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Contents

[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.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

DECISIONS

COUNCIL DECISION (EU) 2021/1868

of 15 October 2021

on guidelines for the employment policies of the Member States

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 148(2) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament ([1]),

Having regard to the opinion of the European Economic and Social Committee ([2]),

After consulting the Committee of the Regions,

Having regard to the opinion of the Employment Committee ([3]),

Whereas:

(1) Member States and the Union are to work towards developing a coordinated strategy for employment and particularly for promoting a skilled, trained and adaptable workforce, as well as labour markets that are future-oriented and responsive to economic change, with a view to achieving the objectives of full employment and social progress, balanced growth, a high level of protection and improvement of the quality of the environment laid down in Article 3 of the Treaty on European Union (TEU). Member States are to regard promoting employment as a matter of common concern and are to coordinate their action in that respect within the Council, taking into account national practices related to the responsibilities of management and labour.

(2) The Union is to combat social exclusion and discrimination, and promote social justice and protection, equality between women and men, solidarity between generations and the protection of the rights of the child as laid down in Article 3 TEU. In defining and implementing its policies and activities, the Union is to take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against poverty and social exclusion, a high level of education and training and protection of human health as laid down in Article 9 of the Treaty on the Functioning of the European Union (TFEU).

(3) In accordance with the TFEU, the Union has developed and implemented policy coordination instruments for economic and employment policies. As part of those instruments, the Guidelines for the Employment Policies of the Member States (the 'Guidelines') set out in the Annex to Council Decision (EU) 2020/1512 ([4]), together with the Broad Guidelines for the Economic Policies of the Member States and of the Union set out in Council Recommendation (EU) 2015/1184 ([5]), form the Integrated Guidelines. They are to guide policy implementation in

([1]) Opinion of 16 September 2021 (not yet published in the Official Journal).
([2]) Opinion of 23 September 2021 (not yet published in the Official Journal).
([3]) Opinion of 24 June 2021 (not yet published in the Official Journal).
([4]) Council Decision (EU) 2020/1512 of 13 October 2020 on guidelines for the employment policies of the Member States (OJ L 344, 19.10.2020, p. 22).
([5]) Council Recommendation (EU) 2015/1184 of 14 July 2015 on broad guidelines for the economic policies of the Member States and of the European Union (OJ L 192, 18.7.2015, p. 27).

the Member States and in the Union, reflecting the interdependence between the Member States. The resulting set of coordinated European and national policies and reforms are to constitute an appropriate overall sustainable economic and employment policy mix, which should achieve positive spillover effects.

(4) The Guidelines are consistent with the Stability and Growth Pact, existing Union legislation and various Union initiatives, including Council Recommendations of 10 March 2014 ([6]), 15 February 2016 ([7]), 19 December 2016 ([8]), 15 March 2018 ([9]), 22 May 2018 ([10]), 22 May 2019 ([11]), 8 November 2019 ([12]), 30 October 2020 ([13]) and 24 November 2020 ([14]), Commission Recommendation (EU) 2021/402 ([15]) and Council Recommendation (EU) 2021/1004 ([16]).

(5) The European Semester combines the different instruments in an overarching framework for integrated multilateral coordination and surveillance of economic and employment policies. While pursuing environmental sustainability, productivity, fairness and stability, the European Semester integrates the principles of the European Pillar of Social Rights and of its monitoring tool, the Social Scoreboard, and provides for strong engagement with social partners, civil society and other stakeholders. It supports the delivery of the Sustainable Development Goals. The Union's and Member States' employment and economic policies should go hand in hand with Europe's transition to a climate neutral, environmentally sustainable and digital economy, improve competitiveness, ensure adequate working conditions, foster innovation, promote social justice and equal opportunities, as well as tackle inequalities and regional disparities.

(6) Climate change and environment-related challenges, globalisation, digitalisation, artificial intelligence, teleworking, the platform economy and demographic change are transforming European economies and societies. The Union and its Member States are to work together to effectively address those structural factors and adapt existing systems as needed, recognising the close interdependence of the Member States' economies and labour markets, and related policies. That requires coordinated, ambitious and effective policy action at both Union and national levels, in accordance with the TFEU and the Union's provisions on economic governance, and taking into account the European Pillar of Social Rights. Such policy action should encompass a boost in sustainable investment, a renewed commitment to appropriately sequenced reforms that enhance economic growth, the creation of quality jobs, productivity, adequate working conditions, social and territorial cohesion, upward convergence, resilience and the exercise of fiscal responsibility. It should combine supply- and demand-side measures, while taking into account their environmental, employment and social impacts.

(7) The European Parliament, the Council and the Commission proclaimed the European Pillar of Social Rights ([17]). It sets out twenty principles and rights to support well-functioning and fair labour markets and welfare systems, structured around three categories: equal opportunities and access to the labour market, fair working conditions, and social protection and inclusion. The principles and rights give direction to the Union's strategy, making sure that the transitions to climate-neutrality and environmental sustainability, digitalisation and demographic change are socially fair and just. The European Pillar of Social Rights, with its accompanying Social Scoreboard, constitutes a reference framework to monitor the employment and social performance of Member States, to drive reforms at national, regional and local level and to reconcile the 'social' and the 'market' in today's modern economy, including

