and shall recognise legitimate employee associations with whom it can enter into dialogue about workplace issues.

The audit process shall include consultation with external industry-independent organisation stakeholders in local areas around sites, including trade unions, community organisations, NGOs and labour experts. Meaningful consultations shall take place with at least two stakeholders from two different subgroups. In locations where national law cannot ensure adequacy of corporate social responsibility with the aforementioned international conventions, the audit process shall include third-party site audits composed of unannounced spot inspections by industry-independent evaluators.

During the validity period of the EU Ecolabel licence, the applicant shall publish the aggregated results and key findings from the audits (including details on (a) how many and how serious violations of each labour rights and OHS standard; (b) strategy for remediation – where remediation includes prevention per UNGP concept; (c) assessment of root causes of persistent violations resulting from stakeholder consultation – who was consulted, what issues were raised, how did this influence the corrective action plan), online in order to provide evidence of their performance to interested consumers.

Assessment and verification:

The applicant shall demonstrate compliance with the requirements by providing copies of the most recent version of their code of conduct which shall be consistent with the provisions specified above and copies of the supporting audit reports for each final product assembly plant for the model(s) to be ecolabelled, together with a web link to where online publication of the results and findings can be found.

Third-party site audits shall be carried out by auditors qualified to assess the compliance of the industry manufacturing sites with social standards or codes of conduct or, in countries where the ILO Labour Inspection Convention, 1947 (No 81) has been ratified and ILO supervision indicates that the national labour inspection system is effective (**) and where the scope of the inspection systems covers the areas listed above (**), by labour inspector(s) appointed by a public authority.

(**) Please, refer to the footnote 21.
(*** Please, refer to the footnote 21.
Valid certifications from third-party schemes or inspection processes that audit compliance with the applicable principles of the listed fundamental ILO Conventions and the supplementary provisions on working hours, remuneration and health & safety and consultation with external stakeholders, shall be accepted. These certifications shall be not more than 12 months old, on the date of application.

**Criterion 12. Information appearing on the EU Ecolabel**

The EU Ecolabel logo may be displayed on the sales packaging of the product. If the optional label with text box is used, it shall contain the following three statements:
- 'Designed to reduce impact on the environment',
- 'Fulfils strict requirements on harmful substances',
- 'Verified performance'.

The applicant shall follow the instructions on how to use the EU Ecolabel logo as provided in the EU Ecolabel Logo Guidelines:

**Assessment and verification:**

The applicant shall provide a declaration of compliance with the requirement and a high resolution photograph of the product sales packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.
ANNEX II

EU Ecolabel criteria for awarding the EU Ecolabel to reusable menstrual cups

The EU Ecolabel criteria target the best reusable menstrual cups on the market, in terms of environmental performance. The criteria focus on the main environmental impacts associated with the life cycle of these products and promote circular economy aspects.

Assessment and verification requirements

For the EU Ecolabel to be awarded to a specific product, the product shall comply with each requirement. The applicant shall provide a written confirmation stating that all the criteria are fulfilled.

Specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or their supplier(s) as appropriate.

Competent bodies shall preferentially recognise attestations that are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories, and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

Changes in suppliers and production sites pertaining to products to which the EU Ecolabel has been awarded shall be notified to competent bodies, together with supporting information to enable verification of continued compliance with the criteria.

As pre-requisite, the product shall meet all respective legal requirements of the country or countries in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.

The following information shall be provided together with the application for the EU Ecolabel:

(a) a description of the product, together with the weight of the individual product units and the total weight of the product;
(b) a description of the sales packaging, together with its total weight, if applicable;
(c) a description of the grouped packaging, together with its total weight, if applicable;
(d) a description of the separate components, together with their individual weight;
(e) the components, materials and all substances used in the product with their respective weights and, whenever applicable, their respective CAS numbers.

For the purposes of this Annex, the following definitions shall apply:

(1) ‘additives’ means substances added to components, materials or the final product in order to improve or preserve some of its characteristics;
(2) ‘composite packaging’ means a unit of packaging made of two or more different materials, excluding materials used for labels, closures and sealing, which cannot be separated manually and therefore form a single integral unit;
(3) ‘grouped packaging’, also known as secondary packaging, means packaging conceived so as to constitute a grouping of a certain number of sales units at the point of sale whether the latter is sold as such to the end user or it serves only as a means to replenish the shelves at the point of sale or create a stock-keeping or distribution unit, and which can be removed from the product without affecting its characteristics;
(4) ‘impurities’ means residuals, pollutants, contaminants etc. from production, including the production of raw materials, that remain in the raw material/ingredient and/or in the chemical product (used in the final product and any component therein) in concentrations less than 100 ppm (0.0100 %w/w, 100 mg/kg);
(5) ‘ingoing substance’ means all substances included in the chemical product (used in the final product and any component therein), including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances in stabilized manufacturing conditions (e.g. formaldehyde and arylamine) are also considered as ingoing substances;

(6) ‘packaging’ means items of any materials that are intended to be used for the containment, protection, handling, delivery or presentation of products and that can be differentiated into packaging formats based on their function, material and design, including:

(a) items that are necessary to contain, support or preserve the product throughout its lifetime without being an integral part of the product which is intended to be used, consumed or disposed of together with the product;

(b) components of, and ancillary elements to, an item referred to in point (a) that are integrated into the item;

(c) ancillary elements to an item referred to in point (a) that are hung directly on, or attached to, the product and that perform a packaging function without being an integral part of the product which is intended to be used, consumed or disposed of together with the product; etc.;

(7) ‘plastic materials’, also referred to as ‘plastics’, means polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006, to which additives or other substances may have been added, and which are capable of functioning as main structural components of final products and/or packaging, with the exception of natural polymers that have not been chemically modified;

(8) ‘polymer’ means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition, a ‘monomer unit’ means the reacted form of a monomer substance in a polymer, as defined in Regulation (EC) No 1907/2006;

(9) ‘recyclability’ means the amount (mass or percentage) of an item available for recycling;

(10) ‘recycled content’ means the amount of an item (by area, length, volume or mass) sourced from post-consumer and/or post-industrial recycled material. Item can refer to the product or packaging in this case;

(11) ‘recycling’ means, in accordance with Article 3 of Directive 2008/98/EC, any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and the reprocessing into materials that are to be used as fuels or for backfilling operations;

(12) ‘sales packaging’, also known as primary packaging, means packaging conceived so as to constitute a sales unit consisting of products and packaging to the final user or consumer at the point of sale;

(13) ‘separate component’, also known as additional component, means a packaging component that is distinct from the main body of the packaging unit, which may be of a different material, that needs to be disassembled completely and permanently from the main packaging unit in order to access the product, and that is typically discarded prior to and separately from the packaging unit. In the case of reusable menstrual cups, it is any component (with protective or hygienic function) that is removed before the use of the product, e.g. the bag/pouch the menstrual cups are usually sold with;

(14) ‘substances identified to have endocrine disrupting properties’, also referred to as endocrine disruptors, means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 (candidate list of substances of very high concern for authorisation), or Regulation (EU) No 528/2012 or Regulation (EC) No 1107/2009, or Regulation (EC) No 1272/2008;
(15) ‘synthetic polymers’ means macromolecular substances other than cellulose pulp intentionally obtained either by:

(a) a polymerisation process such as poly-addition or poly-condensation or by any other similar process of combination of monomers and other starting substances;

(b) chemical modification of natural or synthetic macromolecules;

(c) microbial fermentation.

**Criterion 1. Emissions during the production of the raw material**

1.1. *Emissions of dust and of chlorides to air*

(a) Emissions of dust

(i) This requirement applies to silicones only.

The storage and handling of the elemental silicon raw material shall use at least one of the following techniques:

— Storing of elemental silicon in silos (after grinding);

— Storing of elemental silicon in covered areas protected from rain and wind (after grinding);

— Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon into storage (after grinding);

— Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.

(ii) This requirement applies to both silicones and other elastomers.

The yearly average of channelled emissions of dust shall be below 5 mg/Nm$^3$. The dust emissions should be continuously monitored.

(b) Emissions of chlorides

(i) This requirement applies to silicones only.

The off-gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. Burning of chlorinated compounds shall be authorised in the thermal oxidation process.

(ii) This requirement applies to elastomers other than silicones.

Polychlorinated dibenzodioxins (PCDDs) and dibenzofurans (PCDF) emissions shall be below 0.01 ng TEQ/Nm$^3$ (average over the sampling period). Monitoring of the PCDD/F emissions should take place every six months.

**Assessment and verification:**

The applicant shall provide a declaration of compliance from the raw material supplier with criterion 1.1. In addition, the declaration shall demonstrate compliance with:

— criterion 1.1(a)(i), the silicone supplier shall indicate which technique is used on site, providing pictures or technical descriptions, as supplementary data;

— criterion 1.1(a)(ii), the raw material supplier shall provide the results of the dust measurements taken on site, together with the yearly average of the dust emission. Methods accepted are EN 15267-1, EN 15267-2, EN 15267-3, EN 15267-4, EN 13284-1 and EN 13284-2. For the production of silicones, the measurement shall cover grinding, storage and handling of elemental silicon as a minimum;

— criterion 1.1(b)(i), the silicone supplier shall provide details on the processing of the off-gases from the methyl chloride, direct synthesis and distillation steps;

— criterion 1.1(b)(ii), the raw material supplier shall provide the results of the PCDD/F emissions measurements of the treated gases. Methods accepted are EN 1948-1, EN 1948-2 and EN 1948-3.
1.2. **Emissions of copper and of zinc to water**

This criterion applies to silicones only.

