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[1] Text with EEA relevance.

EN

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.

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DECISIONS

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([1]) Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2022/1369

of 5 August 2022

on coordinated demand-reduction measures for gas

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 122(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Russian Federation, the Union's main external gas supplier, has started a military aggression against Ukraine, a Contracting Party of the Energy Community. The escalation of the Russian military aggression against Ukraine since February 2022 has led to gas supplies declining markedly, in a deliberate attempt to use gas supply as a political weapon. Pipeline flows of gas from Russia through Belarus have stopped and gas supplies through Ukraine have steadily decreased. Overall gas flows from Russia are now less than 30 % of average gas flows in the period 2016-2021. That supply reduction has led to historically high and volatile energy prices, contributing to inflation and creating a risk of further economic downturn in Europe.

(2) Against this background, the Commission, further to its communication of 8 March 2022 entitled 'REPowerEU: Joint European Action for more affordable, secure and sustainable energy', presented the REPowerEU plan on 18 May 2022 with the aim to end the Union's dependence on Russian fossil fuels as soon as possible, and at the latest by 2027. To achieve that aim, the REPowerEU plan sets out measures related to energy savings and energy efficiency and proposes an accelerated roll-out of clean energy to replace fossil fuels in homes, industry and power generation. Further measures on the supply side could include, inter alia, better coordination of gas purchases and the facilitation of joint purchases by European gas market operators on the international gas market, as well as best efforts to preserve electricity production capacities that do not rely on imported gas supplies.

(3) The Union has taken further measures to increase its level of preparedness as regards gas supply disruption. Regulation (EU) 2022/1032 of the European Parliament and of the Council [1] was adopted to ensure the filling of underground storage sites for the coming winter seasons.

(4) Furthermore, in February 2022 and in May 2022 the Commission carried out in-depth reviews of all national emergency plans and has also carried out in-depth monitoring of the security of supply situation. The measures taken by the Union since February 2022 were designed to enable a full phase-out of Russian gas by 2027, and to reduce the risks stemming from a further major supply disruption.

[1] Regulation (EU) 2022/1032 of the European Parliament and of the Council of 29 June 2022 amending Regulations (EU) 2017/1938 and (EC) No 715/2009 with regard to gas storage (OJ L 173, 30.6.2022, p. 17).

(5) However, the recent escalation of disruption of gas supply from Russia points to a significant risk that a complete halt of Russian gas supplies may materialise in the near future, in an abrupt and unilateral way. The Union should therefore anticipate such a risk and prepare, in a spirit of solidarity, for the possibility of a full disruption of gas supply from Russia at any moment. Immediate proactive action is necessary to anticipate further disruptive action and strengthen the resilience of the Union to future shocks. Coordinated action at Union level can avoid serious harm to the economy and to citizens resulting from a possible gas supply interruption.

(6) The current legal framework for security of gas supply set by Regulation (EU) 2017/1938 of the European Parliament and of the Council ([2]) does not adequately address disruptions of a major gas supplier lasting more than 30 days. The lack of a legal framework for such disruption leads to a risk of uncoordinated action by Member States, which threatens to endanger security of supply in neighbouring Member States and may place an additional burden on the Union's industry and consumers.

(7) In its resolution of 7 April 2022 on the conclusions of the European Council meeting of 24-25 March 2022, the European Parliament called for a plan to continue ensuring the Union's security of energy supply in the short term to be presented. In its meetings on 31 May and 23 June 2022, the European Council requested the Commission to make proposals for improving preparedness for possible major supply disruption as a matter of urgency, with a view to securing energy supply at affordable prices. Following that request from the European Council, the Commission is exploring together with the Union's international partners ways to curb rising energy prices, including the feasibility of introducing temporary import price caps where appropriate. Further to that request, the Commission is also pursuing work on the optimisation of the functioning of the European electricity market, including the effect of gas prices on it, so that it is better prepared to withstand future excessive price volatility, delivers affordable electricity and fully fits a decarbonised energy system, while preserving the integrity of the single market, maintaining incentives for the green transition, preserving the security of supply and avoiding disproportionate budgetary costs.

(8) Article 122(1) of the Treaty on the Functioning of the European Union enables the Council to decide, on a proposal from the Commission and in a spirit of solidarity between Member States, upon the measures appropriate to the economic situation, in particular if severe difficulties arise in the supply of certain products, notably in the area of energy. The risk of a complete halt of Russian gas supplies by the end of 2022 constitutes such a situation.

(9) Given the imminent risk of disruption of gas supplies to the Union, Member States should take measures now to reduce their demand ahead of the 2022-23 winter season. Such voluntary demand reduction would contribute in particular to the filling of storage capacities, which would not be depleted by the end of the 2022-23 winter season and would therefore enable Member States to cope with possible cold spells in February and March of 2023 and facilitate the filling of storage capacities to ensure adequate levels of security of supply for the 2023-24 winter season. Reducing demand for gas will also help ensure adequate supply and drive energy prices down, to the benefit of Union consumers. Therefore, measures taken at Union level to reduce demand would benefit all Member States by decreasing the risk of a more substantial impact on their economies.

(10) The volume of the voluntary demand reduction takes into account the volumes of gas demand which would be at risk of non-delivery in the event of a full disruption of Russian gas supply. The reduction effort should be the same for all Member States, based on a comparison with each Member State's average consumption over the last five years.

(11) Voluntary demand-reduction measures may not by themselves be sufficient to ensure security of supply and market functioning. Therefore, in order to promptly address the specific challenges of the ongoing and anticipated severe worsening of gas supply shortages and avoid distortions between Member States, a new instrument introducing the possibility for a mandatory gas demand reduction for all Member States should be established. It should become operational sufficiently in advance of autumn 2022. Under such instrument, the Council could, on a proposal from the Commission, declare a Union alert by means of an implementing decision. Conferring an implementing power

([2]) Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010 (OJ L 280, 28.10.2017, p. 1).

on the Council adequately takes into account the political nature of the decision to trigger a mandatory Union-wide demand-reduction obligation and its horizontal implications for Member States. Before presenting such a proposal, the Commission should consult the relevant risk groups, as set out in Annex I of Regulation (EU) 2017/1938 ('risk groups'), and the Gas Coordination Group (GCG), established by that Regulation. A Union alert should only be declared in the event that the voluntary demand-reduction measures prove to be insufficient to address the risk of a serious supply shortage. Five or more competent authorities of Member States which have declared national alerts pursuant to Article 11(1), point (b), of Regulation (EU) 2017/1938 should be given the possibility to request the Commission to present a proposal to the Council to declare a Union alert.

(12) The Union alert should serve as a Union-specific crisis level, which should trigger a mandatory demand reduction, independently of national crisis levels pursuant to Article 11(1) of Regulation (EU) 2017/1938. Once a Union alert has been declared, Member States should reduce their gas consumption within a pre-defined period. The volume of the mandatory demand reduction takes into account the volumes of gas demand which could be at risk in the event of a full disruption of Russian gas supplies to the Union and should fully take into account any demand reduction already achieved. The volume of the mandatory demand reduction should also take into account the level of storage filling as reported pursuant to Article 6d(1) and (2) of Regulation (EU) 2017/1938, the development concerning the diversification of sources of gas, including liquefied natural gas (LNG) supplies and the development of fuel substitutability in the Union.

(13) Demand reductions achieved by Member States before the Union alert is declared will be reflected in the volume of the mandatory demand reduction.

(14) In view of the significant distortions of the internal market which are likely to occur if Member States react in an uncoordinated manner to a potential or actual further disruption of Russian gas supply, it is crucial that all Member States reduce their gas demand in a spirit of solidarity. All Member States should therefore achieve the voluntary and mandatory demand-reduction targets. While some Member States might be more exposed to the effects of a disruption of Russian gas supplies, all Member States could be negatively affected and could contribute to limiting the economic harm caused by such disruption, be it by freeing up additional volumes of pipeline gas or LNG cargoes which can be used by Member States with significant gas deficits, by the positive effect on gas prices which a demand reduction is likely to have or by avoiding market distortion through uncoordinated and contradicting demand-reduction measures. This Regulation therefore reflects the principle of energy solidarity, which has recently been confirmed by the Court of Justice as a fundamental principle of Union law ([3]).

(15) However, certain Member States are, due to their specific geographical or physical situation, such as not being synchronised with the European electricity system, or their lack of direct interconnection to the gas interconnected system of another Member State, not able to free up significant volumes of pipeline gas to the benefit of other Member States. Member States should therefore be given a possibility to rely on one or more grounds to limit their mandatory demand-reduction obligations. The Member States concerned should commit to making all efforts to remove the interconnection deficits as soon as possible.

(16) Regulation (EU) No 347/2013 of the European Parliament and of the Council ([4]) puts in place a framework for Member States and relevant stakeholders to work together in a regional setting to develop better-connected energy networks with the aim, in particular, to connect regions currently isolated from European energy markets and to strengthen existing and promote new cross-border interconnections. Cross-border interconnections strongly contribute to the security of supply. In light of the current disruption of gas supply from Russia, such cross-border interconnections play a key role in ensuring the functioning of the internal energy market and in the distribution of gas to other Member States, in a spirit of solidarity. In this context, Member States should pursue their efforts to improve the integration of their networks, including by assessing the potential increase of new cross-border interconnection capacity in line with the objectives of Regulation (EU) 2022/869 of the European Parliament and of the Council ([5]).

([3]) Judgment of the Court of Justice of 15 July 2021, *Germany v Poland*, C-848/19 P, ECLI:EU:C:2021:598.

([4]) Regulation (EU) No 347/2013 of the European Parliament and of the Council of 17 April 2013 on guidelines for trans-European energy infrastructure and repealing Decision No 1364/2006/EC and amending Regulations (EC) No 713/2009, (EC) No 714/2009 and (EC) No 715/2009 (OJ L 115, 25.4.2013, p. 39).

([5]) Regulation (EU) 2022/869 of the European Parliament and of the Council of 30 May 2022 on guidelines for trans-European energy infrastructure, amending Regulations (EC) No 715/2009, (EU) 2019/942 and (EU) 2019/943 and Directives 2009/73/EC and (EU) 2019/944, and repealing Regulation (EU) No 347/2013 (OJ L 152, 3.6.2022, p. 45).

(17) In order to facilitate Member States' efforts to fulfil the objectives of Regulation (EU) 2022/1032 with regard to gas storage, the volume of gas used by Member States for storage in excess of the intermediate target for 1 August 2022 should also be taken into account for the purpose of determining the volume of their mandatory demand reduction.

(18) In addition, to take proper account of the high dependency on gas of Member States' critical industries, Member States should be able to exclude gas consumption in those industries when determining the volume of their mandatory demand reduction. Monitoring by the Commission should ensure that national limitations do not lead to undue distortions of the internal market. Member States should also be able to limit the volume of their mandatory demand reduction where such limitation is necessary to maximise the supply of gas to other Member States and where they are able to produce evidence that their interconnector commercial export capacities to other Member States or their domestic LNG infrastructure are used to re-direct gas to other Member States to the utmost extent. The Commission should monitor that the conditions for the application of those derogations are fulfilled.

(19) The Member States, with regard to specific demand circumstances from interconnected Member States, should be able to temporarily limit the mandatory demand reduction where necessary to ensure security of energy supply, including where a Member State faces an electricity crisis as referred to in Regulation (EU) 2019/941 of the European Parliament and of the Council ([6]). Account should also be taken of the storage capacity and the storage level in excess of the intermediate target, as set out in Annex Ia to Regulation (EU) 2017/1938.

(20) Member States should be free to choose the appropriate measures to achieve the demand reduction. When identifying appropriate demand-reduction measures and prioritising customer groups, Member States should consider making use of the measures identified by the Commission in its communication of 20 July 2022 entitled "Save Gas for a Safe Winter". Member States should in particular consider economically efficient measures such as auctions or tender schemes, by which they can incentivise a reduction of consumption in an economically efficient manner. The measures taken at national level may also include financial incentives or compensation to market participants affected.

(21) Any measure taken by Member States to achieve the demand reduction must comply with Union law and in particular Regulation (EU) 2017/1938. In particular, such measures should be necessary, clearly defined, transparent, proportionate, non-discriminatory and verifiable, and should not unduly distort competition or the proper functioning of the internal market in gas or endanger the security of gas supply of other Member States or of the Union. It is necessary to consider the interests of protected customers also in relation to gas supply to centralised heating systems in the case of security of supply crisis.

(22) In order to ensure that demand-reduction measures are implemented in a coordinated manner, Member States should establish regular cooperation within each of the relevant risk groups. Member States are free to agree on the coordination measures best suited in a given region. The Commission and the GCG should be able to have an overview of the national measures implemented by the Member States and share best practices for the coordination of measures within the risk groups. Member States should also use other bodies to coordinate their action.

(23) In order to ensure that the national emergency plans reflect the voluntary or mandatory demand-reduction measures set out in this Regulation, the competent authority of each Member State should take the necessary steps to update the national emergency plan established pursuant to Article 8 of Regulation (EU) 2017/1938 by 31 October 2022. Given the short timeframe for that update, the coordination procedures pursuant to Article 8(6) to (11) of Regulation (EU) 2017/1938 should not apply. However, each Member State should consult other Member States on the update of its national emergency plan. The Commission should convene the risk groups, the GCG or other relevant bodies to discuss potential issues related to demand-reduction measures.

([6]) Regulation (EU) 2019/941 of the European Parliament and of the Council of 5 June 2019 on risk-preparedness in the electricity sector and repealing Directive 2005/89/EC (OJ L 158, 14.6.2019, p. 1).

(24) Regular and effective monitoring and reporting are essential for the assessment of progress made by the Member States in the implementation of the voluntary and mandatory demand-reduction measures, and for measuring the social and economic impact of those measures as well as the impact on employment. The competent authority of each Member State or another entity designated by the Member State should monitor the demand reduction achieved on its territory and regularly report the results to the Commission. The GCG should assist the Commission in monitoring the fulfilment of the demand-reduction obligations.

(25) To prevent significant economic harm to the Union as a whole, it is crucial that each Member State reduce its demand after a Union alert has been declared. That reduction will ensure that there is sufficient gas for all, even during the winter. The demand reduction across the Union is an expression of the principle of solidarity, enshrined in the Treaty. It is therefore warranted that the Commission supervise strictly that the mandatory demand reductions are carried out by Member States. In the event that the Commission identifies a risk that a Member State may not be able to fulfil its mandatory demand-reduction obligation, the Commission should be able to request that Member State to submit a plan setting out a strategy and measures to effectively achieve the mandatory demand reduction. That Member State should take due account of any comments and suggestions made by the Commission regarding that plan.