([6]) Council Recommendation of 10 March 2014 on a Quality Framework for Traineeships (OJ C 88, 27.3.2014, p. 1).
([7]) Council Recommendation of 15 February 2016 on the integration of the long-term unemployed into the labour market (OJ C 67, 20.2.2016, p. 1).
([8]) Council Recommendation of 19 December 2016 on Upskilling Pathways: New Opportunities for Adults (OJ C 484, 24.12.2016, p. 1).
([9]) Council Recommendation of 15 March 2018 on a European Framework for Quality and Effective Apprenticeships (OJ C 153, 2.5.2018, p. 1).
([10]) Council Recommendation of 22 May 2018 on key competences for lifelong learning (OJ C 189, 4.6.2018, p. 1).
([11]) Council Recommendation of 22 May 2019 on High-Quality Early Childhood Education and Care Systems (OJ C 189, 5.6.2019, p. 4).
([12]) Council Recommendation of 8 November 2019 on access to social protection for workers and the self-employed (OJ C 387, 15.11.2019, p. 1).
([13]) Council Recommendation of 30 October 2020 on A Bridge to Jobs – Reinforcing the Youth Guarantee and replacing the Council Recommendation of 22 April 2013 on establishing a Youth Guarantee (OJ C 372, 4.11.2020, p. 1).
([14]) Council Recommendation of 24 November 2020 on vocational education and training (VET) for sustainable competitiveness, social fairness and resilience (OJ C 417, 2.12.2020, p. 1).
([15]) Commission Recommendation (EU) 2021/402 of 4 March 2021 on an effective active support to employment following the COVID-19 crisis (EASE) (OJ L 80, 8.3.2021, p. 1).
([16]) Council Recommendation (EU) 2021/1004 of 14 June 2021 establishing a European Child Guarantee (OJ L 223, 22.6.2021, p. 14).
([17]) Interinstitutional Proclamation on the European Pillar of Social Rights (OJ C 428, 13.12.2017, p. 10).

by promoting the social economy. On 4 March 2021, the Commission put forward an Action Plan for the implementation of the European Pillar of Social Rights (the 'Action Plan'), including ambitious but realistic headline targets and complementary sub-targets for 2030, in the areas of employment, skills, education and social protection.

(8) On 8 May 2021, at the Porto Social Summit, Heads of State or Government recognised the European Pillar of Social Rights as a fundamental element of the recovery, noting that its implementation will strengthen the Union's drive towards a digital, green and fair transition and contribute to achieving upward social and economic convergence and addressing demographic challenges. They stressed that the social dimension, social dialogue and the active involvement of social partners are at the core of a highly competitive social market economy. They found that the Action Plan provides useful guidance for the implementation of the European Pillar of Social Rights, including in the areas of employment, skills, health and social protection. They welcomed the new Union headline targets for 2030 on employment (78 % of the population aged 20-64 should be in employment), skills (60 % of all adults should participate in training every year) and poverty reduction (by at least 15 million people, including five million children), as well as the revised Social Scoreboard with a view to monitoring progress towards the implementation of the principles of the European Pillar of Social Rights as part of the policy coordination framework in the context of the European Semester. Moreover, they noted that, as Europe gradually recovers from the COVID-19 pandemic, the priority will be to move from protecting to creating jobs and improving job quality, and stressed that implementation of the principles of the European Pillar of Social Rights will be essential to ensure the creation of more and better jobs for all within the framework of an inclusive recovery. They emphasised their commitment to unity and solidarity, which also means ensuring equal opportunities for all and that no one is left behind.

They affirmed their determination, as established by the European Council's Strategic Agenda 2019-2024, to continue deepening the implementation of the European Pillar of Social Rights at Union and national levels, with due regard for respective competences and the principles of subsidiarity and proportionality. Lastly, they stressed the importance of closely following, including at the highest level, the progress achieved towards the implementation of the European Pillar of Social Rights and the Union headline targets for 2030.

(9) Reforms to the labour market, including the national wage-setting mechanisms, should follow national practices of social dialogue, with a view to providing fair wages that enable a decent standard of living and sustainable growth. They should allow for the necessary opportunity for a broad consideration of socioeconomic issues, including improvements in sustainability, competitiveness, innovation, the creation of quality jobs, working conditions, in-work poverty, education and skills, public health and inclusion, and real incomes. Member States and the Union should ensure that the social, employment and economic impact of the COVID-19 pandemic is mitigated and that transitions are socially fair and just. Strengthening the recovery and the drive towards an inclusive and resilient society in which people are protected and empowered to anticipate and manage change, and in which they can actively participate in society and the economy, should be pursued. A coherent set of active labour market policies, consisting of temporary hiring and transition incentives, skills policies and improved employment services, is needed to support labour market transitions, as highlighted in Recommendation (EU) 2021/402.

(10) Discrimination in all its forms should be tackled, gender equality ensured and youth employment supported. Access and opportunities for all should be ensured and poverty and social exclusion, including that of children, should be reduced, in particular by ensuring an effective functioning of labour markets and adequate and inclusive social protection systems, and by removing barriers to education, training and labour-market participation, including through investments in early childhood education and care, and in digital skills. Timely and equal access to affordable long-term care and healthcare services, including prevention and healthcare promotion, are particularly relevant in light of the COVID-19 pandemic and in a context of ageing societies. The potential of persons with disabilities to contribute to economic growth and social development should be further realised. As new economic and business models take hold in Union workplaces, employment relationships are also changing. Member States should ensure that employment relationships stemming from new forms of work maintain and strengthen Europe's social model.

(11) The Integrated Guidelines should serve as a basis for country-specific recommendations that the Council may address to Member States. Following the launch of the Recovery and Resilience Facility by Regulation (EU) 2021/241 of the European Parliament and of the Council ([18]), the Commission adjusted the 2021 European Semester cycle and only proposed recommendations on the budgetary situation of the Member States in 2021 as envisaged under the Stability and Growth Pact.

(12) Member States are to make full use of REACT-EU established by Regulation (EU) 2020/2221 of the European Parliament and of the Council ([19]), which reinforces cohesion policy funds until 2023, the European Social Fund Plus established by Regulation (EU) 2021/1057 of the European Parliament and of the Council ([20]), the Recovery and Resilience Facility, and other Union funds, including the Just Transition Fund established by Regulation (EU) 2021/1056 of the European Parliament and of the Council ([21]) and InvestEU established by Regulation (EU) 2021/523 of the European Parliament and of the Council ([22]), to foster employment, social investments, social inclusion and accessibility, and to promote upskilling and reskilling opportunities of the workforce, lifelong learning and high-quality education and training for all, including digital literacy and skills.