The water effluents from the polydimethylsiloxane (PDMS) production step shall be pre-treated by precipitation or flocculation under alkaline conditions, followed by sedimentation and filtration. This shall include:

(a) dewatering of the sludge before disposal; and

(b) recovering of the solid metal residues in metal recovery plants.

The concentration of copper in the treated effluent shall be below 0.5 mg/l, while the concentration of zinc shall be below 2 mg/l.

**Assessment and verification:**

The applicant shall provide a declaration of compliance from the silicone supplier with criterion 1.2, together with a proof that the plant has in place a wastewater system consisting of a precipitation/flocculation step followed by a sedimentation step. Moreover, the silicone supplier shall provide the measurement results for copper and zinc in the treated effluent.

1.3. **Emissions of CO\(_2\)**

This criterion applies to silicones only.

CO\(_2\) emissions from the production of the silicone shall not exceed 6.58 kg per kg silicone, including emissions from the production of electricity (whether on-site or off-site). CO\(_2\) emissions shall include all sources of non-renewable energy used during the production of the silicone. Reference emission values according to Table 1 shall be used for the calculation of CO\(_2\) emission from energy sources. If needed, CO\(_2\) emission factors for other energy sources can be found in Annex VI to Regulation (EU) 2018/2066, whereas the CO\(_2\) emission factors for grid electricity should be in line with Delegated Regulation (EU) 2019/331.

**Table 1**

*Reference values for CO\(_2\) emissions from different energy sources*

<table>
<thead>
<tr>
<th>Fuel</th>
<th>CO(_2) emissions</th>
<th>Unit</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coal</td>
<td>94.6</td>
<td>g CO(_2) fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>Crude oil</td>
<td>73.3</td>
<td>g CO(_2) fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>Fuel oil 1</td>
<td>74.1</td>
<td>g CO(_2) fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>Fuel oil 2-5</td>
<td>77.4</td>
<td>g CO(_2) fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>LPG</td>
<td>63.1</td>
<td>g CO(_2) fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>Natural Gas</td>
<td>56.1</td>
<td>g CO(_2) fossil/MJ</td>
<td>Regulation (EU) 2018/2066</td>
</tr>
<tr>
<td>Grid Electricity</td>
<td>376</td>
<td>g CO(_2) fossil/kWh</td>
<td>Regulation (EU) 2019/331</td>
</tr>
</tbody>
</table>

**Assessment and verification:**

The applicant shall provide data and detailed calculations for the CO\(_2\) emissions from the production of the silicone. The CO\(_2\) emission data shall include all sources of energy used during the production of the raw material, including the emissions from the production of electricity (whether on-site or off-site).
When calculating CO\(_2\) emissions, the amount of energy from renewable sources purchased and used for the production processes shall count as zero CO\(_2\) emission. For biomass combustion, this means that the biomass needs to fulfil the relevant sustainability and greenhouse gas savings criteria as specified in the Directive (EU) 2018/2001. The applicant shall provide appropriate documentation that this kind of energy is actually used at the plant or has been externally purchased (copy of the contract and an invoice indicating the renewable share of the purchased electricity).

The period for the calculations and/or mass balances shall be based on the production over 12 months. The calculations shall be repeated on a yearly basis. In case of a new or a rebuilt production plant, the calculations shall be based on at least 45 subsequent days of stable running of the plant. The calculations shall be representative of the respective campaign.

For the grid electricity, the value provided above (the European average) shall be used unless the applicant presents documentation establishing the specific value for its suppliers of electricity (contract for specified electricity or certified electricity). In this case, the applicant may use this value instead of the value quoted. The documentation used as proof of compliance shall include technical specifications that indicate the average value (e.g. copy of a contract).

**Criterion 2. Environmental management of production**

All plants producing either raw materials (silicone or other elastomers) or the final products shall have systems for the implementation of:

(a) water-savings. The water management system shall be documented or explained and shall include information on at least the following aspects: monitoring of water flows; proof of circulating water in closed systems; and continuous improvement objectives and targets relating to the reduction of wastewater generation and optimisation rates (if relevant, i.e. if water is used in the plant);

(b) integrated waste management, in form of a plan to prioritise treatment options other than disposal for all the waste generated at the manufacturing facilities and to follow the waste hierarchy in relation to prevention, reuse, recycling, recovery and final disposal of waste. The waste management plan shall be documented or explained and shall include information on at least the following aspects: separation of different waste fractions; handling, collection, separation and use of recyclable materials from the non-hazardous waste stream; recovery of materials for other uses; handling, collection, separation and disposal of hazardous waste, as defined by the relevant local and national regulatory authorities; and continuous improvement objectives and targets relating to waste prevention, reuse, recycling and, recovery of waste fractions that cannot be prevented (including energy recovery);

(c) optimisation of energy efficiency and energy management. The energy management system shall address all energy consuming devices, including machinery, lighting, air conditioning and cooling. The energy management system shall include measures for the improvement of energy efficiency and shall include information on at least the following aspects: establishing and implementing an energy data collection plan in order to identify key energy figures; analysis of energy consumption that includes a list of energy consuming systems, processes and facilities; identification of measures for more efficient use of energy; continuous improvement objectives and targets relating to the reduction of energy consumption.

**Assessment and verification:**

The applicant shall provide a declaration of compliance with the criterion from (1) the producer of raw materials (silicone or other elastomers); and (2) from the manufacturer of reusable menstrual cups. The declaration shall be supported by a report describing in detail the procedures adopted by the suppliers in order to fulfil the requirements for each of the sites concerned in accordance with standards, such as ISO 14001 and/or ISO 50001 for water, waste and energy plans.

If waste management is outsourced, the sub-contractor shall provide a declaration of compliance with this criterion as well.

Applicants registered with EU Eco-Management and Audit Scheme (EMAS) and/or certified according to ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme shall be considered as having fulfilled these requirements if:

(a) the inclusion of water, waste and energy management plans for the production site(s) is documented in the company's EMAS environmental statement; or
(b) the inclusion of water, waste and energy management plans for the production site(s) is sufficiently addressed by the ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme.

**Criterion 3. Material efficiency in the manufacturing of the final product**

The requirements in this criterion shall apply to the final product manufacturing site.

The quantity of waste generated during the manufacturing and packaging of the end products which is sent to landfill or incineration without energy recovery, shall not exceed 4% by weight of the end products.

**Assessment and verification:**

The applicant shall confirm compliance with the above requirement.

The applicant shall provide evidence of the quantity of waste that has not been reused within the manufacturing process or that is not converted into materials and/or energy.

The applicant shall present all of the following:

(a) the weight of the product and of the packaging,

(b) all the waste streams generated during the manufacture, and

(c) the respective treatment processing of the fraction of recovered waste and that disposed of to landfill or incineration.

The quantity of waste sent to landfill or to incineration without energy recovery shall be calculated as the difference between the amount of waste produced and the amount of waste recovered (reused, recycled, etc.).

**Criterion 4. Excluded and restricted substances**

4.1. **Restrictions on substances classified under Regulation (EC) No 1272/2008**

This criterion applies to the final product and any components therein.

Unless derogated in Table 4, the final product and any components therein shall not contain ingoing substances (alone or in mixtures) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 2, in accordance with Regulation (EC) No 1272/2008.