(26) As the solidarity principle gives every Member State the right to be supported by neighbouring Member States under certain circumstances, Member States who ask for such support should also act in a spirit of solidarity when it comes to reducing their domestic gas demand. Therefore, when requesting a solidarity measure under Article 13 of Regulation (EU) 2017/1938, Member States should have implemented all appropriate gas demand-reduction measures. The Commission should be able to request the Member State requesting a solidarity measure to submit a plan with measures to achieve possible further demand reductions. That Member State should take due account of the Commission's opinion.

(27) The Commission should inform the European Parliament and the Council regularly about the implementation of this Regulation.

(28) Considering the imminent danger to the security of gas supply brought about by the Russian military aggression against Ukraine, this Regulation should enter into force as a matter of urgency.

(29) Given the exceptional nature of the measures set out in this Regulation, this Regulation should apply for one year after its entry into force. By 1 May 2023, the Commission should report on its functioning to the Council and may, if appropriate, propose to prolong its period of application.

(30) Since the objective of this Regulation cannot be sufficiently achieved by the Member States, but can rather 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 to achieve that objective,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation establishes rules to address a situation of severe difficulties in the supply of gas, with a view to safeguarding Union security of gas supply, in a spirit of solidarity. Those rules include improved coordination, monitoring of and reporting on national gas demand-reduction measures and the possibility for the Council to declare, on a proposal from the Commission, a Union alert as a Union-specific crisis level, triggering a mandatory Union-wide demand-reduction obligation.

Article 2

Definitions

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

(1) 'competent authority' means a national governmental authority or a national regulatory authority designated by a Member State to ensure the implementation of the measures provided for in Regulation (EU) 2017/1938;

(2) 'Union alert' means a Union-specific crisis level triggering a mandatory demand reduction and which is not related to any of the crisis levels pursuant to Article 11(1) of Regulation (EU) 2017/1938;

(3) 'gas consumption' means the overall supply of natural gas for activities on the territory of a Member State, including the final consumption of households, industry and electricity generation, but excluding, inter alia, gas used to fill storage capacities, in line with the definition for 'supply, transformation and consumption of gas' used by the Commission (Eurostat);

(4) 'feedstock' means 'non-energy use of natural gas' as referred to in energy balances calculations by the Commission (Eurostat);

(5) 'reference gas consumption' means the volume of a Member State's average gas consumption during the reference period; for Member States where gas consumption increased at least by 8 % in the period from 1 August 2021 to 31 March 2022 compared to the average gas consumption during the reference period, 'reference gas consumption' means only the volume of gas consumption in the period from 1 August 2021 to 31 March 2022;

(6) 'reference period' means the periods from 1 August to 31 March during the five consecutive years preceding the date of entry into force of this Regulation, starting with the period from 1 August 2017 to 31 March 2018;

(7) 'intermediate target' means the intermediate target as set out in Annex Ia to Regulation (EU) 2017/1938.

Article 3

Voluntary demand reduction

Member States shall use their best efforts to reduce their gas consumption in the period from 1 August 2022 to 31 March 2023 at least by 15 % compared to their average gas consumption in the period from 1 August to 31 March during the five consecutive years preceding the date of entry into force of this Regulation ('voluntary demand reduction'). Articles 6, 7 and 8 shall apply to those voluntary demand-reduction measures.

Article 4

Declaration of a Union alert by the Council

1. The Council, on a proposal from the Commission, by means of an implementing decision, may declare a Union alert.

2. The Commission shall present the proposal for such a Union alert where it considers that there is a substantial risk of a severe gas supply shortage or where an exceptionally high demand for gas occurs, for which the measures in Article 3 are not sufficient and which results in a significant deterioration of the gas supply situation in the Union, but where the market is able to manage the disruption without the need for non-market-based measures.

3. The Commission shall also submit a proposal to the Council to declare a Union alert where five or more competent authorities that have declared an alert at national level pursuant to Article 11(1), point (b), of Regulation (EU) 2017/1938 so request.

4. The Council, acting by a qualified majority, may amend the Commission's proposal.

5. Before submitting a proposal to the Council to declare a Union alert, the Commission shall consult the relevant risk groups, as set out in Annex I of Regulation (EU) 2017/1938 ('risk groups'), and the Gas Coordination Group (GCG), established by Article 4 of that Regulation.

6. On a proposal from the Commission, the Council may, by means of an implementing decision, declare an end to the Union alert and to the obligations pursuant to Article 5. The Commission shall present the proposal for such implementing decision to the Council where it considers, following an assessment, that the underlying basis for the Union alert no longer justifies the maintenance of that alert, and after consultation of the relevant risk groups and the GCG.

Article 5

Mandatory demand reduction in the event of a Union alert

1. Where the Council declares a Union alert, each Member State shall reduce its gas consumption in accordance with paragraph 2 ('mandatory demand reduction').

2. For the purpose of mandatory demand reduction, for as long as the Union alert is declared, gas consumption in each Member State over the period from 1 August 2022 to 31 March 2023 ('reduction period') shall be 15 % lower compared to its reference gas consumption. Any demand reductions achieved by Member States during the period before the Union alert was declared shall be taken into account for the purpose of the mandatory demand reduction.

3. A Member State whose electricity system is synchronised only with the electricity system of a third country shall be exempted from applying paragraph 2 in the event it is desynchronised from that third country's system for as long as isolated power system services or other services to the power transmission system operator are required to ensure the safe and reliable operation of the power system.

4. A Member State shall be exempted from applying paragraph 2 for as long as that Member State is not directly interconnected to a gas interconnected system of any other Member State.

5. A Member State may limit the reference gas consumption used for calculation of the mandatory demand-reduction target pursuant to paragraph 2 by the volume of gas equal to the difference between its intermediate target for 1 August 2022 and the actual volume of stored gas on 1 August 2022, if it fulfils the intermediate target on that date.

6. A Member State may limit the reference gas consumption used for calculation of the mandatory demand-reduction target pursuant to paragraph 2 by the volume of gas consumed during the reference period as feedstock.

7. A Member State may limit the mandatory demand reduction by 8 percentage points, provided that it demonstrates that its interconnection with other Member States measured in firm technical export capacity compared to its yearly gas consumption in 2021 is below 50 % and that capacity on interconnectors to other Member States has in fact been used for the transport of gas at a level of at least 90 % for at least one month before the notification of the derogation, unless the Member State can show there was no demand and the capacity was maximised, and that its domestic LNG facilities are commercially and technically ready to re-direct gas to other Member States up to the volumes required by the market.

8. A Member State facing an electricity crisis may temporarily limit the mandatory demand reduction pursuant to paragraph 2 to the level necessary to mitigate the risk for electricity supply if there are no other economic alternatives to replace the gas necessary for producing electricity without seriously endangering security of supply. In that case, the Member State shall notify the reasons for the limitation and provide sufficient evidence for the exceptional circumstances justifying the limitation. Where necessary, the Member State shall update the risk preparedness plan pursuant to Article 10 of Regulation (EU) 2019/941.

9. A Member State shall notify its decision to limit the mandatory demand reduction pursuant to paragraphs 5, 6, 7 and 8 to the Commission, together with the necessary evidence that the conditions for limiting the mandatory demand reduction are fulfilled. A notification in respect of paragraphs 5, 6 and 7 may already be made after the entry into force of this Regulation and shall not be made later than two weeks after a Union alert has been declared. A notification in respect of paragraph 8 may be made no later than two weeks after the situation of an electricity crisis referred to in that paragraph has arisen. The Member State shall also inform the relevant risk groups and the GCG of its intention.

10. On the basis of the notification and after consultation of the risk groups and the GCG, the Commission shall assess whether the conditions for a limitation pursuant to paragraphs 5, 6, 7 and 8 are fulfilled. In the event that the Commission finds that a limitation is not justified, it shall adopt an opinion indicating the reasons why the Member State should remove or modify the limitation of the mandatory demand reduction. That opinion shall be adopted no later than 30 working days after the complete notification pursuant to paragraph 9.

11. Where the conditions for the limitation of the mandatory demand reduction in paragraphs 5, 6, 7 and 8 are no longer fulfilled, the Member State shall apply the mandatory demand-reduction target pursuant to paragraph 2.

12. The Commission shall continuously monitor whether the conditions for a limitation of the mandatory demand reduction pursuant to paragraphs 5, 6, 7 and 8 are fulfilled.

13. Articles 6, 7 and 8 shall apply to mandatory demand-reduction measures without prejudice to existing long-term contracts.

Article 6

Measures to achieve the demand reduction

1. Member States shall be free to choose the appropriate measures to reduce demand. The measures referred to in Articles 3 and 5 shall be clearly defined, transparent, proportionate, non-discriminatory and verifiable. When selecting the measures, Member States shall take into account the principles set out in Regulation (EU) 2017/1938. The measures shall, in particular:

(a) not unduly distort competition or the proper functioning of the internal market in gas;

(b) not endanger the security of gas supply of other Member States or of the Union;

(c) comply with the provisions of Regulation (EU) 2017/1938 as regards protected customers.

2. When taking demand-reduction measures, Member States shall consider prioritising measures affecting customers other than protected customers, as defined in Article 2, point 5, of Regulation (EU) 2017/1938, and may also exclude those customers from such measures on the basis of objective and transparent criteria which shall take into account their economic importance as well as, among others, the following elements:

(a) the impact of a disruption on supply chains that are critical for society;

(b) the possible negative impacts in other Member States, in particular on supply chains of downstream sectors that are critical for society;

(c) the potential long-lasting damage to industrial installations;

(d) the possibilities for reducing consumption and substituting products in the Union.

3. When deciding the demand-reduction measures, the Member States shall consider measures to reduce gas consumed in the electricity sector, measures to encourage fuel switch in the industry, national awareness-raising campaigns, and targeted obligations to reduce heating and cooling, to promote switching to other fuels and reduce consumption by industry.

Article 7

Coordination of demand-reduction measures

1. To ensure appropriate coordination of voluntary and mandatory demand-reduction measures pursuant to Articles 3 and 5, Member States shall cooperate with each other within each of the relevant risk groups.

2. The competent authority of each Member State shall update its national emergency plan established pursuant to Article 8 of Regulation (EU) 2017/1938 by 31 October 2022 at the latest, to reflect voluntary demand-reduction measures. Each Member State shall also update its national emergency plan, as appropriate, in the event of a declaration of a Union alert pursuant to Article 4 of this Regulation. Articles 8(6) to (10) of Regulation (EU) 2017/1938 shall not apply to the updates of the national emergency plans made pursuant to this paragraph.

3. Member States shall consult the Commission and the relevant risk groups before adopting the revised emergency plans. The Commission may call for meetings of the risk groups and the GCG, taking into account any views expressed by the Member States in that context, to discuss issues related to national demand-reduction measures.

Article 8

Monitoring and enforcement

1. The competent authority of each Member State shall monitor the implementation of the demand-reduction measures on its territory. Member States shall report on the demand reduction achieved to the Commission every two months and not later than by the 15th of the following month. The risk groups and the GCG shall assist the Commission in the monitoring of the voluntary and mandatory demand reduction.

2. Where the Commission identifies, on the basis of the reported demand-reduction figures, a risk that a Member State will not be able to fulfil the mandatory demand-reduction obligation pursuant to Article 5, the Commission shall request the Member State to submit a plan setting out a strategy to effectively achieve the demand-reduction obligation. The Commission shall also request a Member State requesting a solidarity measure pursuant to Article 13 of Regulation (EU) 2017/1938 to submit a plan setting out the strategy to achieve possible further gas demand reductions, in line with Article 10(2) of Regulation (EU) 2017/1938. In both cases, the Commission shall issue an opinion with comments and suggestions on the submitted plans and inform the Council of its opinion. The Member State in question shall take due account of the Commission's opinion.

3. The Commission shall inform the European Parliament and the Council regularly about the implementation of this Regulation.

Article 9

Review

By 1 May 2023, the Commission shall carry out a review of this Regulation in view of the general situation of gas supply to the Union and present a report on the main findings of that review to the Council. Based on that report, the Commission may in particular propose to prolong the period of application of this Regulation.

Article 10

Entry into force and application

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

It shall apply for a period of one year from its entry into force.

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

Done at Brussels, 5 August 2022.

For the Council
The President
M. BEK

COMMISSION REGULATION (EU) 2022/1370

of 5 August 2022

amending Regulation (EC) No 1881/2006 as regards maximum levels of ochratoxin A in certain foodstuffs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ([1]), and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 ([2]) sets maximum levels for certain contaminants, including ochratoxin A, in foodstuffs.

(2) Ochratoxin A is a mycotoxin naturally produced by fungi of the genus *Aspergillus* and *Penicillium* and is found as a contaminant in a wide variety of foods, such as cereals and cereal products, coffee beans, dried fruits, wine and grape juice, spices and liquorice. Ochratoxin A is formed during sun drying and storage of crops. The formation can be prevented by applying good drying and storage practices.

(3) In 2020, the European Food Safety Authority ('the Authority') adopted an update of the scientific opinion on ochratoxin A in food ([3]). The Authority considered that it was not appropriate to establish a health based guidance value for ochratoxin A and that the Tolerable Weekly Intake of 120 ng/kg body weight (bw) as established by the Authority in 2006 is consequently no longer valid. It further concluded that the calculated margins of exposure for carcinogenic effects of ochratoxin A indicate a possible health concern for certain consumer groups.

(4) Maximum levels for ochratoxin A have already been established for certain foods by Regulation (EC) No 1881/2006. Taking into account that ochratoxin A has been found in foods for which no maximum level has been established yet and which contribute to the human exposure to ochratoxin A, it is appropriate to set a maximum level also for these foods such as dried fruit other than dried vine fruit, certain liquorice products, dried herbs, certain ingredients for herbal infusions, certain oilseeds, pistachio nuts and cocoa powder. Even if the relationship between the level of ochratoxin A in malt and in non-alcoholic malt beverages, and in dried dates and date syrup needs to be further clarified, it is also appropriate to set already a maximum level in non-alcoholic malt beverages and date syrup. Also taking into account the available occurrence data, it is appropriate to lower the existing maximum levels of ochratoxin A in certain foods, such as bakery products, dried vine fruit, roasted coffee and soluble coffee. In addition, the existing provisions for ochratoxin A in certain spices has been broadened to all spices. For cheese and ham, additional monitoring on the presence of ochratoxin A is appropriate before establishing maximum levels.