Member States are also to make full use of the European Globalisation Adjustment Fund for Displaced Workers established by Regulation (EU) 2021/691 of the European Parliament and of the Council ([23]) to support workers made redundant as a result of major restructuring events, such as the COVID-19 pandemic, socioeconomic transformations that are the result of globalisation, and technological and environmental changes. While the Integrated Guidelines are addressed to Member States and the Union, they should be implemented in partnership with all national, regional and local authorities, closely involving parliaments, as well as the social partners and representatives of civil society.

(13) The Employment Committee and the Social Protection Committee are to monitor how the relevant policies are implemented in light of the guidelines for employment policies, in line with their respective Treaty-based mandates. Those Committees and other Council preparatory bodies involved in the coordination of economic and social policies are to work closely together. Policy dialogue between the European Parliament, the Council and the Commission should be maintained, in particular as regards the guidelines for the employment policies of the Member States.

(14) The Social Protection Committee was consulted,

HAS ADOPTED THIS DECISION:

Article 1

The guidelines for the employment policies of the Member States, as set out in the Annex to Decision (EU) 2020/1512, are maintained for 2021 and shall be taken into account by the Member States in their employment policies and reform programmes.

([18]) Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility (OJ L 57, 18.2.2021, p. 17).

([19]) Regulation (EU) 2020/2221 of the European Parliament and of the Council of 23 December 2020 amending Regulation (EU) No 1303/2013 as regards additional resources and implementing arrangements to provide assistance for fostering crisis repair in the context of the COVID-19 pandemic and its social consequences and for preparing a green, digital and resilient recovery of the economy (REACT-EU) (OJ L 437, 28.12.2020, p. 30).

([20]) Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21).

([21]) Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1).

([22]) Regulation (EU) 2021/523 of the European Parliament and of the Council of 24 March 2021 establishing the InvestEU Programme and amending Regulation (EU) 2015/1017 (OJ L 107, 26.3.2021, p. 30).

([23]) Regulation (EU) 2021/691 of the European Parliament and of the Council of 28 April 2021 on the European Globalisation Adjustment Fund for Displaced Workers (EGF) and repealing Regulation (EU) No 1309/2013 (OJ L 153, 3.5.2021, p. 48).

Article 2

This Decision is addressed to the Member States.

Done at Luxembourg, 15 October 2021.

For the Council
The President
J. CIGLER KRALJ

COUNCIL DECISION (EU) 2021/1869

of 19 October 2021

amending Decision 1999/70/EC concerning the external auditors of the national central banks, as regards the external auditors of the Banca d'Italia

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Protocol No 4 on the Statute of the European System of Central Banks and of the European Central Bank, annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, and in particular Article 27.1 thereof,

Having regard to the Recommendation of the European Central Bank of 7 September 2021 to the Council of the European Union on the external auditors of the Banca d'Italia (ECB/2021/41) ([1]),

Whereas:

(1) The accounts of the European Central Bank (ECB) and of the national central banks of the Member States whose currency is the euro are to be audited by independent external auditors recommended by the Governing Council of the ECB and approved by the Council of the European Union.

(2) The mandate of the current external auditors of the Banca d'Italia, BDO Italia S.p.A., ended after the audit for the financial year 2020. It is therefore necessary to appoint external auditors as from the financial year 2021.

(3) The Banca d'Italia has selected Deloitte & Touche S.p.A. as its external auditors for the financial years 2021 to 2022.

(4) The Governing Council of the ECB recommended that Deloitte & Touche S.p.A. be appointed as the external auditors of the Banca d'Italia for the financial years 2021 to 2022.

(5) Following the recommendation of the Governing Council of the ECB, Council Decision 1999/70/EC ([2]) should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In Article 1 of Decision 1999/70/EC, paragraph 6 is replaced by the following:

'6. Deloitte & Touche S.p.A. are hereby approved as the external auditors of the Banca d'Italia for the financial years 2021 to 2022.'.

Article 2

This Decision shall take effect on the date of its notification.

Article 3

This Decision is addressed to the ECB.

([1]) OJ C 370, 15.9.2021, p. 1.

([2]) Council Decision 1999/70/EC of 25 January 1999 concerning the external auditors of the national central banks (OJ L 22, 29.1.1999, p. 69).

Done at Luxembourg, 19 October 2021.

For the Council
The President
G. DOVŽAN

COMMISSION DECISION (EU) 2021/1870

of 22 October 2021

establishing the EU Ecolabel criteria for cosmetic products and animal care products

(notified under document C(2021) 7500)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel ([1]) , and in particular Article 8(2) thereof,

After consulting the European Union Ecolabelling Board,

Whereas:

(1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to those products with a reduced environmental impact during their entire life cycle.

(2) Regulation (EC) No 66/2010 provides that specific EU Ecolabel criteria are to be established according to product groups.

(3) Commission Decision 2014/893/EU ([2]) established EU Ecolabel criteria and related assessment and verification requirements for the product group 'rinse-off cosmetics'. The period of validity of those criteria and requirements has been extended to 31 December 2021 by Commission Decision (EU) 2018/1590 ([3]).

(4) In order to better reflect best practice in the market for this product group and to take account of innovations introduced in the intervening period, it is appropriate to establish a new set of criteria for 'rinse-off cosmetics'.

(5) The EU Ecolabel Fitness check Report ([4]) of 30 June 2017, reviewing the implementation of Regulation (EC) No 66/2010, concluded on the need to develop a more strategic approach for the EU Ecolabel, also including the bundling of closely related product groups where appropriate.