**Table 2**

<table>
<thead>
<tr>
<th>Excluded hazard classes, categories and associated hazard statement codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenic, mutagenic or toxic for reproduction</td>
</tr>
<tr>
<td>Categories 1A and 1B</td>
</tr>
<tr>
<td>H340 May cause genetic defects</td>
</tr>
<tr>
<td>H350 May cause cancer</td>
</tr>
<tr>
<td>H350i May cause cancer by inhalation</td>
</tr>
<tr>
<td>H360F May damage fertility</td>
</tr>
<tr>
<td>H360D May damage the unborn child</td>
</tr>
<tr>
<td>H360FD May damage fertility. May damage the unborn child</td>
</tr>
<tr>
<td>H360Fd May damage fertility. Suspected of damaging the unborn child</td>
</tr>
<tr>
<td>H360Df May damage the unborn child. Suspected of damaging fertility</td>
</tr>
<tr>
<td>Category 2</td>
</tr>
<tr>
<td>H341 Suspected of causing genetic defects</td>
</tr>
<tr>
<td>H351 Suspected of causing cancer</td>
</tr>
<tr>
<td>-</td>
</tr>
<tr>
<td>H361f Suspected of damaging fertility</td>
</tr>
<tr>
<td>H361d Suspected of damaging the unborn child</td>
</tr>
<tr>
<td>H361fd Suspected of damaging fertility. Suspected of damaging the unborn child</td>
</tr>
<tr>
<td>H362 May cause harm to breast fed children</td>
</tr>
</tbody>
</table>
### Acute toxicity

<table>
<thead>
<tr>
<th>Category 1 and 2</th>
<th>Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>H300 Fatal if swallowed</td>
<td>H301 Toxic if swallowed</td>
</tr>
<tr>
<td>H310 Fatal in contact with skin</td>
<td>H311 Toxic in contact with skin</td>
</tr>
<tr>
<td>H330 Fatal if inhaled</td>
<td>H331 Toxic if inhaled</td>
</tr>
<tr>
<td>H304 May be fatal if swallowed and enters airways</td>
<td>EUH070 Toxic by eye contact</td>
</tr>
</tbody>
</table>

### Specific target organ toxicity

<table>
<thead>
<tr>
<th>Category 1</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>H370 Causes damage to organs</td>
<td>H371 May cause damage to organs</td>
</tr>
<tr>
<td>H372 Causes damage to organs through prolonged or repeated exposure</td>
<td>H373 May cause damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>

### Respiratory and skin sensitisation

<table>
<thead>
<tr>
<th>Category 1A</th>
<th>Category 1B</th>
</tr>
</thead>
<tbody>
<tr>
<td>H317 May cause allergic skin reaction</td>
<td>H317 May cause allergic skin reaction</td>
</tr>
<tr>
<td>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled</td>
<td>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled</td>
</tr>
</tbody>
</table>

### Endocrine disruptors for human health and the environment

<table>
<thead>
<tr>
<th>Category 1</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUH380: May cause endocrine disruption in humans</td>
<td>EUH381: Suspected of causing endocrine disruption in humans</td>
</tr>
<tr>
<td>EUH430: May cause endocrine disruption in the environment</td>
<td>EUH431: Suspected of causing endocrine disruption in the environment</td>
</tr>
</tbody>
</table>

### Persistent, Bioaccumulative and Toxic

<table>
<thead>
<tr>
<th>PBT</th>
<th>vPvB</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUH440: Accumulates in the environment and living organisms including in humans</td>
<td>EUH441: Strongly accumulates in the environment and living organisms including in humans</td>
</tr>
</tbody>
</table>

### Persistent, Mobile and Toxic

<table>
<thead>
<tr>
<th>PMT</th>
<th>vPvM</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUH450: Can cause long-lasting and diffuse contamination of water resources</td>
<td>EUH451: Can cause very long-lasting and diffuse contamination of water resource</td>
</tr>
</tbody>
</table>

Moreover, the final product and any components therein shall not contain ingoing substances (alone or in mixtures) in concentrations greater than 0,010 % (weight by weight) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 3, in accordance with Regulation (EC) No 1272/2008 – unless derogated in Table 4.
Table 3

**Restricted hazard classes, categories and associated hazard statement codes**

<table>
<thead>
<tr>
<th>Hazardous to the aquatic environment</th>
<th>Hazardous to the ozone layer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Categories 1 and 2</td>
<td>H420 Harms public health and the environment by destroying ozone in the upper atmosphere</td>
</tr>
<tr>
<td>H400 Very toxic to aquatic life</td>
<td></td>
</tr>
<tr>
<td>Category 3 and 4</td>
<td></td>
</tr>
<tr>
<td>H412 Harmful to aquatic life with long-lasting effects</td>
<td></td>
</tr>
<tr>
<td>H410 Very toxic to aquatic life with long-lasting effects</td>
<td></td>
</tr>
<tr>
<td>H413 May cause long-lasting effects to aquatic life</td>
<td></td>
</tr>
<tr>
<td>H411 Toxic to aquatic life with long-lasting effects</td>
<td></td>
</tr>
</tbody>
</table>

Table 4

**Derogations to restrictions on substances with a harmonised classification under Regulation (EC) No 1272/2008**

<table>
<thead>
<tr>
<th>Substance type</th>
<th>Derogated hazard class, category and hazard statement code</th>
<th>Derogation conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substances with a harmonised classification as H304</td>
<td>H304</td>
<td>Substances with a viscosity under 20.5 cSt at 40 °C.</td>
</tr>
<tr>
<td>Titanium dioxide (nano-form)</td>
<td>H351</td>
<td>Only when used as pigment. It cannot be used in powder or spray form</td>
</tr>
</tbody>
</table>

The hazard statement codes generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures shall apply.

The use of substances or mixtures that are chemically modified during the production process, so that any relevant hazard for which the substance or mixture has been classified under Regulation (EC) No 1272/2008 no longer applies, shall be exempted from the above requirement.

This criterion shall not apply to:

— substances not included in the scope of Regulation (EC) No 1907/2006 as defined in Article 2(2) of that Regulation,

— substances covered by Article 2(7)(b) of Regulation (EC) No 1907/2006, which sets out the criteria for exempting substances included in Annex V to that Regulation from the registration, downstream user and evaluation requirements.

**Assessment and verification:**

The applicant shall provide a signed declaration of compliance with sub-criterion 4.1, together with relevant declarations from the producers of the components, a list of all chemicals used, their safety data sheet or chemical supplier declaration and any relevant declarations that demonstrate the compliance with the requirement.
For restricted substances and unavoidable impurities with a restricted classification, the concentration of the restricted substance or impurity and an assumed retention factor of 100 %, shall be used to estimate the quantity of the restricted substance or impurity remaining in the final product. Impurities can be present in the chemical product up to 0,0100 % w/w. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

Justifications for any deviation from a retention factor of 100 % (e.g. solvent evaporation) or for chemical modification of a restricted impurity shall be provided.

For substances exempted from sub-criterion 4.1 (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to demonstrate compliance.

Since multiple products or potential products using the same process chemicals may be covered by one EU Ecolabel licence, the calculation only needs to be presented for each impurity for the worst-case product or component covered by the licence (e.g. the most heavily printed component article when screening for inks with restricted classifications).

The above evidence can also be provided directly to competent bodies by any supplier in the applicant’s supply chain.

4.2. **Substances of Very High Concern (SVHCs)**

This criterion applies to the final product and any components therein.

The final product and any components therein shall not contain ingoing substances (alone or in mixtures) that meet the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of that Regulation and included in the candidate list for substances of very high concern for authorisation.

**Assessment and verification**

The applicant shall provide a signed declaration that the final product and the components therein do not contain any SVHCs. The declaration shall be supported by safety data sheets of all supplied chemicals and materials used to produce the final product and the components therein.

The list of substances identified as SVHCs and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here:


Reference to the list shall be made on the submission date of the EU Ecolabel application.

For unavoidable impurities identified as SVHCs, the concentration of the impurity and an assumed retention factor of 100 %, shall be used to estimate the quantity of the SVHC impurity remaining in the final product. Impurities can be present in the chemical product up to 0,0100 % w/w. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

Justifications for any deviation from a retention factor of 100 % (e.g. solvent evaporation) or for chemical modification of a SVHC impurity shall be provided.

4.3. **Other specific restrictions**

4.3.1. **Specified excluded substances**

This criterion applies to the final product and any components therein.

The following substances shall not be added (alone or in mixtures) to the chemical product used in the final product nor in any components therein:

(a) 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT);
(b) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1];
(c) Antibacterial agents (e.g. nanosilver and triclosan);
(d) Formaldehyde and formaldehyde releasers;
(e) Methylisothiazolinone (MIT);
(f) Nitromusks and Polycyclic musks.
(g) Organotin compounds used as a catalyst in the production of silicone;
(h) Parabens;
(i) Phthalates;
(j) Substances identified to have endocrine disrupting properties;
(k) Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU’s priority list of substances that are to be investigated further for endocrine disruptive effects.

**Assessment and verification:**

The applicant shall provide a signed declaration of compliance with the sub-criterion, supported by declarations from suppliers, if relevant. The substances listed in this sub-criterion are only allowed as impurities, and nevertheless in concentrations lower than 0.0100 % w/w in the chemical product. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

[Note:


4.3.2. **Fragrances**

This criterion applies to the final product, any components therein, the separate components and the packaging.

Fragrances shall not be added to the final product, nor to any components therein, nor to the separate components, nor to the packaging.

**Assessment and verification:**

The applicant shall provide a signed declaration of compliance with the sub-criterion.

4.3.3. **Inks and dyes**

This sub-criterion applies to the final product and any components therein. This requirement does not apply to the separate components, the sales packaging and the information sheets.

The dying colorants and inks used in the reusable menstrual cup shall not exceed 2 % of total weight of the cup.

The content of antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, primary aromatic amines and polychlorinated biphenyl occurring as impurity in the dying colorants and inks shall be below the limits given in the Council of Europe’s Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food (†).

The dying colorants used shall moreover comply with BfR’s recommendations IX for Colorants for Plastics and other Polymers Used in Commodities (‡) or Swiss Ordinance 817.023.21 Annex 2 (§) and Annex 10 (¶).

The dying colorants and inks used shall also comply with sub-criteria 4.1 and 4.2.