(5) Regulation (EC) No 1881/2006 should therefore be amended accordingly.

(6) To enable economic operators to prepare for the new rules introduced by this Regulation, it is appropriate to provide for a reasonable time until the new maximum levels apply. It is also appropriate to provide for a transitional period for foodstuffs lawfully placed on the market before the date of application of this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 37, 13.2.1993, p. 1.

([2]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

([3]) Scientific Opinion on the risk assessment of ochratoxin A in food. EFSA Journal 2020; 18(5):6113, 150 pp. https://doi.org/10.2903/j.efsa.2020.6113.

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

Article 2

Foodstuffs listed in the Annex, lawfully placed on the market before 1 January 2023, may remain on the market until their date of minimum durability or use-by-date.

Article 3

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 2023.

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

Done at Brussels, 5 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In section 2 of the Annex to Regulation (EC) No 1881/2006, entry 2.2 is replaced by the following:

	Foodstuffs [1]	Maximum level (µg/kg)
'2.2	**Ochratoxin A**	
2.2.1	Unprocessed cereals [18]	5,0
2.2.2	All products, derived/processed from unprocessed cereals, with the exception of foodstuffs listed in 2.2.3, 2.2.4, 2.2.5, 2.2.12 and 2.2.13 Cereals placed on the market for the final consumer	3,0
2.2.3	Bakery wares, cereal snacks and breakfast cereals — products not containing oilseeds, nuts or dried fruit — products containing at least 20 % dried vine fruit and/or dried figs — other products containing oilseeds, nuts and/or dried fruit	2,0 4,0 3,0
2.2.4	Non-alcoholic malt beverages	3,0
2.2.5	Wheat gluten not placed on the market for the final consumer	8,0
2.2.6	Dried fruit — dried vine fruit (currants, raisins and sultanas) and dried figs — other dried fruit	8,0 2,0
2.2.7	Date syrup	15
2.2.8	Roasted coffee — roasted coffee beans and ground roasted coffee, excluding soluble coffee — soluble coffee (instant coffee)	3,0 5,0
2.2.9	Wine (including sparkling wine, excluding liqueur wine and wine with an alcoholic strength of not less than 15 % vol.) and fruit wine [11]	2,0 [12]
2.2.10	Aromatised wine, aromatised wine-based drinks and aromatised wine-product cocktails [13]	2,0 [12]
2.2.11	Grape juice, concentrated grape juice as reconstituted, grape nectar, grape must and concentrated grape must as reconstituted, placed on the market for the final consumer [14]	2,0 [12]
2.2.12	Processed cereal-based foods for infants and young children and baby foods [3] [7]	0,50
2.2.13	Dietary foods for special medical purposes intended for infants and young children [3] [10]	0,50
2.2.14	Spices, including dried spices, except *Capsicum spp*. *Capsicum spp*. (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne or paprika) Mixtures of spices	15 20 15
2.2.15	Liquorice (*Glycyrrhiza glabra*, *Glycyrrhiza inflate* and other species) — liquorice root, including as an ingredient in herbal infusions — liquorice extract [42] for use in food in particular beverages and confectionary — liquorice confectionary containing ≥ 97 % liquorice extract on dry basis — other liquorice confectionary	20 80 50 10,0

2.2.16	Dried herbs	10,0
2.2.17	Ginger roots for use in herbal infusions Marshmallow roots, dandelion roots and orange blossoms for use in herbal infusions or in coffee substitutes	15 20
2.2.18	Sunflower seeds, pumpkin seeds, (water) melon seeds hempseeds, soybeans	5,0
2.2.19	Pistachios to be subjected to sorting, or other physical treatment, before placing on the market for final consumer or use as ingredient in food Pistachios placed on the market for final consumer or use as ingredient in foodstuffs	10,0 5,0
2.2.20	Cocoa powder	3,0’

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1371

of 5 August 2022

correcting certain language versions of Implementing Regulation (EU) 2018/2066 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a system for greenhouse gas emission allowance trading within the Union and amending Council Directive 96/61/EC ([1]), and in particular Article 14(1) thereof,

Whereas:

(1) The Bulgarian, Czech, Danish, Dutch, Estonian, Finnish, French, German, Italian, Latvian, Portuguese, Slovenian and Swedish language versions of Commission Implementing Regulation (EU) 2018/2066 ([2]) contain in Article 38(6) an error that alters the meaning of the provision or wording that can lead to misinterpretation, as regards the indicated period of time and to what it refers.

(2) The Bulgarian, Czech, Danish, Dutch, Estonian, Finnish, French, German, Italian, Latvian, Portuguese, Slovenian and Swedish language versions of Implementing Regulation (EU) 2018/2066 should therefore be corrected accordingly. The other language versions are not affected.

(3) The measures provided for in this Implementing Regulation are in accordance with the opinion of the Climate Change Committee delivered on 9 February 2022,

HAS ADOPTED THIS REGULATION:

Article 1

(does not concern the English language)

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, 5 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

([1]) OJ L 275, 25.10.2003, p. 32.
([2]) Commission Implementing Regulation (EU) 2018/2066 of 19 December 2018 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 601/2012 (OJ L 334, 31.12.2018, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1372

of 5 August 2022

as regards temporary measures to prevent the entry into, the movement and spread within, the multiplication and release in the Union of *Meloidogyne graminicola* (Golden & Birchfield)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC ([1]), and in particular Articles 30(1) and 41(2) thereof,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC ([2]), and in particular Article 128(1) thereof,

Whereas:

(1) *Meloidogyne graminicola* (Golden & Birchfield) is not listed as a Union quarantine pest, protected zone quarantine pest or as a Union regulated non-quarantine pest in accordance with Commission Implementing Regulation (EU) 2019/2072 ([3]).

(2) In 2016, Italy informed the Commission that *Meloidogyne graminicola* (Golden & Birchfield) was first found in its territory in a rice-producing area of Northern Italy. Since then, it has also been found in additional rice fields and the most serious infestations led to crop losses of up to 50 % of the ordinary production.

(3) In 2017, Italy adopted official measures to prevent the further introduction and spread within its territory of *Meloidogyne graminicola* (Golden & Birchfield) ([4]). *Meloidogyne graminicola* (Golden & Birchfield) is mainly associated with rooted plants of *Oryza sativa* L. that have been grown in soil and are intended for planting. It is also associated with other host plants, such as barley, but to a lesser extent than with rooted plants of *Oryza sativa* L.

([1]) OJ L 317, 23.11.2016, p. 4.
([2]) OJ L 95, 7.4.2017, p. 1.
([3]) Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).
([4]) Misure d'emergenza per impedire la diffusione di *Meloidogyne graminicola* Golden & Birchfield nel territorio della Repubblica italiana. Decreto 6 luglio 2017, Gazzetta ufficiale della Repubblica Italiana. Serie generale n. 202, 30.8.2017.

(4) Italy is currently the only Member State where the presence of *Meloidogyne graminicola* (Golden & Birchfield) has been confirmed. Based on a risk assessment carried out by Italy in 2018 ([5]), it is concluded that that pest fulfils the criteria set out in Subsection 2 of Section 3 of Annex I to Regulation (EU) 2016/2031. It is therefore deemed necessary to adopt temporary measures against that pest. Those measures should take account of the major pathways for its spread, such as plants for planting, soil, machinery and tools, and human-assisted transfer.

(5) In a certain region within that rice-producing area of Italy, it has been concluded that the eradication of *Meloidogyne graminicola* (Golden & Birchfield) is no longer possible. Italy should therefore be allowed to apply measures for its containment within that region, instead of eradication. Those measures should be aimed at keeping the levels of *Meloidogyne graminicola* (Golden & Birchfield) stable. However, if surveys show an increase of the levels of *Meloidogyne graminicola* (Golden & Birchfield), measures aimed at its eradication should be applied to reduce its levels again and prevent its spread.

(6) Member States should inform the general public and relevant professional operators about the threat of *Meloidogyne graminicola* (Golden & Birchfield) and the measures taken against it to ensure a more effective approach by all persons possibly concerned. In particular, Member States should raise awareness about the danger of its spread through footwear and vehicles, because those means are most commonly used by the general public.

(7) Surveys should be carried out in the demarcated areas and on host plants outside those areas, in order to detect early the potential presence of *Meloidogyne graminicola* (Golden & Birchfield) and prevent its spread to the rest of the Union territory. Member States should conduct annual surveys based on an assessment of the risk of introduction of *Meloidogyne graminicola* (Golden & Birchfield).

(8) In view of the evidence from Italy and of the wide distribution of *Meloidogyne graminicola* (Golden & Birchfield) in rice-producing third countries, it is necessary to check that certain conditions were fulfilled in those third countries, with respect to the rooted plants for planting of *Oryza sativa* L., prior to their introduction into the Union. In particular, those conditions should concern the freedom of the site or place of production from the pest, the official inspections to be carried out and the necessary declarations on the phytosanitary certificate. These conditions are necessary to ensure freedom of those plants from *Meloidogyne graminicola* (Golden & Birchfield).

(9) Furthermore, it is necessary that, at arrival, rooted plants for planting of *Oryza sativa* L. are visually inspected and, where showing symptoms of *Meloidogyne graminicola* (Golden & Birchfield), sampled and tested for the presence of that pest, in order to identify its possible presence or ascertain its absence.

(10) Measures should also be provided for the movement within the Union of rooted plants of *Oryza sativa* L. that originate in the Union. In order to ensure the appropriate level of phytosanitary protection, the movement of those plants and soil from the demarcated areas to the rest of the Union territory should be prohibited.

(11) This Regulation should apply for an adequate length of time to allow for its review and the review of the presence and the spread of *Meloidogyne graminicola* (Golden & Birchfield).

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([5]) Pest risk analysis on *Meloidogyne graminicola* (Golden & Birchfield) carried out by Consiglio per la ricerca in agricoltura e l'analisi dell'economia agraria (CREA).

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation sets out rules to prevent the entry into, the movement and spread within, the multiplication and release in the Union of *Meloidogyne graminicola* (Golden & Birchfield).

Article 2

Definitions

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

(1) 'the specified pest' means *Meloidogyne graminicola* (Golden & Birchfield);

(2) 'specified plants' means plants for planting, other than seeds, with roots of *Oryza sativa* L., that have been grown in soil;

(3) 'host plants' means plants for planting with roots of the genera and species listed in Annex I, that have been grown in soil;

(4) 'volunteer host plants' means host plants which appear in the places of production without having been planted;

(5) 'specified seeds' means seeds of *Oryza sativa* L.;

(6) 'specified objects' means machinery, tools, vehicles, and personal equipment, which have been used for activities relating to the planting, treatment or harvesting of the host plants;

(7) 'demarcated area' means the area consisting of an infested zone and a buffer zone that is established when the specified pest has been found;

(8) 'infested zone' means a zone in which the field or fields of *Oryza sativa* L. contains:

(a) all host plants known to be infested by the specified pest;

(b) all host plants showing symptoms indicating possible infestation by the specified pest;

(c) all other plants suspected to be infested or infested by the specified pest, including plants prone to be infested due to their susceptibility to that pest and their close proximity to infested specified plants, or plants grown from them;

(d) land, soil or other elements infested, or liable to be infested, by the specified pest;

(9) 'buffer zone' means a zone of a width of at least 100 m, surrounding the infested zone;

(10) 'trap-crop method' means the method under which certain specified plants are temporarily planted in an infested field, in order to trap the specified pest, and later removed and destroyed, for the purpose of protecting in the same field other specified plants from that pest.

Article 3

Prohibition of introduction and movement within the Union

The specified pest shall not be introduced into, moved within, or held, multiplied or released in the Union territory.

Article 4

Establishment of demarcated areas

1. Where the presence of the specified pest in the Union territory is confirmed, each Member State concerned shall immediately establish a demarcated area.

2. If the presence of the specified pest is confirmed in the buffer zone, the Member State concerned shall immediately review and modify accordingly the delimitation of the infested zone and the buffer zone.

3. The Member State concerned shall notify the Commission and the other Member States of the number and locations of the demarcated areas established for the specified pest pursuant to Article 18 of Regulation (EU) 2016/2031.

4. Where, on the basis of the surveys referred to in Article 8, the specified pest is not detected in a demarcated area for a period of 3 consecutive years, that demarcated area may be abolished. In such cases, the Member State concerned shall notify the Commission and the other Member States that the demarcated area has been abolished pursuant to Article 19(4) of Regulation (EU) 2016/2031.

Article 5

Eradication measures

The Member State concerned shall apply all of the following measures in the demarcated area(s) for the purpose of eradication of the specified pest:

(1) the specified plants in the infested zone shall be removed and destroyed in fields close to harvesting. The specified plants shall be destroyed, *in situ* or in a nearby location designated for this purpose within the infested zone, in a manner ensuring that the specified pest is not spread;

(2) specified seeds shall not be sown and host plants shall not be planted in the infested zone;

(3) volunteer host plants shall be regularly eliminated;

(4) fields in the infested zone shall be continuously flooded for more than 18 months. If continuous flooding is not possible, the trap-crop method, or other methods preventing the pest from concluding its life cycle, shall be applied;

(5) specified plants that are used for the trap-crop method shall be destroyed within 5 weeks after planting;

(6) specified objects that have been used in an infested zone shall be cleaned from soil and plant debris before being moved to the surrounding fields. During cleaning, residue dispersal out of the infested field shall be avoided.

Article 6

Containment measures

1. In the demarcated areas listed in Annex II, the competent authority shall apply all of the following measures for the purpose of containing the specified pest within those areas and preventing its spread outside those areas:

(a) specified seeds may be sown and specified plants may be planted only if one of the following phytosanitary measures has been carried out:

  (i) continuous flooding for at least 6 months since the last harvest;

  (ii) trap-crop method whereby specified plants shall be destroyed within five weeks after planting;

  (iii) crop rotation with non-host plants or cultivated host plants of the genus *Brassica* L. or species *Allium cepa* L., *Glycine max* (L.) Merr., *Hordeum vulgare* L., *Panicum miliaceum* L., *Sorghum bicolor* (L.) Moench, *Triticum aestivum* L. and *Zea mays* L., intended for the production of bulbs, vegetables or grains for final users other than the use as plants for planting;

(b) volunteer host plants shall be regularly eliminated;

(c) specified objects that have been used in the infested field shall be cleaned from soil and plant debris before moving them to the surrounding fields. During cleaning, residue dispersal out of the infested field shall be avoided.