(6) In line with those conclusions, it is appropriate to revise the criteria for the product group 'rinse-off cosmetics', including the expansion of its scope to other cosmetic products covered by Commission Regulation (EC) No 1223/2009 ([5]) and to animal care products. In order to reflect that expansion of its scope it is also appropriate to modify the product group name to 'Cosmetic products and animal care products' subsuming cosmetic products manufactured for human and animal use.

([1]) Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 27, 30.1.2010, p. 1).

([2]) Commission Decision 2014/893/EU establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products (OJ L 354, 11.12.2014, p. 47).

([3]) Commission Decision (EU) 2018/1590 of 19 October 2018 amending Decisions 2012/481/EU, 2014/391/EU, 2014/763/EU and 2014/893/EU as regards the period of validity of the ecological criteria for the award of the EU Ecolabel for certain products, and of the related assessment and verification requirements (OJ L 264, 23.10.2018, p. 24).

([4]) Report from the Commission to the European Parliament and the Council on the review of implementation of Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) and the Regulation (EC) No 66/2010 of the parliament and of the Council of 25 November 2009 on the EU Ecolabel (COM(2017) 355).

([5]) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

(7) The New Circular Economy Action Plan for a cleaner and more competitive Europe ([6]) adopted on 11 March 2020 stipulates that the durability, recyclability and recycled content requirements will be more systematically included in the EU Ecolabel criteria.

(8) The revised EU Ecolabel criteria for cosmetic products and animal care products should aim, in particular, at promoting products that have limited impacts in terms of eco-toxicity and biodegradability, which may only contain a limited amount of hazardous substances and that use less packaging, which can be easily recycled. The use of recycled material and refillable packaging should be promoted. In the revision, appropriate attention should be paid to the coherence between relevant EU policies, legislation and scientific evidence.

(9) The new criteria and related assessment and verification requirements for the product group should remain valid until 31 December 2027, taking into account the innovation cycle for that product group.

(10) For reasons of legal certainty, Decision 2014/893/EU should be repealed.

(11) A transitional period should be allowed for producers whose products have been awarded the EU Ecolabel for rinse-off cosmetics on the basis of the criteria set out in Decision 2014/893/EU, so that they have sufficient time to adapt their products to comply with the new criteria and requirements. For a limited period after adoption of this Decision, producers should also be allowed to submit applications based either on the criteria established by Decision 2014/893/EU or on the new criteria stablished by this Decision. EU Ecolabel licences awarded in accordance with the criteria set out in Decision 2014/893/EU should be allowed to be used for twelve months from the date of adoption of this Decision.

(12) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010,

HAS ADOPTED THIS DECISION:

Article 1

The product group 'cosmetic products' shall comprise any substance or mixture falling under the scope of Regulation (EC) No 1223/2009, intended to be placed in contact with the external parts of the human body, or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

The product group 'Cosmetic products' shall include rinse-off and leave-on products for both private and professional use.

Article 2

The product group 'animal care products' shall comprise any substance or mixture intended to be placed in contact with animal hair to clean them or to improve the condition of it, such as shampoos and conditioners for animals.

Animal care products shall not cover products that are specifically marketed for disinfecting or anti-bacterial use.

The product group 'Animal care products' shall include rinse-off products for both private and professional use.

([6]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A new Circular Economy Action Plan for a cleaner and more competitive Europe (COM(2020) 98 final).

Article 3

For the purpose of this Decision, the following definitions shall apply:

(1) 'leave on products' means products marketed as not intended to be removed with water after use in normal conditions;

(2) 'rinse off products' means products marketed as intended to be removed with water after use in normal conditions.

Article 4

In order for a product to be awarded the EU Ecolabel under Regulation (EC) No 66/2010 for the product group 'cosmetic products and animal care products', it shall fall within the definition of that product group as specified in Articles 1 and 2 of this Decision and shall comply with the criteria and related assessment and verification requirements set out in Annex I to this Decision, for cosmetic products, or in Annex II for animal care products.

Article 5

The EU Ecolabel criteria for the product group 'cosmetic products and animal care products' and the related assessment and verification requirements shall be valid until 31 December 2027.

Article 6

For administrative purposes, the code number assigned to the product group 'cosmetic products' shall be '030'.

For administrative purposes, the code number assigned to the product group 'animal care products' shall be '054'.

Article 7

Decision 2014/893/EU is repealed.

Article 8

1. Notwithstanding Article 7, applications submitted before the date of adoption of this Decision for the EU Ecolabel for the product group 'rinse-off cosmetics', as defined in Decision 2014/893/EU shall be evaluated in accordance with the conditions laid down in that Decision.

2. Applications for the EU Ecolabel for products falling within the product group 'rinse-off cosmetics' submitted on or within two months from the date of adoption of this Decision may be based either on the criteria set out in this Decision, or on the criteria set out in Decision 2014/893/EU. Those applications shall be evaluated in accordance with the criteria on which they are based.

3. EU Ecolabel licenses awarded on the basis of an application evaluated in accordance with the criteria set out in Decision 2014/893/EU may be used for twelve months from the date of adoption of this Decision.

Article 9

This Decision is addressed to the Member States.

Done at Brussels, 22 October 2021.

For the Commission
Virginijus SINKEVIČIUS
Member of the Commission

ANNEX I

EU Ecolabel criteria for awarding the EU Ecolabel to cosmetic products

FRAMEWORK

Aims of the criteria

The EU Ecolabel criteria target the best cosmetic products on the market, in terms of environmental performance. The criteria focus on the main environmental impacts associated with the life cycle of these products and promote circular economy aspects.

In particular, the criteria aim to promote products that have limited impacts in terms of eco-toxicity and biodegradability, which may only contain a limited amount of hazardous substances and that use less packaging, which can be easily recycled. The use of recycled material and refillable packaging is promoted.