**Assessment and verification:**

The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant, as well as documentation to ensure that impurities in the dying colorant or ink comply with the Council of Europe’s Resolution AP (89) 1, and that the used dyes and inks are authorised according to the BfR’s recommendations IX. Colorants for Plastics and other Polymers Used in Commodities, Swiss Ordinance 817.023.21 Annex 2 and Annex 10, or the BfR’s recommendation XXXVI. Paper and board for food contact.

(†) Please, refer to the footnote 16
(‡) Please, refer to the footnote 17
(§) Please, refer to the footnote 18
(¶) Please, refer to the footnote 19.
4.3.4. Cyclosiloxanes

This sub-criterion applies to the final product and any components therein.

Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and dodecamethyl-cyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the silicone raw materials in concentrations above 100 ppm (0.0100 % w/w). The 100 ppm limit is to be applied to each substance separately.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant.

Criterion 5. Packaging

This criterion sets requirements for sales and grouped packaging.

Grouped packaging shall be avoided or made only of cardboard and/or paper.

(a) Cardboard and/or paper used for packaging

Sales packaging made of cardboard and/or paper shall contain a minimum 40 % of recycled material.

Grouped packaging made of cardboard and/or paper shall contain a minimum 80 % of recycled material.

The remaining share (100 % minus recycled content percentage) of cardboard and/or paper used for the sales and grouped packaging shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The certification bodies issuing Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

(b) Plastic used for packaging

— Until 31 December 2026, sales packaging made of plastic shall contain a minimum 20 % recycled material.

— From 1 January 2027, sales packaging made of plastic shall contain a minimum 35 % recycled material.

(c) Recyclability

The content of the sales packaging (either cardboard and/or paper or plastic) and grouped packaging (cardboard and/or paper) that is available for recycling shall be a minimum of 95 % by weight, while 5 % residuals shall be compatible with recycling.

(d) Additional requirements

— Utilisation of composite packaging (sales and grouped), mixed plastics or the coating of the cardboard and/or paper with plastics or metals are not allowed.

— Recycled content and recyclability of sales and grouped packaging shall be stated on the sales packaging.

(e) Separate component: bag or pouch

Reusable menstrual cups shall be sold with a reusable bag or pouch made of 100 % certified sustainable fibres.

Assessment and verification:

The applicant shall submit (1) a signed declaration of compliance specifying the percentages of recycled content in the sales and grouped packaging when relevant; (2) a declaration of compliance specifying the recyclability of the sales and grouped packaging; and (3) a high resolution photograph of the sales packaging where information regarding recycled content and recyclability of the sales and grouped packaging appears clearly.

Competent bodies shall check the declaration of compliance specifying the percentages of plastic recycled content for sales packaging again after 1 January 2027.
The applicant shall provide audited accounting documents that demonstrate that the remaining share (100 % minus recycled content percentage) of the cardboard and/or paper used for the sales and grouped packaging is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel licence. Competent bodies shall check the accounting documents again 12 months after the awarding of the licence.

Recycled content shall be verified by complying with the EN 45557 or ISO 14021 while recyclability shall be verified by complying with the EN 13430 or ISO 18604.

Plastic recycled content in the packaging shall comply with chain of custody standards such as ISO 22095 or EN 15343. Equivalent methods may be accepted if considered equivalent by a third-party, and shall be accompanied by detailed explanations showing compliance with this requirement and related supporting documentation. Invoices demonstrating the purchase of the recycled material shall be provided.

In addition, recyclability (availability and compatibility for recycling) of the packaging shall be tested by means of standard testing protocols. Cardboard and/or paper packaging recyclability shall be assessed through repulpability testing and in this case, the applicant shall demonstrate cardboard and paper packaging repulpability supported by the result(s) of test report(s) according to the PTS method PTS-RH 021, the ATICELCA 501 evaluation system or equivalent standard methods that are accepted by the competent body as providing data of equivalent scientific quality. Segregation schemes or controlled blending schemes like RecyClass shall be accepted as independent third-party certification for plastic packaging. Equivalent testing methods may be accepted if considered equivalent by a third-party.

Moreover, the applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificate for the reusable bag or pouch. FSC, PEFC, OEKO-TEX, GOTS, or equivalent schemes shall be accepted as independent third-party certification.

**Criterion 6. Guidance on the disposal of the product and of the packaging**

The sales packaging shall contain guidance regarding disposal of the sales packaging, the grouped packaging (if any), the separate components and for the disposal of the used product. The following information shall be written or indicated through visual symbols on the sales packaging:

(a) that the sales packaging, the grouped packaging (if any), the separate components and the cup shall not be flushed into toilets; and

(b) how to dispose correctly the sales packaging, the grouped packaging (if any), the separate components and the cup at the end of its life.

**Assessment and verification:**

The applicant shall provide a high resolution photograph of the sales packaging, where information regarding disposal appears clearly.

**Criterion 7. Information on the use of the product**

The product shall be accompanied by instruction for its use. The manufacturer shall make sure that the user receives at least the following information:

(a) How to choose the right size of cup. Such information shall be placed where it can be accessed by the user before purchase (e.g. on the primary packaging).

(b) How to correctly wear the cup to avoid leakage and/or discomfort.

(c) How long to wear the cup before emptying it. Information on the longest wearing time shall be backed up by test studies. This information shall be given in a visible way, e.g. via a logo or in bold characters, and shall be placed both on the packaging and on the instructions for use.

(d) How to clean the cup before and after use during the same menstrual period, including, as a minimum, information about the importance of washing the hands, the need for boiling (yes/no, and if yes for how long), the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning. This information should be backed up by test studies.
(e) How to clean and store the cup between menstrual periods, including, as a minimum, information about the importance of washing the hands, the importance of boiling (and information on how long), the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning. This information should be backed up by test studies.

(f) How long it is possible to use the cup (the lifetime of the cup). It should moreover be stated that eventual discolouring of the cup has no influence on its lifetime and function.

(g) Information about the risk of developing toxic shock syndrome shall be provided.

Assessment and verification:

The applicant shall provide a sample of the information sheet/leaflet and, if relevant, the packaging sold with the cup displaying the information for the user. The applicant shall also provide relevant tests/studies, e.g. biological risk assessments or toxicology studies, supporting the above requirements.

Criterion 8. Fitness for use and quality of the product

The effectiveness/quality of the final product shall be satisfactory and at least equivalent to that of products already on the market.

Fitness for use shall be tested with respect to the characteristics and the parameters reported in Table 5. Performance thresholds shall be matched, where these have been identified.

Fitness for use shall be tested with respect to the technical tests referred to as for biocompatibility of the materials used for the manufacturing of reusable menstrual cups. Biocompatibility test shall provide the biological evaluation of cytotoxicity, pyrogenicity, sensitization, dermal irritation and implantation (90 days).

Table 5

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Testing practice required (performance threshold)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-use tests</td>
<td></td>
</tr>
<tr>
<td>U1. Leakage protection</td>
<td>Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)</td>
</tr>
<tr>
<td>U2. Fit and comfort</td>
<td></td>
</tr>
<tr>
<td>U3. Overall performance</td>
<td></td>
</tr>
<tr>
<td>Technical tests</td>
<td></td>
</tr>
<tr>
<td>T1. Biocompatibility</td>
<td>No relevant biological effects in the studies performed for cytotoxicity, pyrogenicity, sensitization, dermal irritation and implantation (90 days) as indicated by ISO 10993. Alternatively compliance with USP Class VI standard (acute systemic toxicity, intracutaneous toxicity and implantation test) could be reported.</td>
</tr>
</tbody>
</table>

Assessment and verification:

A test report shall be provided describing test methods, test results and data used. Tests shall be carried out by laboratories certified to implement quality management systems.

In-use tests shall be conducted for the specific products for which the EU Ecolabel application is made. Nevertheless, if it can be demonstrated that products have the same performance, it can be enough to test only one size or a representative mix of sizes per each product design.

Technical tests shall be conducted for the material(s) used for the manufacturing of reusable menstrual cups for which the EU Ecolabel application is made. If it can be demonstrated that several reusable menstrual cups models are manufactured with the same material, it can be enough to test that material only once. Reusable menstrual cups are not requested to undergo technical tests, only the materials used in the production of cups (this includes silicones, cross-linked silicone elastomers, other elastomers, colorants used and any other materials).
Special care shall be taken regarding sampling, transport and storage of the materials and products to guarantee reproducible results. It is recommended not to blind products or repack them in neutral packaging due to the risk of altering the performance of products and/or packaging, unless alteration can be excluded.

Information on testing shall be made available to the competent bodies under the respect of confidentiality issues. Test results shall be clearly explained and presented in language, units and symbols that are understandable to the data user. The following elements shall be specified: place and date of the tests; criteria used to select the materials tested and their representativeness; selected testing characteristics and, if applicable, the reasons why some were not included; test methods used and their limitations if any. Clear guidelines on the use of test results shall be provided.