2. If survey results demonstrate that the presence of the specified pest has increased, the competent authority shall apply the measures referred to in Article 5 in the respective demarcated areas.

Article 7

Awareness raising

Regarding the demarcated area(s) to which the eradication and the containment measures referred to in Articles 5 and 6 were applied, the Member State concerned shall raise public awareness concerning the threat of the specified pest and the measures adopted to prevent its further spread outside of the demarcated areas. It shall ensure that the general public and relevant operators are aware of the delimitation of the demarcated area(s), the infested zone and the buffer zone.

Article 8

Surveys of the specified pest in the territory of the Member States

1. Member States shall conduct annual official surveys for the presence of the specified pest on host plants in their territory, prioritising the surveys on the specified plants. Those surveys shall be risk-based.

Member States shall transmit, by 30 April of each year, to the Commission and to the other Member States, the results of the surveys carried out outside of the demarcated areas based on the templates referred to in Annex I to Commission Implementing Regulation (EU) 2020/1231 ([6]).

2. In demarcated areas, the Member State concerned shall monitor the development of the presence of the specified pest. The Member State concerned shall, by 30 April of each year, transmit to the Commission and to the other Member States, the results of the surveys carried out using the template set out in Annex III.

3. Those surveys shall consist of visual examinations of host plants, sampling of symptomatic host plants as well as, where appropriate, asymptomatic host plants in the proximity of the symptomatic host plants, and of soil. The root system of sampled plants shall be checked for the presence of galls of the specified pest.

4. Soil samples shall be taken adjacent to symptomatic host plants. Soil shall be sampled at a depth of 20-25 cm. In the fields under surveillance, soil samples shall be taken in a rectangular grid covering the entire field whereby the sampling distance shall not exceed 20 m length by 5 m width. The sample size shall be 500 ml up to a total surface of 1 ha.

Article 9

Movement of the specified plants, soil, specified seeds, and specified objects

1. The movement of the specified plants out of the demarcated areas shall be prohibited.

2. The movement within or out of the demarcated areas of soil in which specified plants have been grown in the previous 3 years shall be prohibited.

3. The movement of specified seeds within or out of the demarcated areas shall be allowed only if the seeds are free from soil and plant debris.

4. The movement of specified objects out of the demarcated areas shall be allowed only if they are cleaned and found free from soil.

([6]) Commission Implementing Regulation (EU) 2020/1231 of 27 August 2020 on the format and instructions for the annual reports on the results of the surveys and on the format of the multiannual survey programmes and the practical arrangements, respectively provided for in Articles 22 and 23 of Regulation (EU) 2016/2031 of the European Parliament and the Council (OJ L 280, 28.8.2020, p. 1).

Article 10

Introduction of specified plants and specified seeds into the Union

Specified plants and specified seeds originating in third countries may only be introduced into the Union if the competent authorities or the professional operators under the official supervision of the competent authorities comply with all of the following requirements:

(1) the specified plants which have been produced in a pest-free place or a pest-free site of production are officially inspected at that place or site of production, at the most appropriate time for detecting symptoms of infection during the last complete cycle of vegetation prior to the export, and are found free from the specified pest;

(2) official inspections were carried out at the most appropriate time for detecting symptoms of infection during the last complete cycle of vegetation prior to the export in a zone with a width of at least 100 m and surrounding the place or site of production referred to in point (1);

(3) any specified plants in the zone surrounding the pest-free place or pest-free site of production showing symptoms of infection during those inspections were immediately destroyed;

(4) the specified plants are accompanied by a phytosanitary certificate including, in accordance with Article 71(2) of Regulation (EU) 2016/2031, under the heading 'Additional declaration', one of the following statements:

(a) 'The national plant protection organisation of origin of the specified plants recognised that country as being free from the specified pest in accordance with the relevant international standards for phytosanitary measures.';

(b) 'The specified plants originate in a pest-free area, established as regards the specified pest by the national plant protection organisation of the third country of the area concerned, in accordance with the relevant international standards for phytosanitary measures. The name of the pest-free area shall be included in the phytosanitary certificate under the heading "Place of origin".';

(c) 'The specified plants have been produced in a pest-free place or a pest-free site of production, established as regards the specified pest by the national plant protection organisation of the third country concerned, in accordance with the relevant international standards for phytosanitary measures (Requirements for the establishment of pest free places of production and pest free production sites. ISPM No 10 (1999), Rome, IPPC, FAO 2016) and have been produced in accordance with Commission Implementing Regulation (EU) 2022/1372 (*).

(*) Commission Implementing Regulation (EU) 2022/1372 of 5 August 2022 as regards temporary measures to prevent the entry into, the movement and spread within, the multiplication and release in the Union of Meloidogyne graminicola (Golden & Birchfield) (OJ L 206, 8.8.2022, p. 16).';

(5) the phytosanitary certificate accompanying specified seeds originating in third countries includes, under the heading 'Additional declaration', the information that the seeds are free from soil and debris.

Article 11

Sampling and testing of specified plants showing symptoms of the specified pest

Specified plants introduced into the Union from a third country and showing symptoms of the specified pest, upon visual inspection, shall be sampled and tested to identify the presence of that pest.

Article 12

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 until 30 June 2025.

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

Done at Brussels, 5 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

List of host plants referred to in Article 2, point (3)

Genus or species

Ageratum conyzoides L.

Alisma plantago L.

Allium cepa L.

Alopecurus L.

Amaranthus spinosus L.

Amaranthus viridis L.

Avena sativa L.

Beta vulgaris L.

Brassica L.

Capsicum annuum L.

Centella asiatica (L.) Urb.

Colocasia esculenta (L.) Schott

Coriandrum sativum L.

Cucumis sativus L.

Cymbopogon citratus (DC.) Stapf

Cynodon dactylon (L.) Pers.

Cyperus compressus L.

Cyperus difformis L.

Cyperus iria L.

Cyperus rotundus L.

Dactyloctenium aegyptium (L.) Willd.

Digitaria filiformis (L.) Köler

Digitaria sanguinalis (L.) Scop.

Echinochloa colona (L.) Link

Echinochloa crus-galli (L.) P. Beauv.

Eclipta prostrata (L.) L.

Eleusine coracana (L.) Gaertn.

Eleusine indica (L.) Gaertn.

Fimbristylis dichotoma var. *pluristriata* (C.B.Clarke) Napper

Gamochaeta coarctata (L.) Cabrera

Glycine max (L.) Merr.

Heteranthera reniformis Ruiz & Pav.

Hordeum vulgare L.

Hydrilla Rich.

Impatiens balsamina L.

Imperata cylindrica (L.) Raeusch.

Kyllinga brevifolia Rottb.

Lactuca sativa L.

Ludwigia L.

Melilotus albus Medik.

Murdannia keisak (Hassk.) Hand.-Mazz.

Musa L.

Oryza sativa L.

Oxalis corniculata L.

Panicum L.

Pennisetum glaucum (L.) R. Br.

Pisum sativum L.

Poa annua L.

Portulaca oleracea L.

Ranunculus L.

Saccharum officinarum L.

Schoenoplectus articulatus (L.) Palla

Schoenoplectiella articulata (L.) Lye

Setaria italica (L.) P. Beauv.

Solanum lycopersicum L.

Solanum melongena L.

Solanum nigrum L.

Solanum sisymbriifolium Lam.

Solanum tuberosum L.

Sorghum bicolor (L.) Moench

Spergula arvensis L.

Spinacia oleracea L.

Stellaria media (L.) Vill.

Trifolium repens L.

Triticum aestivum L.

Urena lobata L.

Vicia faba L.

Zea mays L.

ANNEX II

Demarcated areas referred to in Article 6

Italy

List of municipalities in demarcated areas in Italy

Region	Province	Municipalities
Lombardy	Pavia	Alagna, Carbonara al Ticino, Cilavegna, Dorno, Gambolò, Garlasco, Gropello Cairoli, Linarolo, Parona, Pieve Albignola, Sannazzaro de' Burgondi, Scaldasole, Sommo, Tromello, Trovo, Vigevano, Villanova d'Ardenghi, Zerbolò, Zinasco
Piedmont	Biella	Castelletto Cervo, Gifflenga, Mottalciata
Piedmont	Vercelli	Buronzo

ANNEX III

Template for the reporting of the results of the surveys carried out pursuant to Article 8(2) in demarcated areas

1. **Description of the DA**		2. **Initial size of DA (ha)**	3. **Updated size of DA (ha)**	4. **Approach**	5. **Zone**	6. **Survey sites**		7. **Risk areas identified**	8. **Risk areas inspected**	9. **Plant material/Commodity**	10. **List of host plant species**	11. **Timing**	12. **Survey details** A) Number of visual examinations B) Total number of samples taken C) Type of traps (or other alternative method (e.g. sweep nets)) D) Number of traps (or other capturing method) E) Number of trapping sites, when different from data reported in (D) F) Type of tests (e.g. microscopic identification, PCR, ELISA, etc.) G) Total number of tests H) Other measures (e.g. sniffer dogs, drones, helicopters, awareness raising campaigns etc.) I) Number of other measures									13. **N° of symptomatic samples analysed:** i: Total ii: Positive iii: Negative iv: Undetermined				14. **N° of asymptomatic samples analysed:** i: Total ii: Positive iii: Negative iv: Undetermined				15. **Comments**
Name	**Date of establishment**					**Description**	**Number**						**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	i	ii	iii	iv	i	ii	iii	iv	

Instructions for how to report

For column 1: Indicate the name of the geographical area, outbreak number or any information that allows identification of the demarcated area (DA) and the date when it was established.

For column 2: Indicate the size of the DA before the start of the survey.

For column 3: Indicate the size of the DA after the survey.

For column 4: Indicate the approach: Eradication (E)/Containment (C). Please, include as many rows as necessary, depending on the number of DA per pest and the approaches these areas are subject to.

For column 5: Indicate the zone of the DA where the survey was carried out, including as many rows as necessary: Infested zone (IZ) or buffer zone (BZ), using separate rows. When applicable, indicate the area of the IZ where the survey was carried out (e.g. last 20 km adjacent to the BZ, around nurseries, etc.) in different rows.

For column 6: Indicate the number and the description of the survey sites, by choosing one of the following entries for the description:

1. Open air (production area): 1.1. field (arable, pasture); 1.2. orchard/vineyard; 1.3. nursery; 1.4. forest;
2. Open air (other): 2.1. private garden; 2.2. public sites; 2.3. conservation area; 2.4. wild plants in areas other than conservation areas; 2.5. other, with specification of the particular case (e.g. garden centre, commercial sites that uses wood packaging material, wood industry, wetlands, irrigation and drainage network, etc.);
3. Physically closed conditions: 3.1. greenhouse; 3.2. private site, other than greenhouse; 3.3. public site, other than greenhouse; 3.4. other, with specification of the particular case (e.g. garden centre, commercial sites that uses wood packaging material, wood industry).

For column 7: Indicate which are the risk areas identified based on the biology of the pest(s), presence of host plants, eco-climatic conditions and risk locations.

For column 8: Indicate the risk areas included in the survey, from those identified in column 7.

For column 9: Indicate plants, fruits, seeds, soil, packaging material, wood, machinery, vehicles, water, other, specifying the specific case.

For column 10: Indicate the list of plant species/genera surveyed. When required by the specific legal pest survey requirement, use one row per plant species/genera.

For column 11: Indicate the months of the year when the survey was carried out.

For column 12: Indicate the details of the survey, depending on the specific legal requirements of each pest. Indicate with NA when the information of certain column is not applicable.

For columns 13 and 14: Indicate the results, if applicable, providing the information available in the corresponding columns. 'Undetermined' are those analysed samples for which no result was obtained due to different factors (e.g. below detection level, unprocessed sample-not identified, old, etc.)

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1373

of 5 August 2022

authorising the placing on the market of iron hydroxide adipate tartrate as a novel food and amending Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ([1]), and in particular Article 12(1) thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ([2]) has established a Union list of novel foods.

(3) On 21 February 2020, the company Nemysis Limited ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place iron hydroxide adipate tartrate ('IHAT') on the Union market as a novel food to be used as a source of iron in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]), in the form of capsules, at levels up to 100 mg/day that would correspond to up to 36 mg iron (Fe) per day, intended for the general population excluding infants and young children. In the application, the applicant indicated that IHAT as engineered nanomaterial is a novel food within the meaning of Article 3(2)(a)(viii) of Regulation (EU) 2015/2283.

(4) On 21 February 2020, the applicant also made a request to the Commission for the protection of proprietary data for an *in vitro* mammalian cell micronucleus test ([4]), an *in vitro* mammalian cell gene mutation test using the thymidine kinase gene ([5]), and a 90-day oral toxicity study in rodents ([6]), submitted in support of the application.

(5) On 3 July 2020, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of IHAT as a novel food.

(6) On 27 October 2021, the Authority adopted its scientific opinion on the 'Safety of Iron Hydroxide Adipate Tartrate as a Novel food pursuant to Regulation (EU) 2015/2283 and as a source of iron in the context of Directive 2002/46/EC' ([7]) in accordance with Article 11 of Regulation (EU) 2015/2283.

([1]) OJ L 327, 11.12.2015, p. 1.
([2]) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).
([3]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).
([4]) Nemysis Limited (2019, unpublished).
([5]) Nemysis Limited (2019, unpublished).
([6]) Nemysis Limited (2019, unpublished).
([7]) EFSA Journal 2021;19(12):6935.

(7) In its scientific opinion, the Authority concluded that IHAT is safe under the proposed conditions of use for the proposed target populations at levels not exceeding 100 mg/day and that it is a source from which iron is bioavailable. In that opinion however, the Authority noted that, since it had not set a tolerable Upper intake Limit ('UL'), the intake of iron from food supplements containing the novel food could exceed population guidance levels that have been set by Member States, and that the combined intake of iron from food supplements containing the novel food and the background diet would be high. In light of the Authority's considerations and of the pivotal role of iron in human physiology, growth and development, particularly in the early stages of life, and the rather fine line between beneficial and adverse health effects of iron depending on intakes, the Commission considers that a precautionary approach is needed.