To this end, the criteria:

(1) set requirements to limit the overall aquatic toxicity;

(2) set requirements to ensure that the ingredients are biodegradable and will not persist in water;

(3) recognise and reward products with restricted use of hazardous substances;

(4) set requirements to allow the maximum usage of the product contained in a container, promote the minimisation of use of packaging material and promote plastics recyclability;

(5) recognise and reward products containing renewable ingredients from sustainable origin;

(6) guarantee that the product meets certain quality requirements and user satisfaction;

(7) set a requirement to inform consumers on the environmental benefits associated with the product, in order to encourage its purchase.

The criteria for awarding the EU Ecolabel to 'cosmetic products' are the following:

(1) toxicity to aquatic organisms: Critical Dilution Volume (CDV) of rinse-off products;

(2) biodegradability of rinse-off products;

(3) aquatic toxicity and biodegradability of leave-on products;

(4) excluded and restricted substances;

(5) packaging;

(6) sustainable sourcing of palm oil, palm kernel oil and their derivatives;

(7) fitness for use;

(8) information on EU Ecolabel.

Assessment and verification

a) ***Requirements***

Specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or his/her supplier(s) and/or their supplier(s), etc. as appropriate.

Competent bodies shall preferentially recognise attestations which are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications or site inspections to check compliance with these criteria.

Changes in suppliers and production sites pertaining to products to which the EU Ecolabel has been granted shall be notified to competent bodies, together with supporting information to enable verification of continued compliance with the criteria.

As a prerequisite the product shall meet all applicable legal requirements of the country or countries in which the product is placed on the market. The applicant shall declare the product's compliance with this requirement.

The Appendix makes reference to the 'Detergent Ingredient Database' list (DID list) which contains the most widely used ingredients in detergents and cosmetics formulations. It shall be used for deriving the data for the calculations of the Critical Dilution Volume (CDV) (criterion 1), for the assessment of the biodegradability (criterion 2) of the ingoing substances and for the assessment of the biodegradability and aquatic toxicity of leave-on products (criterion 3). For substances not included in the DID list, guidance is given on how to calculate or extrapolate the relevant data. The latest version of the DID list is available from the EU Ecolabel website ([1]) or via the websites of the individual competent bodies.

A list of all ingoing substances in the final product shall be provided to the competent body, indicating the trade name (if existing), the chemical name, the CAS No, International Nomenclature of Cosmetic Ingredients (INCI) designations, DID No ([2]) (if existing), its function, form and concentration in mass percentage (including and excluding water), regardless of concentration in the final product formulation. All listed substances present in the form of nanomaterials shall be clearly indicated on the list with the word 'nano' written in brackets.

For each substance listed, the Safety Data Sheets (SDS) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]) shall be provided. Where an SDS is not available for a single substance because it is part of a mixture, the applicant shall provide the SDS of the mixture.

A written confirmation from the applicant that all the criteria are fulfilled shall also be required for the assessment.

Note: Label, claims and/or instructions information accompanying the product shall be used to categorise the cosmetic product. Where a cosmetic product is marketed for different cosmetic uses, the cosmetic product category for which stricter criteria applies shall be assigned to the product.

b) ***Measurement thresholds***

Compliance with the ecological criteria is required for all substances as specified in Table 1.

([1]) http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf
http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf

([2]) DID No is the number of the ingoing substance on the DID list.

([3]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Table 1

Threshold levels applicable to substances for cosmetic products (% weight by weight, %w/w), shown by criterion. Abbreviations: CLP: Classification, Labelling and Packaging; CMR: carcinogenic, mutagenic, toxic for reproduction; N/A: not applicable

Criterion name		Preservatives	Colourants	Fragrances	Impurities	Other substances (e.g. surfactants, enzymes, UV filters)
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV) of rinse-off cosmetic products		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)
Criterion 2. Biodegradability of rinse-off cosmetic products		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)
Criterion 3. Biodegradability and aquatic toxicity of leave-on cosmetic products		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0010	no limit (*1)
Criterion 4. Excluded and restricted substances	Criterion 4 (a) (i): Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council [4] (rinse-off)	≥ 0,0100 (*2)	≥ 0,0100 (*2)	≥ 0,0100	≥ 0,0100	≥ 0,0100
	Criterion 4 (a) (i): Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 (leave-on)	≥ 0,0010 (*2)	≥ 0,0010 (*2)	≥ 0,0010	≥ 0,0010	≥ 0,0010
	Criterion 4 (a) (ii): Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 (carcinogenic, mutagenic, toxic for reproduction) (rinse-off and leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 4 (a) (iii): product classification (rinse-off and leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 4 (b): Specified excluded substances (rinse-off and leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 4 (c): Restrictions on Substances of Very High Concern (rinse-off and leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

Criterion name		Preservatives	Colourants	Fragrances	Impurities	Other substances (e.g. surfactants, enzymes, UV filters)
	Criterion 4 (d): Fragrances (rinse-off)	N/A	N/A	no limit (*1)	≥ 0,0100	N/A
	Criterion 4 (d): Fragrances (leave-on)	N/A	N/A	no limit (*1)	≥ 0,0010	N/A
	Criterion 4 (e): Preservatives (rinse-off)	no limit (*1)	N/A	N/A	≥ 0,0100	N/A
	Criterion 4 (e): Preservatives (leave-on)	no limit (*1)	N/A	N/A	≥ 0,0010	N/A
	Criterion 4 (f): Colourants (rinse-off)	N/A	no limit (*1)	N/A	≥ 0,0100	N/A
	Criterion 4 (f): Colourants (leave-on)	N/A	no limit (*1)	N/A	≥ 0,0010	N/A
	Criterion 4 (g): UV filters (leave-on)	N/A	N/A	N/A	≥ 0,0010	no limit (*1) (*3)
Criterion 6. Sustainable sourcing of palm oil, palm kernel oil and their derivatives	Criterion 6: Sustainable sourcing of palm oil, palm kernel oil and their derivatives (rinse-off)	no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)
	Criterion 6 (a): Sustainable sourcing of palm oil, palm kernel oil and their derivatives (leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0010	no limit (*1)

(*1) 'no limit' means: regardless of the concentration (analytical limit of detection) for all substances, with the exception of impurities, which can be present up to a concentration of 0,0100 %w/w in the final formulation in rinse-off products and up to 0,0010 %w/w in the final formulation in leave-on products.
(*2) For preservatives and colourants classified as H317 and H334 the threshold is 'no limit'.
(*3) Applicable only to UV filters.