Additional guidelines for in-use tests:

- Sampling, test design, panel recruitment and the analysis of test results shall comply with standard statistical practices (AFNOR Q 34-019, ASTM E1958-07e1 or equivalent).
- Each product shall be assessed on the basis of a questionnaire. The test is to last at least 72 hours, a full week when possible, and shall be realised in normal conditions of use of the product.
- The recommended number of testers shall be at least 30. All the individuals participating to the survey shall be current users of the specific type/size of product tested.
- A mixture of individuals representing proportionally different groups of consumers available on the market shall take part to the survey. Age and countries shall be clearly stated.
- Sick individuals and those with a chronic condition shall not participate in the test. In cases where individuals become ill during the course of the user trial, this is to be indicated on the questionnaire and the answers shall not be taken into consideration for the assessment.
- For all in-use tests (leakage protection, fit and comfort and overall performance), 80 % of the consumers testing the product shall rate the performance as satisfactory, with a rate above 60 assigned by the consumer (on a quantitative scale from 1 to 100). Alternatively 80 % of the consumers testing the product shall rate it as good or very good (among five qualitative options: very poor, poor, average, good, very good).
- The results shall be statistically evaluated after the user trial has been completed.
- External factors such as branding, market shares and advertising that may have an impact on the perceived performance of the products shall be communicated.

Additional requirements for technical tests:

- Test methods shall be based as much as possible on product-relevant, reproducible and rigorous methods.
- Technical tests shall be performed in accordance to ISO 10993 series or the USP Class VI standard.
- Test methods whose scope and requirement standards is considered equivalent to the one of the named national and international standards and whose equivalency have been confirmed by an independent third party shall be accepted.

Weight, dimensions and design features of the product shall be described and provided in accordance with information provided in the application general assessment and verification text.

**Criterion 9. Corporate Social Responsibility with regard to labour aspects**

This criterion sets requirements applying to the final reusable menstrual cup manufacturing site.

Having regard to the International Labour Organisation’s (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy (1), the UN Global Compact (Pillar 2) (2), the UN Guiding Principles on Business and Human Rights (3) and the OECD Guidelines for Multinational Enterprises (4), the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the aforementioned international texts and the supplementary provisions below have been respected at the final assembly site for the product.

1 Please, refer to the footnote 21.
2 Please, refer to the footnote 22.
3 Please, refer to the footnote 23.
4 Please, refer to the footnote 24.
Fundamental conventions of the ILO:

(a) Child Labour:
   — Minimum Age Convention, 1973 (No 138)
   — Worst Forms of Child Labour Convention, 1999 (No 182)

(b) Forced and Compulsory Labour:
   — Forced Labour Convention, 1930 (No 29) and 2014 Protocol to the Forced Labour Convention
   — Abolition of Forced Labour Convention, 1957 (No 105)

(c) Freedom of Association and Right to Collective Bargaining:
   — Freedom of Association and Protection of the Right to Organise Convention, 1948 (No 87)
   — Right to Organise and Collective Bargaining Convention, 1949 (No 98)

(d) Discrimination:
   — Equal Remuneration Convention, 1951 (No 100)
   — Discrimination (Employment and Occupation) Convention, 1958 (No 111)

Supplementary provisions:

(e) Working Hours:
   — ILO Hours of Work (Industry) Convention, 1919 (No 1)
   — ILO Weekly Rest (Industry) Convention, 1921 (No 14)

(f) Remuneration:
   — ILO Minimum Wage Fixing Convention, 1970 (No 131)
   — ILO Holidays with Pay Convention (Revised), 1970 (No 132)
   — Living wage: The applicant shall ensure that wages (excluding any taxes, bonuses, allowances, or overtime wages) paid for a normal work week (not exceeding 48 hours) shall be sufficient to afford basic needs (housing, energy, nutrition, clothing, health care, education, potable water, childcare, and transportation) of worker and of a family of four people, and to provide some discretionary income. Implementation shall be audited with reference to the SA8000 (*) guidance on 'Remuneration'.

(g) Health & Safety:
   — ILO Safety in the use of chemicals at work Convention, 1981 (No 170)
   — ILO Occupational Safety and Health Convention, 1990 (No 155)
   — ILO Working Environment (Air Pollution, Noise and Vibration) Convention, 1977 (No 148)

(h) Social protection and inclusion:
   — ILO Medical Care and Sickness Benefits Convention, 1969 (No 130)
   — ILO Social Security (Minimum Standards) Convention, 1952 (No 102)
   — ILO Employment Injury Benefits Convention, 1964 (No 121)
   — ILO Equality of Treatment (Accident Compensation) Convention, 1925 (No 19)
   — ILO Maternity Protection Convention, 2000 (No 183)

(i) Fair dismissal:
   — ILO Termination of Employment Convention, 1982 (No 158).

In locations where the right to freedom of association and collective bargaining are restricted under law, the company shall not restrict workers from developing alternative mechanisms to express their grievances and protect their rights regarding working conditions and terms of employment, and shall recognise legitimate employee associations with whom it can enter into dialogue about workplace issues.

(*) Please, refer to the footnote 25.
The audit process shall include consultation with external industry-independent organisation stakeholders in local areas around sites, including trade unions, community organisations, NGOs and labour experts. Meaningful consultations shall take place with at least two stakeholders from two different subgroups. In locations where national law cannot ensure adequacy of corporate social responsibility with the aforementioned international conventions, the audit process shall include third-party site audits composed of unannounced spot inspections by industry-independent evaluators.

During the validity period of the EU Ecolabel licence, the applicant shall publish the aggregated results and key findings from the audits (including details on (a) how many and how serious violations of each labour rights and OHS standard; (b) strategy for remediation – where remediation includes prevention per UNGP concept; (c) assessment of root causes of persistent violations resulting from stakeholder consultation – who was consulted, what issues were raised, how did this influence the corrective action plan), online in order to provide evidence of their performance to interested consumers.

**Assessment and verification:**

The applicant shall demonstrate compliance with the requirements by providing copies of the most recent version of their code of conduct which shall be consistent with the provisions specified above and copies of the supporting audit reports for each final product assembly plant for the model(s) to be ecolabelled, together with a web link to where online publication of the results and findings can be found.

Third-party site audits shall be carried out by auditors qualified to assess the compliance of the industry manufacturing sites with social standards or codes of conduct or, in countries where the ILO Labour Inspection Convention, 1947 (No 81) has been ratified and ILO supervision indicates that the national labour inspection system is effective (\(^{(10)}\)) and where the scope of the inspection systems covers the areas listed above (\(^{(11)}\)), by labour inspector(s) appointed by a public authority.

Valid certifications from third party schemes or inspection processes that audit compliance with the applicable principles of the listed fundamental ILO Conventions and the supplementary provisions on working hours, remuneration and health & safety and consultation with external stakeholders, shall be accepted. These certifications shall be not more than 12 months old, on the date of application.

**Criterion 10. Information appearing on the EU Ecolabel**

The EU Ecolabel logo may be displayed on the sales packaging of the product. If the optional label with text box is used, it shall contain the following three statements:

- ‘Designed to reduce impact on the environment’,
- ‘Fulfils strict requirements on harmful substances’,
- ‘Verified performance’.

The applicant shall follow the instructions on how to use the EU Ecolabel logo as provided in the EU Ecolabel Logo Guidelines:


**Assessment and verification:**

The applicant shall provide a declaration of compliance with the requirement and a high resolution photograph of the product sales packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.

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\(^{(10)}\) Please, refer to the footnote 21.

\(^{(11)}\) Please, refer to the footnote 21.
COMMISSION DECISION (EU) 2023/1810
of 19 September 2023

on a request for extended cumulation between Cambodia and Vietnam, in accordance with Article 56(1) of Delegated Regulation (EU) 2015/2446, as regards the rules of origin used for the purposes of the scheme of generalized tariff preferences pursuant to Delegated Regulation (EU) 2015/2446 for certain materials or parts used in the production of bicycles

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (1), and in particular Article 64(3) thereof,


 Whereas:

(1) Article 56(1) of Delegated Regulation (EU) 2015/2446 provides that beneficiary countries of the European Union’s generalised scheme of preferences (GSP) may request extended cumulation with a country with which the Union has a free-trade agreement (FTA) in accordance with Article XXIV of the General Agreement on Tariffs and Trade (GATT) in force.

(2) Articles 56(1) and 56(2) of Delegated Regulation (EU) 2015/2446 set the conditions under which beneficiary countries of the GSP may be allowed to use, under extended cumulation, materials from a country with which the Union has a free-trade agreement in accordance with Article XXIV GATT in force. In particular, Article 56(1) provides that such cumulation may only be applied after the countries involved in extended cumulation have undertaken to comply or ensure compliance with the GSP rules of origin, the rules of origin laid down in the EU-Vietnam FTA and all other provisions concerning the implementation of the rules of origin, and to provide the administrative cooperation necessary to ensure the correct implementation of these rules both with regard to the Union and also between themselves.

(3) The Commission is to take a decision on such a request in accordance with its internal procedures.

(4) By letter dated 2 December 2022, Cambodia submitted a request for extended cumulation with Vietnam pursuant to Article 56(1) of Delegated Regulation (EU) 2015/2446. The request concerns certain materials or parts used in the production of bicycles originating in Vietnam to be used as originating materials in Cambodia in order to produce and export to the European Union under the GSP preferential rates bicycles under Harmonised System (HS) headings 87.11, 87.12 and 95.03.