(8) The Commission therefore requested the applicant to reconsider the levels of IHAT proposed in their application (levels up to 100 mg/day that would correspond to up to 36 mg iron (Fe) per day for the general population, excluding infants and young children). In response to the Commission's request, the applicant modified its request and proposed the use of IHAT at levels not exceeding 100 mg/day and limiting the corresponding iron levels to up to 30 mg Fe/day in food supplements intended for the adult population, and at levels not exceeding 50 mg IHAT/day and limiting the corresponding iron levels to up to 14 mg Fe/day in food supplements intended for children and adolescents under 18 years of age, excluding children under 4 years of age. In addition, the applicant indicated that it will adjust the levels of IHAT in food supplements placed on the market of a Member State to limit the corresponding maximum levels of iron to the guidance values set by that Member State for each age group of the population. The Commission considers that the revised uses would fulfil the conditions for the placing on the market of IHAT in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(9) It is appropriate that the inclusion of IHAT as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

(10) In the same scientific opinion, the Authority considered that, due to the presence of nickel in the novel food, the consumption of food supplements containing 100 mg of IHAT may elicit dermatitis related allergic reactions to persons of 10 years of age and younger that have been previously sensitised to nickel following skin contact as the intake of nickel from the novel food would not result in a Margin of Exposure ('MoE') for the intake of nickel deemed by the Authority to be of low health concern for children and adolescents under 18 years of age in the upper 95th percentile of dietary nickel exposure ([8]). However, in light of the modified proposed uses of the novel food at levels not exceeding 50 mg IHAT/day in food supplements intended for children and adolescents under 18 years of age and excluding children under 4 years of age, the intake of nickel from the novel food will be either above or close to the MoE considered by the Authority to be of low health concern, and will not contribute significantly in the overall intake of nickel from food and drinking water. Taking into account these considerations and the built-in conservativism in the Authority's intake assessment that used the 95th percentile dietary exposure to derive the nickel MoE of low health concern, the Commission considers that the risk of elicitation of contact dermatitis allergic reactions to that age group of the population is unlikely to manifest in real life situations. Therefore, the Commission considers that no labelling requirement provided for in Article 9(3)(b) of Regulation (EU) 2015/2283 is necessary as to allergenicity.

(11) In addition, in its scientific opinion, the Authority also considered that its conclusion on the safety of IHAT and the bioavailability of iron is closely linked to the specific physicochemical properties and particle size distribution and agglomeration profile of the novel food that is achieved by the combined effect of the use of the capsular form of the food supplements containing the novel food, and the absence of substances other than the adipate, tartrate and sodium chloride used in the production of IHAT. The Authority therefore considered that the safety profile of the novel food and the bioavailability of the nutrient source may be affected and will have to be assessed on a case by case basis, if other forms of food supplements (e.g. tablets, pastilles, sachets of powders, gummies, syrups, etc.) are used alone or in combination with adipate, tartrate and sodium chloride or with substances other than the adipate, tartrate and sodium chloride or, if other substances are used in the capsular forms of the food supplements. It is therefore appropriate that when other forms of food supplements (e.g. tablets, pastilles, sachets of powders, gummies, syrups, etc.) are used in combination with adipate, tartrate and sodium chloride or in combination with other substances, or if other substances are used in the capsular form food supplements containing the novel food, the particle size distribution and agglomeration state of the novel food should be in accordance with the authorised specifications and that the bioavailability of iron should be in accordance with the bioavailability assessed by the Authority in its scientific opinion.

([8]) EFSA Journal 2020;18(11):6268.

(12) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on scientific data from the *in vitro* mammalian cell micronucleus test, the *in vitro* mammalian cell gene mutation test using the thymidine kinase gene, and the 90-day oral toxicity study in rodents, contained in the applicant's file, without which it could not have assessed the novel food and reached its conclusion.

(13) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those studies and to clarify its claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.

(14) The applicant declared that it held proprietary and exclusive rights of reference to the scientific data from the *in vitro* mammalian cell micronucleus test, the *in vitro* mammalian cell gene mutation test using the thymidine kinase gene, and the 90-day oral toxicity study in rodents at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.

(15) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific data from the *in vitro* mammalian cell micronucleus test, the *in vitro* mammalian cell gene mutation test using the thymidine kinase gene and the 90-day oral toxicity study in rodents should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place IHAT on the market within the Union during a period of 5 years from the entry into force of this Regulation.

(16) However, restricting the authorisation of IHAT and the reference to the scientific data contained in the applicant's file for the sole use by them does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.

(17) IHAT is an engineered nanomaterial as defined in Article 3(2)(f) of Regulation (EU) 2015/2283. It is therefore appropriate that the novel food should be clearly indicated in the list of ingredients of the foodstuffs containing it followed by the word 'nano' in brackets, in accordance with Article 18 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council ([9]).

(18) IHAT should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. Iron hydroxide adipate tartrate is authorised to be placed on the market within the Union.

Iron hydroxide adipate tartrate shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

([9]) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

Article 2

Only the company 'Nemysis Limited' ([10]) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from 28 August 2022, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of 'Nemysis Limited'.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of 'Nemysis Limited'.

Article 4

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, 5 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

([10]) Address: Suite 4.01 Ormond Building 31-36 Ormond Quay Upper Arran Quay Dublin 7, D07 F6DC Dublin, Ireland.

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'**Iron hydroxide adipate tartrate**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'iron hydroxide adipate tartrate (nano)'. The labelling of food supplements containing iron hydroxide adipate tartrate shall bear a statement that they should not be consumed by children and adolescents under the age of 18/children under 4 years of age (*) (*) Depending on the age group the food supplement is intended for.		Authorised on 28.8.2022. This inclusion is based on proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Nemysis Limited, Suite 4.01 Ormond Building 31-36 Ormond Quay Upper Arran Quay Dublin 7, D07 F6DC, Dublin, Ireland. During the period of data protection, the novel food iron hydroxide adipate tartrate is authorised for placing on the market within the Union only by Nemysis Limited, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Nemysis Limited. End date of the data protection: 28.8.2027.'
	Food supplements as defined in Directive 2002/46/EC for the adult population	≤ 100 mg/day (≤ 30 mg Fe/day)			
	Food supplements as defined in Directive 2002/46/EC for children and adolescents under 18 years of age, excluding children under 4 years of age	≤ 50 mg/day (≤ 14 mg Fe/day)			

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised novel food	Specification	
'Iron hydroxide adipate tartrate	**Description/Definition:** Iron hydroxide adipate tartrate (IHAT) is an odourless, engineered nanomaterial in powder form that is insoluble in water and is manufactured by a chemical synthesis involving a series of steps involving acid-base reaction, precipitation, filtration, and drying. The food supplements containing the novel food are manufactured in capsular form. Excess adipate, tartrate and sodium chloride are used at levels resulting from the production process to help stabilise IHAT and ensure the authorised particle size distribution. If other forms of food supplements (e. g. tablets, pastilles, sachets of powders, gummies, syrups, etc.) are used in combination with adipate, tartrate and sodium chloride or in combination with other substances, or if other substances are used in the capsular form food supplements containing the novel food, it must be ensured that the authorised IHAT particle size distribution is maintained.	
	Common name	Iron oxo-hydroxide adipate tartrate
	Other names	Iron hydroxide adipate tartrate, Iron oxyhydroxide adipate tartrate
	Trade name	IHAT
	CAS number	2460638-28-0
	Molecular formula (calculated)	$FeO_m(OH)_n(H_2O)_x(C_4H_6O_6)_y(C_6H_{10}O_4)_z$ *where: m and n are undefined as per accepted practice for ferric iron oxohydroxides* (*) x = 0,28-0,88 y = 0,78-1,50 z = 0,04-0,19 Tartaric ($C_4H_6O_6$) and adipic ($C_6H_{10}O_4$) acid are represented in their protonated form.
	Molecular weight	Average molecular weight: 35 803,4 Da (lower-upper bound: 27 670,5-45 319,4 Da)
	Characteristics/Composition: **Physical/chemical** Iron (% dry matter): 24,0-36,0 Adipate: (% dry matter): 1,5-4,5 Tartrate: (% dry matter): 28,0-40,0 Water content (%): 10,0-21,0 Sodium (% dry matter): 9,0-11,0 Chloride (% dry matter): 2,6-4,2	

	Phase distribution Soluble (%): 2,0-4,0 Nano (%): 92,0-98,0 Micro (%): 0,0-3,0 **Primary particle size** Median diameter ([1]): 1,5-2,3 nm Mean diameter ([1]): 1,8-2,8 nm Dv(10) ([2]): 1,5-2,5 nm Dv(50) ([2]): 2,5-3,5 nm Dv(90) ([2]): 5,0-6,0 nm **Heavy metals** Arsenic: < 0,80 mg/kg Nickel: < 50,0 mg/kg **Residual solvents** Ethanol: < 500 mg/kg **Microbiological criteria** Total aerobic microbial count: < 10 CFU/g Total yeast and mould count: < 10 CFU/g

(*) Cornell RM and Schwertmann U, 2003. The Iron Oxides: Structure, Properties, Reactions, Occurrences and Uses. 2nd Edition. Wiley. https://doi.org/10.1002/3527602097

([1]) Number-based (by Transmission Electron Microscopy (TEM)).

([2]) Volume-based (hydrodynamic diameter by Dynamic Light Scattering (DLS)); CFU: Colony Forming Units.'

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1374

of 5 August 2022

concerning the authorisation of potassium diformate as a feed additive for weaned piglets, pigs for fattening and sows, and repealing Implementing Regulation (EU) No 333/2012

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.

(2) Potassium diformate was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 333/2012 ([2]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of potassium diformate as a feed additive for all animal species, requesting the additive to be classified in the additive category 'technological additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation. The applicant has later withdrawn the application for all animal species except for weaned piglets, pigs for fattening and sows.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2022 ([3]) that the applicant had provided evidence that the additive complies with the conditions of authorisation. The Authority further concluded that potassium diformate does not have adverse effects on animal health, consumer safety or the environment. It also concluded that the additive is an eye irritant, but it could not conclude on the potential of the additive to be an irritant to the skin or a respiratory or skin sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of potassium diformate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed.

(6) As a consequence of the renewal of the authorisation of potassium diformate as a feed additive, Implementing Regulation (EU) No 333/2012 should be repealed.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Implementing Regulation (EU) No 333/2012 of 19 April 2012 concerning the authorisation of a preparation of potassium diformate as a feed additive for all animal species and amending Regulation (EC) No 492/2006 (OJ L 108, 20.4.2012, p. 3).

([3]) EFSA Journal 2022;20(3):7167.

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the substance specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'preservatives', is renewed subject to the conditions laid down in that Annex.

Article 2

Implementing Regulation (EU) No 333/2012 is repealed.

Article 3

Transitional measures

1. The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 28 February 2023 in accordance with the rules applicable before 28 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 28 August 2023 in accordance with the rules applicable before 28 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 28 August 2024 in accordance with the rules applicable before 28 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 4

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, 5 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: technological additives. Functional group: preservatives.								
1a237a	Potassium diformate	*Additive composition:* Potassium diformate: 50 ± 5 % Liquid form (50:50 diluted in water) *Characterisation of the active substance:* Potassium diformate $C_2H_3O_4K$ CAS number: 20642-05-1 Einecs number: 243-934-6 Produced by chemical synthesis *Analytical method* (1): For the determination of potassium diformate (as total formic acid) in the feed additive, premixture, feedingstuffs: — Ion chromatography with conductivity detection (IC-CD) – EN 17294; For the determination of potassium in the feed additive: — Atomic absorption spectrometry (AAS) – EN ISO 6869; or	Sows		-	12 000	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Only permitted in raw fish and fish by-products for feed use with a maximum content of 9 000 mg potassium diformate as active substance per kg raw fish. 3. The maximum content of potassium diformate shall be 6 000 mg/kg of complete feedingstuff with a moisture content of 12 % for weaned piglets and pigs for fattening and 12 000 mg/kg of complete feedingstuff with a moisture content of 12 % for sows, whether used alone as a preservative or used in combination with other sources of potassium diformate. 4. The mixture of different sources of formic acid shall not exceed the permitted maximum level in complete feedingstuffs of 10 000 mg/kg complete feedingstuffs for weaned piglets, pigs for fattening and sows.	28.8.2032
			Weaned piglets and pigs for fattening		-	6 000		

		— Inductively coupled plasma-atomic emission spectrometry (ICP-AES) – EN15510.					5. Indicate in the instructions of use of the additive, premixture and related feedingstuffs for food-producing animals: 'The simultaneous use of different organic acids or their salts is contraindicated where one or more of them is used at or near the maximum permitted content'. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eyes, skin and breathing protection.	

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1375

of 5 August 2022

concerning the denial of authorisation of ethoxyquin as a feed additive belonging to the functional group of antioxidants and repealing Implementing Regulation (EU) 2017/962

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Articles 9(2) and 13(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) Ethoxyquin was authorised without a time limit by Directive 70/524/EEC as a feed additive for use for all animal species. The additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of ethoxyquin as a feed additive for all animal species, requesting the additive to be classified in the category 'technological additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') noted in its opinion of 21 October 2015 ([3]) that it could not conclude on the efficacy and safety of the additive ethoxyquin for animals, consumers and the environment, due to an overall lack of data submitted by the applicant. In particular, no conclusion was possible on the absence of genotoxicity of the metabolite ethoxyquin quinone imine and concerns were raised as to the possible mutagenicity of the impurity *p*-phenetidine. Consequently, it had not been established that the additive ethoxyquin does not have an adverse effect on animal health, human health and the environment. Therefore, the existing authorisation of the additive ethoxyquin was suspended by Commission Implementing Regulation (EU) 2017/962 ([4]).

(5) The authorisation of the additive ethoxyquin was suspended pending the submission and assessment of supplementary data to be produced by the applicant, in accordance with a time schedule listing the necessary studies to be carried out. According to that time schedule, the outcome of the last of those studies had to be available by July 2018.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) EFSA Journal 2015;13(11):4272.
([4]) Commission Implementing Regulation (EU) 2017/962 of 7 June 2017 suspending the authorisation of ethoxyquin as a feed additive for all animal species and categories (OJ L 145, 8.6.2017, p. 13).

(6) In accordance with Implementing Regulation (EU) 2017/962, the suspension measure is to be reviewed by 31 December 2022 and in any event after the adoption by the Authority of a non-favourable opinion on the safety and efficacy of the additive ethoxyquin.