For the purpose of this Annex, the following definitions shall apply:

1) 'active content' (AC) means the sum of organic ingoing substances in the product excluding the water content of the ingredients (expressed in grams), calculated on the basis of the complete formulation of the final product. Inorganic rubbing/abrasive agents are not included in the calculation of the active content;

2) 'children products' means products marketed to be used up to the age of 12 years and products marketed as 'family product';

3) 'ingoing substances' means all substances in the cosmetic product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde from preservatives and arylamine from azodyes and azopigments) shall also be regarded as ingoing substances. Residuals, pollutants, contaminants, by-products, etc. from production, incl. production of raw materials, that remain in the raw materials ≥ 1 000 ppm (≥ 0,1000 %w/w ≥ 1 000 mg/kg) are always regarded as ingoing substances, regardless of the concentration in the final product;

4) 'impurities' means residuals, pollutants, contaminants, by-products, etc. from production, incl. production of raw materials that remain in the raw material/ingredient and/or in the in the final product in concentrations less than 100 ppm (0,0100 % w/w, 100 mg/kg) in the rinse-off product and less than 10 ppm (0,0010 % w/w, 10,0 mg/kg) in the leave-on product;

5) 'microplastics' means particles with a size of below 5 mm of insoluble macromolecular plastic, obtained through one of the following processes: a) a polymerisation process such as polyaddition or polycondensation or a similar process using monomers or other starting substances; b) chemical modification of natural or synthetic macromolecules; c) microbial fermentation;

6) 'primary packaging' means packaging in direct contact with the content conceived so as to constitute the smallest sales unit of distribution to the final user or consumer at the point of purchase;

7) 'nanomaterial' means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm, in accordance with Regulation (EC) No 1223/2009 ([5]);

8) 'secondary packaging' means packaging which can be removed from the product without affecting its characteristics and is conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale.

9) 'substances identified to have endocrine disrupting properties' means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([6]) (candidate list of substances of very high concern for authorisation), or according to Regulations (EU) No 528/2012 ([7]) or (EC) No 1107/2009 ([8]) of the European Parliament and of the Council.

([5]) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

([6]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

([7]) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

([8]) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

EU ECOLABEL CRITERIA FOR COSMETIC PRODUCTS

Criterion 1 – Toxicity to aquatic organisms: Critical Dilution Volume (CDV) of rinse-off products

The total CDV toxicity of the rinse-off product, as specified in Table 2, shall not exceed the following limits:

Table 2

CDV limits

Product	CDV (l/g AC)
Shampoos, soaps, shower preparations, shaving soaps and toothpaste (solid form)	2 200
Liquid soaps and shower preparations	10 000
Shampoos (liquid form)	11 000
Feminine hygiene cosmetic products	12 000
Hair conditioners	12 000
Rinse-off hair styling and treatment products (hair dyes)	12 000
Rinse-off skin care products (exfoliants)	12 000
Shaving foams, shaving gels, shaving creams	12 000
Toothpaste and mouthwash	12 000
Other rinse-off products	12 000

The CDV shall be calculated using the following equation:

$$CDV = \sum CDV \text{ (ingoing substance i)} = \sum \text{weight (i)} \times DF \text{ (i)} \times 1000/TF \text{ chronic (i)}$$

Where:

weight (i) — is the weight of the ingoing substance (in grams) per 1 gram of AC (i.e. normalised weight contribution of the ingoing substance to the AC)

DF (i) — is the degradation factor of the ingoing added substance

TF chronic (i) — is the toxicity factor of the ingoing added substance (in milligrams/litre)

Assessment and verification: *the applicant shall provide the calculation of the CDV of the product. A spreadsheet for calculation of the CDV value is available on the EU Ecolabel website. The values of DF and TF chronic shall be as given in the DID list-part A. If the ingoing substance is not included in the DID list-part A, the applicant shall determine the values using the guidelines described in the DID list-part B and attaching the associated documentation (for more information see the Appendix).*

Criterion 2 – Biodegradability of rinse-off products

a) ***Biodegradability of surfactants***

All surfactants shall be readily biodegradable under aerobic conditions and biodegradable under anaerobic conditions.

The following shall be exempt from the requirement on anaerobic biodegradability:

Surfactants with cleaning and/or foaming function in toothpastes.

b) ***Biodegradability of organic ingoing substances***

The content of all organic ingoing substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNBO) or anaerobically non-biodegradable (anNBO) shall not exceed the limits in Table 3:

Table 3

aNBO and anNBO limits

Product	aNBO (mg/g AC)	anNBO (mg/g AC)
Shampoos, soaps, shower preparations, and toothpaste (solid form)	5	5
Shaving solid soaps	10	10
Feminine hygiene cosmetic products	15	15
Hair conditioners	15	15
Liquid soaps and shower preparations	15	15
Rinse-off hair styling and treatment products (hair dyes)	15	15
Rinse-off skin care products (exfoliants)	15	15
Shampoo (liquid form)	20	20
Toothpastes, mouthwashes	15	15
Shaving foams, shaving gels, shaving creams	70	40
Other rinse-off products	15	15

Assessment and verification: *the applicant shall provide documentation for the biodegradability of surfactants, as well as the calculation of aNBO and anNBO for the product. A spreadsheet for calculating aNBO and anNBO values is available on the EU Ecolabel website.*

For surfactant biodegradability values as well for aNBO and anNBO values for organic ingoing substances, reference shall be made to the DID list. For ingoing substances which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, together with a toxicologist declaration showing that they are aerobically and anaerobically biodegradable shall be provided as described in the Appendix.