(5) In support of its request, Cambodia recalled that, since Vietnam has been removed from the list of beneficiary countries of the GSP general arrangement as from 1 January 2023, the Vietnamese materials or parts used in the production of bicycles are considered non-originating, and as a result, the Cambodian bicycle producers are not able to benefit from the GSP duty-free access for Cambodian bicycles into the Union. At the same time, in order to

diversify its economy and to continue to provide employment and livelihood for thousands of people, the Cambodian bicycle industry needs to continue to have access to certain materials or parts used in the production of bicycles originating in Vietnam under extended cumulation as provided by Article 56(1) of Delegated Regulation (EU) 2015/2446.

(6) The request is accompanied by a Joint Undertaking between Cambodia and Vietnam on administrative cooperation in the framework of Article 56(1)(a) of Delegated Regulation (EU) 2015/2446, for ensuring on one hand compliance with the relevant rules of origin under the EU-Vietnam FTA for Vietnamese originating materials to be used in the manufacture of bicycles in Cambodia and the rules of origin under the GSP with regard to the products exported by Cambodia to the Union, and on the other hand to provide the administrative cooperation both with regard to the Union and between themselves.

(7) The Joint Undertaking mentioned above contains in annexes a list of the materials or parts used in the production of bicycles of Vietnamese origin concerned by the extended cumulation, under HS chapters 32, 38, 39, 40, 48, 49, 73, 74, 76, 83, 85 and 87, as well as the list of addresses and contact details of the Cambodian and Vietnamese government authorities responsible for issuing and verifying the proof of origin.

(8) The Commission examined the request from Cambodia, including the Joint Undertaking between Cambodia and Vietnam on administrative cooperation and its annexes, and concluded that the conditions related to the granting of the extended cumulation for the materials or parts used in the production of bicycles originating in Vietnam to be used as originating materials in Cambodia for manufacturing and exporting bicycles to the Union under GSP are fulfilled. Currently Cambodia is a GSP beneficiary country in the sense of Article 2(d) of Regulation (EU) No 978/2012 of the European Parliament and of the Council (3). Also, bicycles do not appear in the list of products in respect of which the tariff preferences granted to Cambodia under the general arrangement referred to in point 1(a) of Article 1(2) of the GSP regulation have been temporarily withdrawn by Commission Delegated Regulation (EU) 2020/550 (4).

(9) In light of the above, the possibility for Cambodia to apply extended cumulation to certain materials or parts used in the production of bicycles under HS chapters 32, 38, 39, 40, 48, 49, 73, 74, 76, 83, 85 and 87 of Vietnamese origin, for manufacturing bicycles under HS headings 87.11, 87.12 should be granted. Nevertheless, due to the fact that the requested products covered by heading 95.03 are already duty free, heading 95.03 shall not be included in the present Decision.

(10) The statements on origin made out in relation to products manufactured using cumulation should contain a specific mention to identify when cumulation is applied in line with Annex 22-07 of Commission Implementing Regulation (EU) 2015/2447 (5).

(11) The cumulation granted by this Decision should apply until the date set in Article 43(3) of Regulation (EU) No 978/2012.

(12) The European Commission will monitor the evolution of the imports resulting from the cumulation in accordance with this Decision.


HAS ADOPTED THIS DECISION:

Article 1

Cambodia is hereby entitled to use, in accordance with Article 56(1) of Delegated Regulation (EU) 2015/2446, materials or parts used in the production of bicycles listed in Annex I, originating in Vietnam in accordance with Annex II to Protocol 1 of the EU-Vietnam FTA, under extended cumulation of origin, in order to produce and export to the Union under the GSP preferential customs duties the bicycles listed in Annex II, provided that Cambodia remains at the time of exportation of the product to the Union, a GSP beneficiary country in the sense of Article 2(d) of Regulation (EU) No 978/2012, and the preferential arrangements referred to in Article 1(2) of the same Regulation for bicycles listed in Annex II are not withdrawn temporarily in accordance with Article 19 of Regulation (EU) No 978/2012, and that the rules of origin laid down in Subsection 2 of Section 2 of Chapter 1 of Title II of Delegated Regulation (EU) 2015/2446 apply.

Article 2

Statements on origin made out by exporters in Cambodia with regard to products referred to in Article 1 shall include the mention ‘extended cumulation with Vietnam’ in the placeholder number (6d) for the origin criterion in Annex 22-07 of Implementing Regulation (EU) 2015/2447.

Article 3

The competent authorities of Cambodia shall forward to the Commission, by the end of the month following each calendar quarter, a quarterly report on the application of the cumulation referred to in Article 1. Such report shall provide the list of statements on origin made out during the last period for the products referred to in Article 1, the exporters concerned identified by their REX number, the quantities and HS heading of materials or parts used in the production of bicycles used originating in Vietnam, and the quantities of bicycles exported to the Union.

Article 4

The products produced under cumulation referred to in Article 1 shall benefit from the general arrangement referred to in point 1(a) of Article 1(2) of Regulation (EU) No 978/2012 when imported into the Union until the date set in Article 43(3) of that Regulation.

Article 5

This Decision shall enter into force on the day of its publication in the Official Journal of the European Union.

Done at Brussels, 19 September 2023.

For the Commission

The President

Ursula VON DER LEYEN
### ANNEX I

**Materials or parts used in the production of bicycles, originating in Vietnam in accordance with the rules established by Protocol 1 of the EU-Vietnam FTA, which are to be cumulated in the manufacture of bicycles in Cambodia under extended cumulation**

<table>
<thead>
<tr>
<th>HS2022 Code</th>
<th>Description of goods</th>
</tr>
</thead>
<tbody>
<tr>
<td>3208 90</td>
<td>- Other</td>
</tr>
<tr>
<td>3209 90</td>
<td>- Other</td>
</tr>
<tr>
<td>3814 00</td>
<td>- Organic composite solvents and thinners, not elsewhere specified or included; prepared paint or varnish removers.</td>
</tr>
<tr>
<td>3923 50</td>
<td>- Stoppers, lids, caps and other closures</td>
</tr>
<tr>
<td>3923 90</td>
<td>- Other</td>
</tr>
<tr>
<td>4011 50</td>
<td>- Of a kind used on bicycles</td>
</tr>
<tr>
<td>4012 90</td>
<td>- Other</td>
</tr>
<tr>
<td>4013 20</td>
<td>- Of a kind used on bicycles</td>
</tr>
<tr>
<td>4016 99</td>
<td>- - Other</td>
</tr>
<tr>
<td>4819 10</td>
<td>- Cartons, boxes and cases, of corrugated paper or paperboard</td>
</tr>
<tr>
<td>4819 20</td>
<td>- Folding cartons, boxes and cases, of non-corrugated paper or paperboard</td>
</tr>
<tr>
<td>4821 10</td>
<td>- Printed</td>
</tr>
<tr>
<td>4823 90</td>
<td>- Other</td>
</tr>
<tr>
<td>4908 90</td>
<td>- Other</td>
</tr>
<tr>
<td>4911 99</td>
<td>- - Other</td>
</tr>
<tr>
<td>7303 00</td>
<td>Tubes, pipes and hollow profiles, of cast iron.</td>
</tr>
<tr>
<td>7304 90</td>
<td>- Other</td>
</tr>
<tr>
<td>7307 99</td>
<td>- - Other</td>
</tr>
<tr>
<td>7315 11</td>
<td>- - Roller chain</td>
</tr>
<tr>
<td>7318 22</td>
<td>- - Other washers</td>
</tr>
<tr>
<td>7318 24</td>
<td>- - Cotter and cotter-pins</td>
</tr>
<tr>
<td>7326 90</td>
<td>- Other</td>
</tr>
<tr>
<td>7415 33</td>
<td>- - Screws; bolts and nuts</td>
</tr>
<tr>
<td>7601 20</td>
<td>- Aluminium alloys</td>
</tr>
<tr>
<td>7606 92</td>
<td>- - Of aluminium alloys</td>
</tr>
<tr>
<td>7608 10</td>
<td>- Of aluminium, not alloyed</td>
</tr>
<tr>
<td>7608 20</td>
<td>- Of aluminium alloys</td>
</tr>
<tr>
<td>7616 10</td>
<td>- Nails, tacks, staples (other than those of heading 8305), screws, bolts, nuts, screw hooks, rivets, coppers, cotter-pins, washers and similar articles;</td>
</tr>
<tr>
<td>8302 50</td>
<td>- Hat-racks, hat-pegs, brackets and similar fixtures</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>8311 30</td>
<td>Coated rods and cored wire, of base metal, for soldering, brazing or welding by flame</td>
</tr>
<tr>
<td>8507 60</td>
<td>Lithium-ion</td>
</tr>
<tr>
<td>8528 72</td>
<td>Other, colour</td>
</tr>
<tr>
<td>8537 10</td>
<td>For a voltage not exceeding 1 000 V</td>
</tr>
<tr>
<td>8714 10</td>
<td>Of motorcycles (including mopeds)</td>
</tr>
<tr>
<td>8714 91</td>
<td>Frames and forks, and parts thereof</td>
</tr>
<tr>
<td>8714 92</td>
<td>Wheel rims and spokes</td>
</tr>
<tr>
<td>8714 93</td>
<td>Hubs, other than coaster braking hubs and hub brakes, and free-wheel sprocket-wheels</td>
</tr>
<tr>
<td>8714 94</td>
<td>Brakes, including coaster braking hubs and hub brakes, and parts thereof</td>
</tr>
<tr>
<td>8714 95</td>
<td>Saddles</td>
</tr>
<tr>
<td>8714 96</td>
<td>Pedals and crank-gear, and parts thereof</td>
</tr>
<tr>
<td>8714 99</td>
<td>Other</td>
</tr>
</tbody>
</table>
ANNEX II