(7) Since the adoption of the Authority's opinion of 21 October 2015, the applicant submitted to the Commission successive packages of supplementary data on 11 March 2016, 15 December 2017, 20 April 2018 and 23 June 2021, which were forwarded to the Authority. Further supplementary data was submitted by the applicant to the Authority in the course of the data assessment, as well as on 24 September 2020.

(8) On 27 January 2022, the Authority adopted an opinion ([5]) following the assessment of the supplementary data submitted by the applicant, taking into account in particular the modified specifications of the additive ethoxyquin, in which the content of the impurity *p*-phenetidine was reduced to a level lower than 2,5 ppm, and considering the proposed inclusion level of 50 mg of the additive per kg in complete feed. In its opinion, the Authority could not conclude on the safety of the additive ethoxyquin at any level for long-living and reproductive animals, considering that the additive contains *p*-phenetidine, a recognised possible mutagen which remains as an impurity in the additive, but in regards to which the applicant did not provide additional information addressing this safety concern. Concerning the safety of the use of ethoxyquin for the consumers, no conclusion could be drawn due to the presence of *p*-phenetidine and in the absence of data on the residues of *p*-phenetidine in tissues and products of animal origin. In addition, in the absence of residue data in milk, the Authority could not conclude on the consumers' safety of ethoxyquin, when used in feed for milk-producing animals. With regard to the safety for the user, the Authority concluded that users' exposure should be minimised in order to reduce the risk of exposure to *p*-phenetidine by inhalation. Regarding the safety for the environment, the Authority stated that supplementary data would be needed to conclude on the safety of ethoxyquin for the terrestrial compartment when fed to terrestrial animals. In addition, the Authority considered that a risk for the aquatic compartment could not be excluded when the additive is used in terrestrial animals and that a risk of secondary poisoning via the aquatic food chain could not be excluded either. Furthermore, the Authority concluded that a risk could not be excluded for ethoxyquin used in sea-cages for marine sediment-dwelling organisms.

(9) The Authority's opinion of 27 January 2022 shows, therefore, that it has not been established that ethoxyquin does not have an adverse effect on animal health, human health or the environment, when used as a feed additive in the functional group 'antioxidants'.

(10) The assessment of ethoxyquin thus shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are not satisfied and accordingly, the authorisation of ethoxyquin as a feed additive belonging to the functional group 'antioxidants' should be denied.

(11) It derives from the above review that Implementing Regulation (EU) 2017/962 should be repealed.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Denial of authorisation

The authorisation of ethoxyquin (E 324) as an additive in animal nutrition belonging to the additive category 'technological additives' and to the functional group 'antioxidants', is denied.

([5]) EFSA Journal 2022;20(3):7166.

Article 2

Repeal of Implementing Regulation (EU) 2017/962

Implementing Regulation (EU) 2017/962 is repealed.

Article 3

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*.

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

Done at Brussels, 5 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2022/1376

of 26 July 2022

on the applicability of Article 34 of Directive 2014/25/EU of the European Parliament and of the Council to electricity generation and wholesale in Denmark

(notified under document C(2022) 5046)

(Only the Danish text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement procedures of entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC ([1]) and in particular Article 35(3) thereof,

After consulting the Advisory Committee for public contracts,

Whereas:

1. **FACTS**

1.1. *THE REQUEST*

(1) On 24 September 2021, the Danish Competition and Consumer Authority (DCCA) ('the applicant') submitted a request to the Commission pursuant to Article 35(1) of Directive 2014/25/EU ('the request'). The request complies with Article 1(1) of Commission Implementing Decision (EU) 2016/1804 ([2]).

(2) The request concerns electricity generation and wholesale from conventional and renewable sources in Denmark.

(3) However, the request does not cover the following:

— electricity produced by onshore and offshore wind turbines outside tenders;

— electricity produced by wind turbines connected to a grid from 21 February 2008 to 31 December 2013 or later, except for wind turbines which are connected to their own consumption installation and offshore wind turbines (electricity produced from consumption installation (§ 41 of the Promotion of the Renewable Energy Act) and offshore wind turbines pursuant to § 35 b of that Act are excluded from the application and are consequently still to be subject to the provisions of Directive 2014/25/EU);

— electricity produced by wind turbines connected to a grid no later than 20 February 2008, except for wind turbines which receive price supplements pursuant to sections 39-41 of the Promotion of the Renewable Energy Act;

([1]) OJ L 94, 28.3.2014, p. 243.

([2]) Commission Implementing Decision (EU) 2016/1804 of 10 October 2016 on the detailed rules for the application of Articles 34 and 35 of Directive 2014/25/EU of the European Parliament and of the Council on procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 275, 12.10.2016, p. 39).

— electricity produced by wind turbines connected to a grid no later than 31 December 2002;

— electricity produced by a brand new wind turbine utilising scrapping certificates issued for the dismantling of wind turbines (additional price supplement); electricity produced by bioenergy (biomass and biogas);

— electricity produced by solar photovoltaic panels, waves and hydropower;

— electricity produced by other special renewable energy installations (electricity produced from renewable energy sources or technologies of significance for the future expansion of renewable electricity or electricity produced from other renewable energy sources than the ones mentioned);

— electricity produced by decentralised heat and power plants and incineration plants;

— electricity produced from other heat and power plants intended to supply district heating;

— electricity produced from industrial power plants connected to a grid no later than 21 March 2012;

— ancillary services.

(4) Electricity generation and wholesale from conventional and renewable sources constitutes an activity relating to the supply of electricity in accordance with Article 9 of Directive 2014/25/EU.

(5) In accordance with point 1(a) of Annex IV to Directive 2014/25/EU, given that free access to the market can be presumed on the basis of the first subparagraph of Article 34(3) of that Directive, the Commission is to adopt an Implementing Decision on the request within 90 working days.

(6) Pursuant to the fourth subparagraph of paragraph 1 to Annex IV of Directive 2014/25/EU, the deadline may be extended by the Commission with the agreement of those having requested the exemption. Given that additional information was provided by the DCCA on 4 March 2022, the period available to the Commission for deciding on this request is hereby set to 31 July 2022.

2. **LEGAL FRAMEWORK**

(7) Directive 2014/25/EU applies to the award of contracts for the pursuit of activities related to the supply of electricity to fixed networks intended to provide a service to the public in connection with the production, transport or distribution of electricity, unless the activity is exempted pursuant to Article 34 of that Directive.

(8) Pursuant to Article 34 of Directive 2014/25/EU, contracts intended to enable the performance of an activity to which that Directive applies are not to be subject to that Directive if, in the Member State in which it is carried out, the activity is directly exposed to competition on markets to which access is not restricted. Direct exposure to competition is assessed on the basis of objective criteria, taking account of the specific characteristics of the sector concerned ([3]). This assessment is, however, limited by the short deadlines applicable and by the need to rely on the information available to the Commission, which cannot be supplemented by more time-consuming methods, including, in particular, public inquiries addressed to the economic operators concerned ([4]). In that context, while the question of whether an activity is directly exposed to competition is to be decided on the basis of criteria that are in conformity with the TFEU provisions on competition, it is not required that those criteria should be exactly the same as those referred to in the provisions of EU competition law ([5]).

([3]) Directive 2014/25/EU, recital 44.
([4]) Ibid.
([5]) Judgment of 27 April 2016 in Case T-463/14, *Österreichische Post AG v. Commission*, EU:T:2016:243, paragraph 28 and recital 44 of Directive 2014/25/EU.

(9) Access is deemed to be unrestricted if the Member State has implemented and applied the relevant Union legislation opening a given sector or a part of it to competition. That legislation is listed in Annex III to Directive 2014/25/EU. For electricity generation and wholesale, that Annex refers to Directive 2009/72/EC, repealed by Directive (EU) 2019/944 ([6]) with effect from 1 January 2021. According to the applicant, Denmark has transposed Directive (EU) 2019/944 ([7]). Consequently, pursuant to Article 34(3) of Directive 2014/25/EU, free access to the market can be presumed.

(10) Direct exposure to competition should be evaluated on the basis of various indicators, none of which is necessarily on its own decisive. In respect of the market concerned by this Decision, market shares constitute one criterion which should be taken into account, along with other criteria, such as the competitive pressure exerted by generators from neighbouring countries or the number of bidders in tenders for renewable energy capacity.

(11) The aim of this Decision is to establish whether the services concerned by the request are exposed to a level of competition (in markets to which access is not restricted within the meaning of Article 34 of Directive 2014/25/EU) sufficient to ensure that, also in the absence of the discipline brought about by the detailed procurement rules set out in Directive 2014/25/EU, procurement for the pursuit of the activities concerned will be carried out in a transparent, non-discriminatory manner, based on criteria allowing purchasers to identify the solution which overall is the economically most advantageous one.

3. **ASSESSMENT**

(12) This Decision is based on the legal and factual situation as of September 2021, as apparent from the information submitted by the applicant and publicly available information.

3.1. *UNRESTRICTED ACCESS TO THE MARKET*

(13) Access to a market is deemed to be unrestricted if the Member State concerned has implemented and applied the relevant Union legislation opening a given sector or a part of it to competition. Denmark has transposed Directive (EU) 2019/944 through 29 national measures, according to the applicant. This was confirmed by the Danish Energy Agency ([8]). Therefore, the Commission considers that the conditions for free market access *de jure* are met.

(14) As far as free access *de facto* is concerned, the Commission notes the progress of liberalisation of the Danish electricity generation market since its opening up to competition in 1999. The participation of Denmark in the Nord pool power exchange and the development of interconnection capacities have played a significant role in fostering competitive pressure. Concerning generation from renewable sources, in particular offshore wind farms, tenders organised by the Danish authorities have attracted an increasing number of participants.

(15) The Commission concludes that access to the market is be considered *de jure* and *de facto* free on the territory of Denmark for the purposes of this Decision.

([6]) Directive (EU) 2019/944 of the European Parliament and of the Council of 5 June 2019 on common rules for the internal market for electricity and amending Directive 2012/27/EU (OJ L 158, 14.6.2019, p. 125).

([7]) This is without prejudice to the Commission's assessment of the transposition of this Directive in Denmark.

([8]) See p. 28 of the application.

3.2. *COMPETITIVE ASSESSMENT*

3.2.1. PRODUCT MARKET DEFINITION

(16) According to Commission merger practice ([9]), the following relevant product markets could be distinguished in the electricity sector: (i) generation and wholesale supply; (ii) transmission; (iii) distribution; and (iv) retail supply. While some of these markets may be further subdivided, to date previous Commission practice ([10]) rejected a distinction between an electricity generation market and a wholesale supply market since generation as such is only a first step in the value chain, but electricity volumes generated are marketed via the wholesale market. This has been confirmed for the Nordics more specifically ([11]).

(17) In its merger practice, the Commission has, moreover, considered that the relevant product market in the Nordic region covered electricity sold both by means of bilateral contracts and on the Nord Pool platform, both on Elspot (day-ahead) and Elbas (intra-day) ([12]).

(18) The applicant argues that corporate Power Purchase Agreements (cPPAs) should be included in the scope of the relevant market. Such agreements are bilateral contracts between an electricity generator and a customer (usually a large electricity user) by which the user purchases electricity directly from the generator. Trading companies enter into Power Purchase Agreements (PPAs) with producers of both conventional and renewable power, competing for the conclusion of PPAs.

(19) As for other bilateral transactions, customers entering into PPAs must enter into an agreement with a balance responsible party to manage their imbalances. Concerning balancing of generation/production, power generators (such as owners of offshore windfarms) have to match their forecasted electricity production in real time, i.e. adapting the forecasted production with the actual production. This responsibility is not affected by how the generator chooses to sell the electricity produced, including by cPPAs.

(20) With regard to whether conventional and renewable electricity belong to the same product market, the Commission has come to different conclusions depending on the factual situation. It found that conventional and renewable electricity generation in Germany ([13]) and Italy ([14]) should be considered as different product markets.

(21) However, in the case of the Netherlands ([15]), the Commission found that generation and wholesale supply of electricity from conventional and renewable sources was part of the same relevant product market. For the Nordic region, the Commission has in its merger practice considered the source of the electricity to be irrelevant for product definition purposes ([16]).

(22) The applicant argues that the situation in Denmark differs from that in Germany and Italy referred to in the above decision, and is similar to that at issue in the Netherlands. The applicant provided tables detailing the similarities and differences between the Danish and, respectively, German, Italian and Dutch cases. The applicant points out that the main differences with the German and Italian situations are the absence of statutory rate of remuneration, the absence of feed-in priority and the fact that renewable electricity is sold on the wholesale market at the same price as conventional electricity.

([9]) Case COMP/M.4110 – E.ON/ENDESA, of 25.4.2006, paragraph 10, p. 3.
([10]) Case COMP/M.3696 – E.ON/MOL, of 21.1.2005, paragraph 223, Case COMP/M.5467 – RWE/ESSENT, of 23.6.2009, paragraph 23.
([11]) See case M.8660 Fortum/Uniper of 15 June 2018, paragraph 18. See also COMP/M.7927 – EPH/ENEL/SE, paras 9-12; COMP/M.6984 – EPH/Stredoslovenska Energetika, para. 15; M.3268 – Sydkraft/Graninge, paras 19-20.
([12]) See case M.8660 Fortum/Uniper of 15 June 2018, paragraph 18. See also COMP/M.7927 – EPH/ENEL/SE, paras 9-12; COMP/M.6984 – EPH/Stredoslovenska Energetika, para. 15; M.3268 – Sydkraft/Graninge, paras 19-20.
([13]) OJ L 114, 26.4.2012, p. 21, paras 36-40.
([14]) OJ L 271, 5.10.2012, p. 4, paras 46-50.
([15]) OJ L 12, 17.1.2018, p. 53, paras 19-23.
([16]) See case M.8660 Fortum/Uniper of 15 June 2018, paragraph 18.

(23) In its merger decision Fortum/Uniper ([17]), the Commission recalled that the relevant product market in the Nordic region covered both generation and wholesale of electricity, irrespective of generation sources and trading channels, and that it comprised electricity sold by means of bilateral contracts and on the Nordic power exchange, Nord Pool.

(24) Concerning electricity produced from renewable sources, the request covers the Horns Rev 3, Vesterhav Syd, Vesterhav Nord and Kriegers Flask offshore windfarms, as well as the wind farms to come, including the Thor offshore windfarm. All of the concerned support schemes were subject to Commission decisions confirming their compatibility with EU State aid rules ([18]).