In the absence of documentation in accordance with the above requirements, an ingoing substance other than a surfactant may be exempted from the requirement for anaerobic biodegradability if one of the following three conditions is fulfilled:

1. *the substance is readily degradable and has low adsorption (A < 25 %);*

2. *the substance is readily degradable and has high desorption (D > 75 %);*

3. *the substance is readily degradable and non-bioaccumulating.*

Testing for adsorption/desorption may be conducted in accordance with Guidelines 106 of the Organisation for Economic Co-operation and Development (OECD).

Criterion 3 – Aquatic toxicity and biodegradability of leave-on products

At least 95 % by weight of the total content of organic ingoing substances shall be:

— readily biodegradable (OECD 301 A-F), and/or

— lowest aquatic toxicity NOEC/ECx > 0,1 mg/l or EC/LC50 > 10,0 mg/l and not be bioaccumulable, and/or

— lowest aquatic toxicity NOEC/ECx > 0,1 mg/l or EC/LC50 > 10,0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or

— lowest aquatic toxicity NOEC/ECx > 0,1 mg/l or EC/LC50 > 10,0 mg/l and not be bioavailable (molecular weight > 700 g/mol)

UV filters in leave-on products with sun protection function shall be exempt from that requirement.

Assessment and verification: *the applicant shall provide documentation for the biodegradability and aquatic toxicity values.*

For ingoing substances which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, showing biodegradability/toxicity/potential for bioaccumulation/bioavailability specifications shall be provided as described in the Appendix.

Criterion 4 – Excluded and restricted substances

4 (a) ***Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008***

(i) Unless derogated in Table 5, the product shall not contain substances at or above the concentration of 0,0100 % weight by weight for rinse-off products and 0,0010 % weight by weight for leave-on cosmetics that meet the criteria for classification with the hazard classes, categories and associated hazard statement codes listed in Table 4, in accordance with Regulation (EC) No 1272/2008.

Where stricter, the generic or specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008 shall prevail.

Table 4

Restricted hazard classes, categories and associated hazard statement codes

Acute toxicity	
Categories 1 and 2	Category 3
H300 Fatal if swallowed	H301 Toxic if swallowed
H310 Fatal in contact with skin	H311 Toxic in contact with skin
H330 Fatal if inhaled	H331 Toxic if inhaled
H304 May be fatal if swallowed and enters airways	EUH070 Toxic by eye contact
Specific target on organ toxicity	
Category 1	Category 2
H370 Causes damage to organs	H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure	H373 May cause damage to organs through prolonged or repeated exposure
Respiratory and skin sensitisation (*[1])	
Category 1A	Category 1B
H317 May cause allergic skin reaction	H317 May cause allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Hazardous to the aquatic environment	
Categories 1 and 2	Category 3 and 4
H400 Very toxic to aquatic life	H412 Harmful to aquatic life with long-lasting effects
H410 Very toxic to aquatic life with long-lasting effects	H413 May cause long-lasting effects to aquatic life
H411 Toxic to aquatic life with long-lasting effects	

Hazardous to the ozone layer	
H420 Harms public health and the environment by destroying ozone in the upper atmosphere	

(*1) The following substances shall be exempt: enzymes (including stabilisers and preservatives in the enzyme raw material) if they are in liquid form or as granulate capsules; α-tocopheryl acetate; Amidoamin, which can be included with a maximum concentration of 0,3 % w/w as an impurity in Cocamidopropyl Betaine (CAPB). In the case of colourants and preservatives with a H317 or H334 hazard class, the requirement applies regardless of the concentration.

Table 5

Derogations to restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 and applicable conditions

Substance type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Surfactants	Rinse-off and leave-on products	H412: Harmful to aquatic life with long-lasting effects	Total concentration < 20 % w/w in the final product
Sodium Fluoride	Rinse-off oral care products	H301: Toxic if swallowed	Only in oral care products (mouthwash and toothpaste)

(ii) Unless derogated in Table 7, substances that meet the criteria for classification with the hazard statements listed in Table 6 shall not be contained in the final product nor in its ingredients, regardless of their concentration.

Table 6

Excluded hazard classes, categories and associated hazard statement codes

Carcinogenic, mutagenic or toxic for reproduction	
Categories 1A and 1B	Category 2
H340 May cause genetic defects	H341 Suspected of causing genetic defects
H350 May cause cancer	H351 Suspected of causing cancer
H350i May cause cancer by inhalation	
H360F May damage fertility	H361f Suspected of damaging fertility
H360D May damage the unborn child	H361d Suspected of damaging the unborn child
H360FD May damage fertility. May damage the unborn child	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child
H360Fd May damage fertility. Suspected of damaging the unborn child	H362 May cause harm to breast fed children
H360Df May damage the unborn child. Suspected of damaging fertility	

Table 7

Derogations to restrictions on substances classified as CMR under Regulation (EC) No 1272/2008 and applicable conditions

Substance type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Titanium dioxide (nano-form)	UV filters in leave-on products with sun protection function	H351: Suspected of causing cancer	Must comply with SCCS/1516/13, SCCS/1580/16, and SCCS/1583/17. It cannot be used in powder or spray form

(iii) Ingoing substances classified as environmentally hazardous according to Regulation (EC) No 1272/2008 may be included in the product to a maximum:

$$100 \cdot c\,[H410] + 10 \cdot c\,[H411] + c\,[H412] \leq 2{,}5\ \%$$

where c is the fraction of the product, measured in percentage by weight, made up of the classified substance.