Finished bicycles produced in Cambodia under extended cumulation with Vietnam

<table>
<thead>
<tr>
<th>HS2022 Code</th>
<th>Description of goods</th>
</tr>
</thead>
<tbody>
<tr>
<td>8711 60</td>
<td>- With electric motor for propulsion</td>
</tr>
<tr>
<td>8712 00</td>
<td>Bicycles and other cycles (including delivery tricycles), not motorised.</td>
</tr>
</tbody>
</table>
COMMISSION IMPLEMENTING DECISION (EU) 2023/1811
of 20 September 2023

amending Implementing Decision (EU) 2020/1550 by establishing the programme of Commission controls for 2024 in the Member States to verify the application of Union agri-food chain legislation

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


Whereas:

(1) The responsibility to enforce Union agri-food chain legislation lies with Member States, whose competent authorities monitor and verify, through the organisation of official controls, that relevant Union requirements are effectively complied with and enforced. Parallel to this monitoring and verification, Article 116 of Regulation (EU) 2017/625 requires Commission experts to perform controls, including audits, in Member States to verify the application of Union legislation. These Commission controls should be performed in the areas of food and feed safety, animal health and welfare, plant health, plant protection products, and the functioning of national control systems and competent authorities, which operate them, taking into account synergies with control arrangements under the common agricultural policy.

(2) Commission Implementing Decision (EU) 2020/1550 (2) established in Chapters 1 to 10 of the Annex thereto a multiannual programme of controls to be carried out by Commission experts in the Member States to verify the application of Union agri-food chain legislation for the period 2021-2025, aligned with the Commission’s term of office and reflecting its priorities.

(3) In accordance with Article 118(1), point (b), of Regulation (EU) 2017/625, Chapter 11 of the Annex to Implementing Decision (EU) 2020/1550 setting out the programme of Commission controls for the following year is to be communicated to the Member States by the end of each year. Chapter 11 should be updated to reflect the programme of Commission controls planned for 2024.

(4) Implementing Decision (EU) 2020/1550 should therefore be amended accordingly.

(5) Given that this amendment concerns the annual programme of controls for 2024, which applies as of 1 January 2024, the date of application of this Decision should be deferred to coincide with that date;’

(2) Commission Implementing Decision (EU) 2020/1550 of 23 October 2020 establishing the multiannual programme of controls for the period 2021-2025 to be carried out by Commission experts in the Member States to verify the application of Union agri-food chain legislation (OJ L 354, 26.10.2020, p. 9).
HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2020/1550 is amended in accordance with the Annex to this Decision.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 1 January 2024.

Done at Brussels, 20 September 2023.

For the Commission
The President
Ursula VON DER LEYEN
ANNEX

The Annex to Implementing Decision (EU) 2020/1550 is amended as follows:

(1) In the sixth paragraph, the second sentence is replaced by the following:

‘Chapter 11 sets out the programme of controls for 2024.’.

(2) Chapter 11 is replaced by the following:

‘11. Programme of controls for 2024

<table>
<thead>
<tr>
<th>Area</th>
<th>Priority area</th>
<th>Focus in 2024</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food &amp; food safety</td>
<td>Food of animal origin</td>
<td>Safety of meat of mammals and birds and products thereof</td>
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<td></td>
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<td>Safety of milk and products thereof</td>
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<td></td>
<td>Safety of fishery products</td>
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<td></td>
<td>Food of non-animal origin</td>
<td>Microbiological safety</td>
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<td></td>
<td>Residues in live animals and food of animal origin</td>
<td>Chemical safety – residues</td>
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<tr>
<td>Feed &amp; feed safety</td>
<td>Feed safety</td>
<td>General feed hygiene (including medicated feed)</td>
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<td>Animal by-products and derived products</td>
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<tr>
<td>Animal health</td>
<td>Category A diseases under Regulation (EU) 2016/429</td>
<td>African swine fever</td>
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<td>Highly pathogenic avian influenza</td>
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<td></td>
<td>Sheep and goat pox</td>
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<td></td>
<td>Category B and C diseases under Regulation (EU) 2016/429</td>
<td>Fish diseases</td>
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<td></td>
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<td>Monitoring system for category B and C diseases</td>
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<td></td>
<td>Preparedness &amp; prevention</td>
<td>Contingency planning covered during African swine fever and highly pathogenic avian influenza audits</td>
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<td>Animal welfare</td>
<td>On farm</td>
<td>Turkeys</td>
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<td></td>
<td>Fish (including slaughter and transport)</td>
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<tr>
<td>Plant health</td>
<td>Plant pest outbreaks</td>
<td>Plant pest outbreaks presenting a significant threat</td>
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<td>Movement of plants, plant products and other objects within the Union</td>
<td>Plant passports</td>
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<td>Preparedness and prevention</td>
<td>Plant health survey programmes</td>
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<tr>
<td>PPP &amp; SUD</td>
<td>Plant protection products (PPP)</td>
<td>Chemical safety (authorisation, marketing and use of pesticides, illegal pesticides, pesticides residues)</td>
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<tr>
<td>Area</td>
<td>Priority area</td>
<td>Focus in 2024</td>
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<tr>
<td>Food quality</td>
<td>Organic farming</td>
<td>Organic farming</td>
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<td>Entry into the Union of animals and goods from third countries</td>
<td>Official controls on animals and goods</td>
<td>Animals and goods</td>
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<tr>
<td>AMR</td>
<td>Monitoring of antimicrobial resistance (AMR) in zoonotic and commensal bacteria</td>
<td>AMR in zoonotic and commensal bacteria</td>
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<tr>
<td>General aspects within the agri-food chain</td>
<td>Follow-up of audit recommendations</td>
<td>General and sectoral follow-up of audit recommendations</td>
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<td></td>
<td>Genetically modified organisms (GMOs)</td>
<td>GMOs</td>
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<tr>
<td></td>
<td>Any emergency situations, emerging problems and new developments</td>
<td>Emergency situations, emerging problems and new developments’</td>
</tr>
</tbody>
</table>
RULES OF PROCEDURE

DECISION No 37-2023 OF THE EUROPEAN COURT OF AUDITORS REGARDING PUBLIC ACCESS TO ECA DOCUMENTS

THE EUROPEAN COURT OF AUDITORS (ECA).

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 15(3) thereof;

Having regard to the Charter of Fundamental Rights of the European Union, and in particular Article 42 thereof;

Having regard to its Rules of Procedure (1), and in particular Article 35 thereof;


Having regard to Regulation (EU) 2018/1725 of the Parliament and of the Council of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the EU institutions and bodies and on the free movement of such data and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (3);

Having regard to Decision of the European Court of Auditors No 6-2019 on the open data policy and the reuse of documents (4);

Having regard to Decision No 41/2021 of the Court of Auditors on the security rules for protecting EU classified information (EUCI) (5);

Having regard to the ECA's Information Classification Policy (6);

Whereas

(1) The second subparagraph of Article 1 of the Treaty on European Union enshrines the concept of openness, stating that the Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely as possible to the citizen;

(2) Article 15(1) of the Treaty on the Functioning of the European Union (TFEU) restates the concept of openness and provides that, in order to promote good governance and ensure the participation of civil society, the Union's institutions, bodies, offices and agencies shall conduct their work as openly as possible;

(3) The first subparagraph of Article 15(3) TFEU states that any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have a right of access to documents of the Union institutions, bodies, offices and agencies, whatever their medium;

(4) In accordance with the third subparagraph of Article 15(3) TFEU, each institution, body, office or agency shall ensure that its proceedings are transparent and shall elaborate in its own Rules of Procedure specific provisions regarding access to its documents;

Openness enhances an administration's legitimacy, effectiveness and accountability, thus strengthening the principles of democracy, making it important to promote good administrative practice on access to documents.

Certain public and private interests should nonetheless be protected by way of exceptions to the principle of public access to documents, in particular the application of international audit standards concerning the confidential nature of audit information.

HAS DECIDED:

Article 1
Purpose

The purpose of this Decision is to define the conditions, limits and procedures under which the European Court of Auditors shall give public access to documents which it holds.

Article 2
Beneficiaries and scope

1. Within the framework and limits of the provisions laid down in this Decision and of international standards governing the confidentiality of audit information, any citizen of the Union, and any other natural or legal person residing or having its registered office in a Member State, has a right of access to documents held by the ECA.