(25) Moreover, the premiums paid out for wind production have decreased to a minimum thanks to increased competition for generation. For all of the abovementioned windfarms, the Danish Energy Agency organised an open tender for generation of electricity from renewable sources. The Horns Rev 3 (400 MW), held in 2015, had four bidders, the Kriegers Flak (600 MW), held in 2016, seven and the Vesterhav Nord/Sud (350 MW), held in 2016, three.

(26) Risk hedging is being carried out prior to the tendering procedures, and the Danish authorities now have a better understanding of the market and have established a real market dialogue.

(27) The total costs of renewable technologies such as offshore wind turbines or solar photovoltaic have also significantly declined. Consequently, the winning bid in 2010 for Anholt Offshore Wind Farm was a premium of 105 øre/kWh while the winning bid in 2016 for Kriegers Flak Offshore Wind Farm was a premium of 37 øre/kWh.

(28) Denmark also intends to launch three new large-scale offshore windfarms. The first offshore wind farm shall have a capacity of approximately 800 MW, while the remaining offshore wind farms shall have a capacity of at least 800 MW. The Danish Energy Agency will call for bids in tender schemes for each future offshore windfarm.

(29) As it did in its exemption Commission Implementing Decision (EU) 2018/71 ([19]) concerning electricity generation and wholesale in the Netherlands, the Commission notes that the allocation of the subsidies is exposed to competition through a bidding process which disciplines the behaviour of renewable electricity producers with regard to their procurement policy. This places conventional and renewable (for those offshore windfarms subject to the request) electricity generation on an equal footing in Denmark.

(30) For the purposes of evaluating the conditions laid down in Article 34(1) of Directive 2014/25/EU and without prejudice to the application of competition law, the Commission considers that the relevant product market is the market for generation and wholesale supply of electricity, including cPPAs, produced from conventional as well as from offshore wind farms that are subject to the application for exemption.

([17]) See cases M.8660 Fortum/Uniper of 15 June 2018, paragraph 18, as well as cases COMP/M.7927 – EPH/ENEL/SE, paras 9-12; COMP/M.6984 – EPH/Stredoslovenska Energetika, para. 15; M.3268 – Sydkraft/Graninge, paras 19-20.

([18]) Cases SA.40305, SA.43751, SA.45974 and SA.57858.

([19]) See paragraph 21 of Commission Implementing Decision (EU) 2018/71 of 12 December 2017 exempting the production and wholesale of electricity in the Netherlands from the application of Directive 2014/25/EU of the European Parliament and of the Council on procurement by entities operating in the water, energy, transport and postal services sector and repealing Directive 2004/17/EC, (OJ L 12, 17.1.2018, p. 53).

3.2.2. GEOGRAPHIC MARKET DEFINITION

(31) In 2006, the Commission has in a merger decision defined ([20]) two separate geographic markets for electricity wholesale: that of East Denmark ('DK2') and that of West Denmark ('DK1'), as at the time there was no direct interconnection between the two Danish bidding (or price) areas. The Commission reached the same conclusion in the *DE/DK Interconnector* decision in 2018 ([21]).

(32) In 2014, the Danish Competition Council investigated the market for generation and wholesale of electricity in Denmark in its Virtual Power Plant ('VPP') decision ([22]). By that decision, the Danish Competition Council repealed previous commitments entered into by Elsam A/S in a merger between Elsam A/S and Nesa A/S in 2004. The Danish Competition Council partly supported a larger geographical market than DK1. DK1 is connected to Norway, Sweden and Germany through transmission connections. The wholesale price for physical electricity in DK1 was different from all of the connected price zones in less than 10 % of the hours during 2013. In most hours, DK1 had a wholesale price equal to at least one of the connected price zones, which supported a wider geographical market than Western Denmark. However, it was left open, whether there was a wider geographical market than Western Denmark. In 2019, the Danish Competition Council ([23]) indicated that the market for generation and wholesale of electricity was national in scope, but left the question open of whether to define either a broader or a narrower geographical market definition. This conclusion was based on the following precedent cases: 1) the *M.8660 Fortum/Uniper decision* in which the Commission concluded on the existence of a national market in Sweden, 2) the *M.3268 Sydkraft and Graninge decision* in which the Commission found that Sweden only constituted a separate market from Finland and Denmark in an insignificant number of hours, which indicated that the wholesale market for electricity was broader than national in scope, and 3) the Danish Competition Council's *VPP decision* in which it found indications of a larger geographical market than DK1 due to developments within the market for generation and wholesale of electricity in Denmark. Interconnection capacity between Denmark and neighbouring countries has been significantly expanded since 2006. Notably, the Skagerrak (with Norway), Kontiskan (with Sweden) and Kontek (with Germany) interconnectors have been put in service or expanded. The Cobra cable (with the Netherlands) was commissioned in 2019. Within Denmark, the Great Belt now connects Western and Eastern Denmark.

(33) Evidence provided by the applicant ([24]) shows increasing price correlation between Eastern and Western Denmark, as well as with neighbouring price zones of Sweden, Norway and Germany (SE3, SE4, NO2 and DE). For instance, DK1 had the same price as one of the other areas (DK2, SE3, SE4, NO2 and DE) for 91,7 % in 2013 and 96,3 % in 2018; for DK2, the figures were 97,8 % in 2013 and 98,6 % in 2018. Conversely, the hours during which the DK1 area had a different price from the other areas dropped from 8,3 % to 3,7 % from 2013 to 2018; for DK2, the percentage dropped from 2,2 % to 1,4 %.

(34) According to Energinet, Denmark has a very large capacity on the interconnectors to its neighbouring countries, equalling approximately 90 % of its domestic peak demand. The close integration with Denmark's neighbouring countries implies that Denmark only has a separate spot market price for electricity during approximately 10 % of the time. In the remaining time, the wholesale price is common with either Norway, Sweden or Germany.

(35) In 2019, the international connection between Eastern Denmark (DK2) and Germany has an available trading capacity of 90 % of the total capacity of the interconnector in the export direction, and of 95 % in the import direction. The remaining foreign connections had an available trading capacity in the export direction of between 60 and 88 % of the total capacity of the interconnector. Trading capacity was lower between Western Denmark

([20]) Commission Decision 2007/353/EC of 14 March 2006 declaring a concentration compatible with the common market and the functioning of the EEA Agreement (Case COMP/M.3868 – DONG/Elsam/Energi E2) (OJ L 133, 25.5.2007, p. 24), paragraphs 258-260.

([21]) Summary of Commission Decision of 7 December 2018 relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union and Article 54 of the EEA Agreement (Case AT.40461 – DK/DE Interconnector) (OJ C 58, 14.2.2019, p. 7), paragraphs 49-50.

([22]) Danish Competition Council, DONG Energys anmodning om ophævelse af VPP tilsagn, 2014: https://www.kfst.dk/media/13295/20140528-ikkefortrolig-afgoerelse-dong.pdf

([23]) Danish Competition Council's decision of 25 June 2019; https://www.kfst.dk/media/54483/20190625-fusion-se-eniig.pdf

([24]) See application, paras 94 to 97.

(DK1) and Norway and Sweden in 2019 compared to 2018. On the other hand, trading capacity against Germany was higher for both Danish bidding areas. The Cobra connection has had an available trading capacity in the export and import direction of 87 % of the total capacity of the interconnector in 2019.

(36) The Commission observes the existence of pricing constraints on both zones from the outside: DK1 has the same prices as other areas 89,3 % of hours, and DK2 for 98,4 % of the hours. For reference, in paragraph 28 of the *Fortum/Uniper* merger decision, the Commission concluded that the four Swedish bidding zones formed a single geographic market because they had a common price for 89,7 % of hours. The Commission also notes that, according to the applicant, the four largest players with market shares higher than 10 % are present in both DK1 and DK2.

(37) For the purposes of evaluating the conditions laid down in Article 34(1) of Directive 2014/25/EU and without prejudice to the application of competition law, the Commission considers that the relevant geographic market for generation and wholesale supply of electricity, including cPPAs, produced from conventional as well as from those renewable sources that are subject to the application can be left open, either in the case of a separate market for DK1 and DK2 or in the case of a single national Danish market.

3.2.3. MARKET ANALYSIS

(38) All market shares calculations and indications related to the share of electricity generation are based on input from the applicant.

(39) In its analysis, the Commission takes account of several factors. While market shares are an important aspect, the competitive pressure exerted by generators from neighbouring countries and the number of bidders in tenders for renewable energy capacity are also taken into account.

(40) On the electricity generation and wholesale market in Denmark, there are at present three main market players subject to public procurement rules pursuant to Directive 2014/25/EU. They are Ørsted A/S (hereinafter Ørsted) (50,1 % owned by the Danish state), the Danish subsidiary of Vattenfall, Vattenfall AB) (hereinafter Vattenfall) (100 % owned by the Swedish state) and HOFOR Energiproduktion A/S (hereinafter HOFOR), ultimately owned by the municipality of Copenhagen.

(41) There are currently 18 Danish companies trading on Nord Pool. A majority of these companies, such as Danske Commodities and Centrica Energy Trading, are not public undertakings according to Directive 2014/25/EU.

(42) In 2018 and 2019, Ørsted's market share on the combined market DK1-DK2 (in terms of generation) was [20 to 30]% and [10 to 20]% respectively, Vattenfall's market share was [5 to 10]% and [10 to 20]% and HOFOR's market share was [0 to 5]% and [0 to 5]%. The larger competitors of these companies, which are not covered by public procurement rules, are Vindenergi Danmark ([40 to 50]% and [40 to 50]% market shares) and Energi Danmark ([10 to 20]% and [10 to 20]%). The market shares on the DK1 and DK2 markets were broadly in the same range (Ørsted [20 to 30]% in DK1 and [10 to 20] % in DK2 in 2018, [20 to 30]% in DK1 and [10 to 20]% in DK2 in 2019, Vattenfall [5 to 10]% in DK1 and [0 to 5]% in DK2 in 2018, [10 to 20]% in DK1 and [0 to 5]% in DK2 in 2019, HOFOR [0 to 5]% in DK1 and [5 to 10]% in DK2 in 2019). If the relevant geographic market is wider than Denmark, these market shares would be smaller.

(43) Imports and exports are a very significant feature of the Danish electricity market. In 2018 and 2019, electricity consumption stood at around 33,5 TWh. Imports represented approximately 45,6 % of total consumption in 2018, while national production covered 41 % of the consumption in 2018 and 48 % in 2019. Exports are also significant, as they stood at 73 % and 62 % of Danish electricity production in 2018 and 2019.

(44) This shows the magnitude of the integration of the Danish electricity market into a wider geographic market and, as a result, the competitive pressure exerted by electricity generators from, most importantly but not exclusively, neighbouring countries on Danish producers via cross-borders interconnectors.

(45) Concerning wholesale spot prices, Nordic prices are set on the Nord Pool exchange. The average hourly price in the spot market for DK1 and DK2 was respectively 38,50 and 39,84 EUR MWh in 2019, which is a decrease of 13 % in both areas from 2018. The system price was 38,94 EUR/MWh in 2019. The price of the Nordic system is the fictitious spot price that would have occurred if the whole Nordic region was one bidding area. DK1 generally has lower prices than DK2 due to the relatively large installed wind turbine capacity in DK1, which helps push prices down. The average spot price in 2019 was 39,28 EUR/MWh in Norway, 37,68 EUR/MWh in Germany and 38,79 EUR/MWh in Sweden, very similar to the price in DK1 and DK2.

(46) In Denmark, approximately 6 percent of electricity is traded in the single European intra-day market Xbid. The intraday market is based on continuous trading with trades made pay-as-bid as opposed to the day ahead market, which is auction-based with a single clearing price. The intraday market is used to adjust consumption and production plans with regard to i.a. restoring portfolio balances. This means that the price in the intraday market for each hour will start at the spot price and then move up or down if there are unforeseen events during the trading window. The annual average price for the intraday market in DK1 was 35,1 EUR/MWh in 2019. In DK2, it was 36,7 EUR/MWh. In 2018, the average price in DK1 was 40,4 EUR/MWh and 41,9 EUR/MWh in DK2.

(47) Further calculations included in the application ([25]) show that prices in DK1 and DK2 are the same as one or more neighbouring price zones a vast majority of the time. In 2018 and 2019, prices in DK1 were the same as in another pricing area of the region (DK2, SE3, SE4, NO2 and DE) 94,8 % and 96,3 % of the time; prices in DK2 were the same as in another pricing area of the region (DK1, SE3, SE4, NO2 and DE) 98,8 % and 98,6 % of the time. In addition, the correlation between the two Danish zones and the Nordic system and German wholesale price is rather high, ranging between 64 % and 83 % over the 2017-2018 period.

(48) Denmark has a very large capacity on the interconnectors to its neighbouring countries, equalling approximately 90 % of its domestic peak demand. The close integration with Denmark's neighbouring countries implies that Denmark only has a separate spot market price for electricity in DK1 and DK2 in approximately 10 % of the time. In the remaining time, the wholesale price in DK1 and DK2 is common with either Norway, Sweden or Germany.

(49) The Commission considers that these elements show a very strong convergence of electricity prices in Denmark with the prices in the countries of the Nordic region and in Germany.

3.2.4. CONCLUSION

(50) Contracting entities hold a limited market share on the electricity generation and wholesale market in Denmark subject to the request.

(51) The high level of electricity imports and exports compared to Danish electricity generation, combined with the interconnection capacity with neighbouring countries, shows that the electricity and wholesale market in Denmark is largely integrated into a wider, transnational market. Even if the geographical market is not necessarily transnational, electricity imports to Denmark in any case exert competitive pressure on the Danish electricity wholesale prices during a significant number of hours each year.

(52) This is further confirmed by the data provided by the applicant on wholesale prices, which demonstrates that the Danish prices are very similar to Nordpool-wide prices and prices in Germany.

(53) The aim of the present Decision is to establish whether the activities of generation and wholesale of electricity are exposed to such a level of competition (on markets to which access is free) that this will ensure that, also in the absence of the discipline brought about by the detailed procurement rules set out in Directive 2014/25/EU, the procurement for the pursuit of the activities concerned will be carried out in a transparent, non-discriminatory manner, based on criteria allowing the contracting entity to identify the solution which overall is the economically most advantageous.

([25]) See application para. 95.

(54) In view of the factors examined above, the Commission can conclude that the activity of electricity generation and wholesale from conventional sources and from offshore wind farms subject to a tendering procedure in Denmark is directly exposed to competition on a market to which access is not restricted, within the meaning of Article 34(1) of Directive 2014/25/EU.

4. **CONCLUSION**

(55) For the purposes of this Decision and without prejudice to the application of competition law, it follows from recitals 11 to 53 that the generation and wholesale of electricity from conventional sources and from offshore wind farms subject to a tendering procedure in Denmark is exposed to competition on a market to which access is not restricted, within the meaning of Article 34 of the Directive 2014/25/EU. Consequently, Directive 2014/25/EU should not continue to apply to contracts intended to enable the pursuit of that activity in Denmark.

(56) Directive 2014/25/EU should continue to apply to contracts intended to enable the pursuit of activities which are specifically excluded from the request.

(57) This Decision is based on the legal and factual situation as of October 2021 to March 2022 as it appears from the information submitted by the applicants. It may be revised, should the conditions for the applicability of Article 34 of Directive 2014/25/EU no longer be met, following significant changes in the legal or factual situation.

(58) It is recalled that Article 16 of Directive 2014/23/EU ([26]) provides for an exemption from the application of that Directive for concessions awarded by contracting entities where, for the Member State in which the concessions are to be performed, it has been established pursuant to Article 35 of Directive 2014/25/EU that the activity is directly exposed to competition in accordance with Article 34 of that Directive. Since it was concluded that the activity of production and wholesale of electricity subject to the request is exposed to competition on a market to which access is not restricted, concession contracts intended to enable the performance of those activities in Denmark will be excluded from the field of application of Directive 2014/23/EU.

(59) The measures provided for in this Decision are in accordance with the opinion of the Advisory Committee for Public Contracts,

HAS ADOPTED THIS DECISION:

Sole Article

Directive 2014/25/EU shall not apply to contracts awarded by contracting entities and intended to enable the electricity generation and wholesale from conventional and renewable sources in Denmark, covered by the request made pursuant to Article 35(1) of Directive 2014/25/EU.

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 26 July 2022.

For the Commission
Thierry BRETON
Member of the Commission

([26]) Directive 2014/23/EU of the European Parliament and of the Council of 26 February 2014 on the award of concession contracts (OJ L 94, 28.3.2014, p. 1).

COMMISSION IMPLEMENTING DECISION (EU) 2022/1377

of 4 August 2022

amending the Annex to Decision 2007/453/EC as regards the BSE status of France

(notified under document C(2022) 5507)

(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 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ([1]), and in particular Article 5(2), third subparagraph, thereof,

Whereas:

(1) Regulation (EC) No 999/2001 provides that Member States or third countries or regions thereof (countries or regions) are to be classified according to their bovine spongiform encephalopathy (BSE) status into one of three categories: negligible BSE risk, controlled BSE risk and undetermined BSE risk.

(2) Article 5(2) of Regulation (EC) No 999/2001 provides that if the World Organisation for Animal Health (OIE) has placed an applicant country in one of the three BSE categories, a re-assessment of the BSE categorisation at Union level may be decided.

(3) Commission Decision 2007/453/EC ([2]) lists the BSE status of countries or regions according to their BSE risk in Parts A, B or C of the Annex to that act. The countries or regions listed in Part A of that Annex are regarded as having a negligible BSE risk, those listed in Part B are regarded as having a controlled BSE risk, while Part C of that Annex provides that countries or regions not listed in Part A or B are to be regarded as having an undetermined BSE risk.

(4) France currently falls within Part B of the Annex to Decision 2007/453/EC under countries or regions with a controlled BSE risk.

(5) On 24 May 2022, the OIE World Assembly of Delegates adopted Resolution No 15, 'Recognition of the Bovine Spongiform Encephalopathy Risk Status of Members' ([3]), in view of an entry into force on 27 May 2022. That Resolution recognised France as having a negligible BSE risk, in accordance with the Terrestrial Animal Health Code of the OIE. After reassessment of the situation at Union level, stemming from OIE Resolution No 15, the Commission has considered that the new OIE BSE status of France should be reflected in the Annex to Decision 2007/453/EC.

(6) The list of countries or regions in the Annex to Decision 2007/453/EC should therefore be amended so that France is listed in Part A of that Annex under countries or regions with a negligible BSE risk.

(7) The Annex to Decision 2007/453/EC should therefore be amended accordingly.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 147, 31.5.2001, p. 1.

([2]) Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84).

([3]) https://www.woah.org/app/uploads/2022/05/a-r15-2022-bse-final-1.pdf

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2007/453/EC is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 4 August 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

The Annex to Decision 2007/453/EC is replaced by the following:

'*ANNEX*

LIST OF COUNTRIES OR REGIONS

A. **Countries or regions with a negligible BSE risk**

Member States

— Belgium
— Bulgaria
— Czechia
— Denmark
— Germany
— Estonia
— Ireland
— Spain
— France
— Croatia
— Italy
— Cyprus
— Latvia
— Lithuania
— Luxembourg
— Hungary
— Malta
— Netherlands
— Austria
— Poland
— Portugal
— Romania
— Slovenia
— Slovakia
— Finland
— Sweden

Regions of Member States (*)

— Northern Ireland

European Free Trade Association countries

— Iceland
— Liechtenstein
— Norway
— Switzerland

Third countries

— Argentina

— Australia

— Brazil

— Canada

— Chile

— Colombia

— Costa Rica

— India

— Israel

— Japan

— Jersey

— Namibia

— New Zealand

— Panama

— Paraguay

— Peru

— Serbia (**)

— Singapore

— United States

— Uruguay

B. **Countries or regions with a controlled BSE risk**

Member States

— Greece

Third countries

— Mexico

— Nicaragua

— South Korea

— Taiwan

— United Kingdom with the exception of Northern Ireland

C. **Countries or regions with an undetermined BSE risk**

— Countries or regions not listed in Parts A or B..

(*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to Member States include the United Kingdom in respect of Northern Ireland.

(**) As referred to in Article 135 of the Stabilisation and Association Agreement between the European Communities and their Member States of the one part, and the Republic of Serbia, of the other part (OJ L 278, 18.10.2013, p. 16).'

GUIDELINES

GUIDELINE (EU) 2022/1378 OF THE EUROPEAN CENTRAL BANK

of 28 July 2022

amending Guideline 2008/596/EC on the management of the foreign reserve assets of the European Central Bank by the national central banks and the legal documentation for operations involving such assets (ECB/2008/5) *(ECB/2022/28)*

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular to the third indent of Article 127(2) thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular the third indent of Article 3.1 and Articles 12.1 and 30.6 thereof,

Whereas:

(1) Guideline 2008/596/EC of the European Central Bank (ECB/2008/5) [1] governs the management of the foreign reserves of the European Central Bank (ECB) by the national central banks of Member States whose currency is the euro, as well as the legal documentation for operations involving such assets. As a result of the regular review of that Guideline, several amendments to it are required.

(2) Firstly, where counterparties do not comply with the applicable laws in relation to the prevention of money laundering and/or terrorist financing, and/or are involved in money laundering and/or terrorist financing, the ECB should have the ability to terminate master netting agreements entered into by it with such counterparties from 1 August 2022 or entered into by the ECB before that date and amended after it. This would reflect the current ECB practice as regards the other master agreements used by the ECB. Secondly, counterparties to transactions involving the ECB's foreign reserve assets should be obliged to observe on a continuing basis any applicable sanctions imposed at European Union and/or United Nations level, or imposed by any other competent authority.

(3) In addition, several other adjustments of an operational or technical nature need to be made.

(4) Therefore, Guideline 2008/596/EC (ECB/2008/5) should be amended accordingly,

HAS ADOPTED THIS GUIDELINE:

Article 1

Amendments

Guideline 2008/596/EC (ECB/2008/5) is amended as follows:

1. in Article 1, the second indent is replaced by the following:

   '"European jurisdictions" means the jurisdictions of all Member States that have adopted the euro in accordance with the Treaty, as well as Denmark, Sweden, Switzerland, and England and Wales.';

[1] Guideline 2008/596/EC of the European Central Bank of 20 June 2008 on the management of the foreign reserve assets of the European Central Bank by the national central banks and the legal documentation for operations involving such assets (ECB/2008/5) (OJ L 192, 19.7.2008, p. 63).

2. in Article 3, paragraph 2 is replaced by the following:

'2. Repurchase, reverse repurchase, buy/sell-back and sell/buy-back operations involving the foreign reserve assets of the ECB shall be documented using the following standard agreements in the edition or version indicated, or in any more recent edition or version approved by the ECB:

(a) the EBF Master Agreement for Financial Transactions (Edition 2004) shall be used for operations with counterparties organised or incorporated under the laws of any of the European jurisdictions and under the laws of Northern Ireland and Scotland;

(b) the Bond Market Association Master Repurchase Agreement (September 1996 version) shall be used for operations with counterparties organised or incorporated under US federal or state laws; and

(c) the TBMA/ISMA Global Master Repurchase Agreement (2000 version) shall be used for operations with counterparties organised or incorporated under the laws of any jurisdiction other than those listed in points (a) or (b).';

3. in Article 3, paragraph 3 is replaced by the following:

'3. Over-the-counter derivatives operations involving the foreign reserve assets of the ECB shall be documented using the following standard agreements in the edition or version indicated, or in any more recent edition or version approved by the ECB:

(a) the EBF Master Agreement for Financial Transactions (Edition 2004) shall be used for operations with counterparties organised or incorporated under the laws of any of the European jurisdictions;

(b) the 1992 International Swaps and Derivatives Association Master Agreement (Multicurrency – cross-border, New York law version) shall be used for operations with counterparties organised or incorporated under US federal or state laws; and

(c) the 1992 International Swaps and Derivatives Association Master Agreement (Multicurrency – cross-border, English law version) shall be used for operations with counterparties organised or incorporated under the laws of any jurisdiction other than those listed in points (a) or (b).';

4. in Article 3, paragraph 5 is replaced by the following:

'5. Deposits involving the ECB's foreign reserve assets with counterparties which: (i) are eligible for the operations mentioned in paragraphs 2 and/or 3 above; and (ii) are organised or incorporated under the laws of any of the European jurisdictions except Ireland, shall be documented using the EBF Master Agreement for Financial Transactions (Edition 2004, or any more recent edition approved by the ECB). In cases not falling under points (i) and (ii) above, deposits involving the ECB's foreign reserve assets shall be documented using the master netting agreement as specified in paragraph 7 below.';

5. in Article 3, paragraph 6 is replaced by the following:

'6. A document in English in the format set out in Annex I (hereinafter the "ECB Annex") shall be annexed to and form an integral part of every standard agreement under which repurchase, reverse repurchase, buy/sell-back, sell/buy-back, securities lending, triparty repo or over-the-counter derivatives operations involving the ECB's foreign reserve assets are conducted unless such operations are conducted under the EBF Master Agreement for Financial Transactions.';

6. in Article 3, paragraph 7, the introductory wording is replaced by the following:

'7. A master netting agreement shall be concluded with all counterparties, except counterparties: (i) with which the ECB has signed an EBF Master Agreement for Financial Transactions; and (ii) which are organised or incorporated under the laws of any of the European jurisdictions, except Ireland, as follows:';

7. in Article 3, the following paragraph 9 is added:

‘9. All master agreements entered into by the ECB from 1 August 2022 or entered into by the ECB before that date and amended after it shall contain a representation on a continuing basis by each counterparty that: (a) the counterparty is in compliance in all material respects with all applicable laws (including instructions given by competent authorities) relating to the prevention of money laundering and of terrorist financing; (b) the counterparty is not involved in money laundering and/or terrorist financing; and (c) the counterparty complies with all applicable restrictive measures (commonly referred to as “sanctions”) adopted at the level of the European Union and/or the United Nations, or imposed by any other competent authority.’;

Article 2

Taking effect

1. This Guideline shall take effect on the day of its notification to the national central banks of the Member States whose currency is the euro.

2. The Eurosystem central banks shall comply with this Guideline from 1 August 2022.

Article 3

Addressees

This Guideline is addressed to all Eurosystem central banks.

Done at Frankfurt am Main, 28 July 2022.

For the Governing Council of the ECB
The President of the ECB
Christine LAGARDE

ANNEX

Annex I to Guideline 2008/596/EC (ECB/2008/5) is replaced by the following:

'**ECB ANNEX**

1. The provisions of this Annex shall be supplemental terms and conditions applying to [*name the standard agreement to which this Annex applies*] dated [*date of agreement]* (the "Agreement") between the European Central Bank (the "ECB") and *[name of counterparty]* (the "Counterparty"). The provisions of this Annex shall be annexed to, incorporated in and form an integral part of the Agreement. If and to the extent that any provisions of the Agreement (other than the provisions of this Annex) or the ECB Master Netting Agreement dated as of *[date]* (the "Master Netting Agreement") between the ECB and the Counterparty, including any other supplemental terms and conditions, annex or schedule to the Agreement, contain provisions inconsistent with or to the same or similar effect as the provisions of this Annex, the provisions of this Annex shall prevail and apply in place of those provisions.

2. Except as required by law or regulation, the Counterparty agrees that it shall keep confidential, and under no circumstances disclose to a third party, any information or advice furnished by the ECB or any information concerning the ECB obtained by the Counterparty as a result of it being a party to the Agreement, including without limitation information regarding the existence or terms of the Agreement (including this Annex) or the relationship between the Counterparty and the ECB created thereby, nor shall the Counterparty use the name of the ECB in any advertising or promotional material.

3. The Counterparty agrees to notify the ECB in writing as soon as reasonably practicable of: (i) any consolidation or amalgamation with, or merger with or into, or transfer of all or substantially all of its assets to, another entity; (ii) the appointment of any liquidator, receiver, administrator or analogous officer or the commencement of any procedure for the winding-up or reorganisation of the Counterparty or any other analogous procedure; or (iii) a change in the Counterparty's name.

4. There shall be no waiver by the ECB of immunity from suit or the jurisdiction of any court, or any relief against the ECB by way of injunction, order for specific performance or for recovery of any property of the ECB or attachment of its assets (whether before or after judgment), in every case to the fullest extent permitted by applicable law.

5. There shall not apply in relation to the ECB any event of default or other provision of any kind in which reference is made to the bankruptcy, insolvency or other analogous event of the ECB.

6. The Counterparty agrees that it has entered into the Agreement (including this Annex) as principal and not as agent for any other entity and that it shall enter into all transactions as principal.'.

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