2. Subject to the same principles, conditions and limits, the ECA may grant access to documents to any natural or legal person not residing or not having its registered office in a Member State.

3. This Decision shall be without prejudice to rights of public access to documents held by the ECA which might derive from instruments of international law or acts implementing them.

Article 3
Definitions

For the purpose of this Decision:

(1) 'document' shall mean any content, whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording), drawn up or received and held by the ECA concerning a matter relating to its policies, activities and decisions;

(2) 'third party' shall mean any natural or legal person, or any entity outside the ECA, including the Member States, non-EU countries, and other EU or non-EU institutions and bodies.

Article 4
Exceptions

1. The ECA shall refuse access to a document where disclosure would undermine the protection of:

(a) the public interest, including:
   — public security,
   — defence and military matters,
   — international relations,
   — the financial, monetary or economic policy of the European Union or a Member State;
(b) the privacy and integrity of individuals and their personal data, in particular in accordance with EU legislation regarding the protection of personal data.

2. In accordance with the confidentiality rules laid down in Articles 258(1) and 259(1) of Regulation (EU, Euratom) 2018/1046, and in corresponding provisions in other instruments of EU law, the ECA shall refuse access to its preliminary audit observations. It may also refuse access to documents used in the preparation of those observations.

3. The ECA shall refuse access to a document where disclosure would undermine the protection of:
   — the commercial interests of a natural or legal person,
   — intellectual property,
   — court, arbitration and dispute settlement proceedings and legal advice,
   — inspections, investigations and audits.

4. Access to the following documents shall be refused if their disclosure would seriously undermine decision-making by the ECA:
   (a) documents drawn up by the ECA for internal use or received by it, which relate to a matter where the decision has not yet been taken;
   (b) documents containing opinions for internal use as part of deliberations and preliminary consultations within the ECA, even after the decision has been taken.

5. Notwithstanding the exceptions set out in paragraphs 2, 3 and 4, the ECA shall decide to allow access to a document, in whole or in part, where there is an overriding public interest in its disclosure.

6. The overriding public interest used to justify disclosure must be both objective and general in nature. The person alleging the existence of an overriding public interest shall state which specific circumstances justify disclosure of the documents concerned.

7. If only parts of the requested document are covered by any of the exceptions in this article, the remaining parts of the document shall be released. Partial access may entail, for instance, data minimisation (anonymisation or pseudonymisation of content), blackening or deletion of some content or removal or one or more pages of the document.

8. The exceptions in this article shall apply without prejudice to the provisions on public access to the historical archives of the European Economic Community and the European Atomic Energy Community laid down in Council Regulation (EEC, Euratom) No 354/83 (7), as further amended.

9. This Article shall apply without prejudice to the provisions of Article 5.

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Article 5

Third-party documents

1. Where an application for access to documents concerns a document held by the ECA but of which it is not the author, the ECA shall confirm receipt of the application and supply the name of the person, institution or body to whom the application must be addressed.

2. Where a document was created jointly with another third party, the ECA shall consult the third party before taking a decision.

Article 6

‘Sensitive’ and ‘EU classified’ ECA documents

1. ‘Sensitive’ or ‘EU classified’ ECA documents are documents classified as such in accordance with the ECA Information Classification Policy or with Decision No 41/2021, respectively.

2. Applications for access to such documents shall be handled only by ECA staff who have a right to acquaint themselves with these documents. The same persons shall also assess whether reference to ‘sensitive’ or ‘EU classified’ ECA documents can be made when replying to applications for access to documents.

3. Access to ‘sensitive’ and ‘EU classified’ ECA documents can only be granted after declassification. If the ECA decides to refuse access to such documents, it shall give the reasons for its decision in a way which does not harm the interests protected in Article 4.

Article 7

Applications

1. Applications for access to documents must be made in writing, preferably using the contact form (*) available on the ECA website, in one of the official languages of the Union. In exceptional circumstances, applications for access to documents can be sent by post.

2. Applications for access to documents must be sufficiently precise and shall contain, in particular, elements enabling identification of the requested document(s) and the applicant’s name and contact details.

3. Applicants shall not be obliged to give reasons for their applications.

4. Where an application is not sufficiently precise, or if the requested documents cannot be identified, the ECA shall ask the applicant to clarify the application and shall assist the applicant in doing so.

5. The time limits provided in Article 8 shall not start to run until the ECA has received the requested clarifications.

6. Where an application relates to a very long document or to a very large number of documents, the ECA may confer with the applicant informally with a view to finding an appropriate solution.

Article 8

Processing of initial applications

1. Applications for access to documents shall be dealt with by the ECA-Info team.

2. Applicants shall be sent an acknowledgement of receipt without delay.

3. Depending on the subject matter of the application, the ECA-Info team shall consult the department concerned, and, where applicable, the Data Protection Officer and/or the Information Security Officer, with a view to deciding how to handle the application. The authority empowered to decide on the reply to be given to an initial application for access to a document shall be the Secretary-General, who may delegate this power.

4. Within a maximum of one month of registering an application, the ECA shall either grant access to the requested document, as described in Article 11, or reply in writing, indicating the reasons for the total or partial refusal, and informing the applicant of his/her right to have the ECA reconsider its position as described in Article 9.

5. Where an application relates to a very long document or to a very large number of documents, or requires internal consultations or consultation of third parties, the time limit indicated in paragraph 4 may be extended by one month, provided that the applicant is notified in advance and that reasons are given.

6. In the event that ECA staff members receive personally an application for access to documents, they shall forward it without delay to the ECA-Info team.

**Article 9**

**Confirmatory applications**

1. In the event of a total or partial refusal, the applicant may, within one month of receiving the ECA’s reply, make a confirmatory application to the President of the ECA, in which it asks the ECA to reconsider its position.

2. Failure by the ECA to reply within the time limits prescribed in Article 8 shall also entitle the applicant to ask for reconsideration.

3. Confirmatory applications shall be subject to the same requirements as set out in Article 7 for initial applications.

**Article 10**

**Processing of confirmatory applications**

1. On receiving a confirmatory application, the President of the ECA shall consult the Legal Service and, depending on the subject matter of the application, the department concerned and, where applicable, the Data Protection Officer and/or the Information Security Officer.

2. Within a maximum of one month of registering a confirmatory application, the ECA shall either grant access to the requested document, as described in Article 11, or reply in writing, indicating the reasons for the total or partial refusal.

3. In the event of a total or partial refusal, the ECA shall inform the applicant of the remedies open to him or her, namely instituting court proceedings against the ECA and/or making a complaint to the Ombudsman, under Articles 263 and 228 TFEU respectively.

4. In exceptional cases, for example, where the application relates to a very long document or to a very large number of documents, or requires internal consultations or consultation of third parties, the time given in paragraph 2 may be extended by one month, provided that the applicant is notified in advance and that reasons are given.

5. Failure by the ECA to reply within the time limits prescribed above shall be considered a negative reply and shall entitle the applicant to make use of the remedies referred to in paragraph 3.

**Article 11**

**Access following an application**

1. Documents shall be supplied in an already existing version and format (preferably electronically using means approved by the ECA to guarantee information security), having regard to the applicant’s preference. The ECA is not obliged to create a new document or compile information for the applicant.

2. If documents are voluminous or difficult to handle, the applicant may be invited to consult them on the spot at a date and time agreed with the ECA.

3. The cost of producing and sending copies may be charged to the applicant, but may not exceed the costs actually incurred. Consultation on the spot, copies of fewer than 20 A4 pages and direct access in electronic form shall be free of charge.
4. If a document is publicly accessible, the ECA may fulfil its obligation of granting access by informing the applicant how to obtain it.

Article 12

Reproduction of documents

1. Documents released in accordance with this Decision shall not be reproduced or exploited for commercial purposes without the ECA’s prior written authorisation.

2. This Decision shall be without prejudice to any rules on copyright which may limit a third party’s right to reproduce or exploit released documents, and to ECA Decision No 6-2019.

Article 13

Transparency portal

1. To make citizens’ rights under this Decision effective, the ECA’s website includes a transparency portal.

2. Documents referred to in the transparency portal shall, wherever possible, be directly accessible through hyperlinks.

Article 14

Final provisions

1. Decision No 12-2005 of the Court of Auditors of 10 March 2005 is hereby repealed.

2. This Decision shall be published in the Official Journal of the European Union.

3. It shall enter into force on the day of its publication in the Official Journal of the European Union.

Done at Luxembourg, 13 July 2023.

For the Court of Auditors

Tony MURPHY
President
CORRIGENDA

Corrigendum to Council Decision (CFSP) 2023/432 of 25 February 2023 amending Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

(Official Journal of the European Union L 100 of 13 April 2023)

This corrigendum should be considered null and void.
Corrigendum to Council Implementing Regulation (EU) 2023/429 of 25 February 2023 implementing Regulation (EU) No 269/2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

(Official Journal of the European Union L 100 of 13 April 2023)

This corrigendum should be considered null and void.