The following exemptions apply:

— Compounds of zinc (classified H410) may however be included in zinc ointment/cream marketed to heal irritated skin to a maximum of 25 % and may, in these cases, be exempted from the calculation.

— Surfactants classified as H412 shall be exempted from the requirement.

Criterion 4 (a) shall not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006 which sets out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any substance and mixture in the final product.

4 (b) ***Specified excluded substances***

The following substances shall not be included in the product, regardless of the concentration, neither as part of the formulation, as part of any mixture included in the formulation, nor as impurities:

(i) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1];

(ii) Butylated Hydroxytoluene (BHT) [2] and Butylated hydroxyanisole (BHA);

(iii) Cocamide DEA;

(iv) Deltamethrin;

(v) Diethylenetriaminepentaacetic acid (DTPA) and its salts;

(vi) Ethylenediaminetetraacetic acid (EDTA) and its salts and non-readily biodegradable phosphonates [3];

(vii) Microplastics and microbeads;

(viii) Mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in lip care products, where the recommendations ([9]) by Cosmetic Europe for mineral oils are not complied;

(ix) Nanomaterials, unless used according to the conditions laid down for specific nanomaterials in Annexes III, IV and VI to Regulation (EC) No 1223/2009 ;

(x) Nitromusks and polycyclic musks;

(xi) Perfluorinated and polyfluorinated substances;

([9]) https://www.cosmeticseurope.eu/files/3715/3907/8160/Recommendation_14_Mineral_Hydro_Carbons.pdf

(xii) Phthalates;

(xiii) Resorcinol;

(xiv) Sodium hypochlorite, chloramine and sodium chlorite;

(xv) Sodium Lauryl Sulphate (SLS) in toothpaste products;

(xvi) Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate [4];

(xvii) Substances identified to have endocrine disrupting properties;

(xviii) The following fragrances: benzyl salicylate, butylphenyl metylpropional, tetramethyl acetyloctahydranophthalenes (OTNE);

(xix) The following isoflavones: daidzein, genistein;

(xx) The following preservatives: benzalkonium chloride, formaldehyde releasers, isothiazolinones, kojic acid, parabens, triclocarban, triclosan;

(xxi) The following UV filters: benzophenone, benzophenone-1, benzophenone-2, benzophenone-3, benzophenone-4, benzophenone-5, ethylhexyl methoxycinnamate, homosalate, octocrylene;

(xxii) Triphenyl phosphate.

Notes:

[1] Substance name = 'Alkyl phenol', under: https://echa.europa.eu/es/advanced-search-for-chemicals

[2] BHT may still be used in perfumes provided that total BHT content in the perfume is below 100 ppm and total BHT concentration in the final product is below 0,0010 % w/w.

[3] non-readily biodegradable phosphonate may still be used in solid rinse-off products up to a total concentration of 0,0600 % w/w.

[4] These substances may be allowed if present as impurities, but up to a total concentration of 500 ppm in the product formulation.

4 (c) ***Restrictions on Substances of Very High Concern (SVHCs)***

Substances meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of that Regulation and included in the candidate list of substances of very high concern for authorisation shall not be present the product, regardless of their concentration.

4 (d) ***Fragrances***

(i) Children products shall be fragrance-free. Criterion 4 (d) (i) shall not apply to toothpaste marketed for children.

(ii) Products marketed as 'mild/sensitive' shall be fragrance-free.

(iii) Substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' ([10]) shall not be present in EU Ecolabel products in concentrations higher than 0,0100 % in rinse-off products and 0,0010 % in leave-on products.

(iv) Any substance or mixture added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on the IFRA website: http://www.ifrafragrance.org/. The manufacturer shall follow the recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials.

4 (e) ***Preservatives***

(i) Preservatives classified as H317 or H334 shall be prohibited regardless of the concentration.

(ii) Preservatives in the product shall not release or degrade to substances that are classified in accordance with the requirements of criterion 4 (a).

([10]) https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

(iii) The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if BCF < 500 or log K_{ow} < 4,0. If both BCF and log K_{ow} values are available, the highest measured value shall be used.

(iv) Preservatives used in products in contact with the mouth (e.g. toothpaste, mouthwash, lip care products, nail polish) shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([11]).

4 (f) ***Colourants***

(i) Colourants classified as H317 or H334 shall be prohibited regardless of the concentration.

(ii) Colourants in the product shall not be bioaccumulating. A colourant is considered not bioaccumulating if BCF < 500 or log K_{ow} < 4,0. If both BCF and log K_{ow} values are available, the highest measured value shall be used. In the case of colouring agents approved for use in food, it is not necessary to submit documentation of bioaccumulation potential.

(iii) Colourants used in products in contact with the mouth (e.g. toothpaste, mouthwash, lip care products, nail polish) shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008.

(iv) The content of barium, bismuth, cadmium, cobalt, hexavalent chromium (Chromium VI), lead and nickel occurring as impurity in decorative cosmetics and hair dyes shall be restricted to concentrations below 10 ppm. The content of mercury occurring as impurity in decorative cosmetics and hair dyes shall be restricted to concentrations below 1 ppm.

4 (g) ***UV filters***

UV filters may only be added to leave-on products that target the solar protection of the user, e.g. sunscreens and multi-purpose products with a sunscreen function. UV filters shall only protect the user – not the product.

All UV filters contained in the product shall not be bioaccumulating (BCF<500 / log K_{ow}<4,0) or shall have a lowest measured toxicity of NOEC/ECx > 0,1 mg/l or EC/LC50 > 10,0 mg/l.

Assessment and verification: *The applicant shall provide a signed declaration of compliance with all above sub-criteria, supported by declarations from suppliers, for criteria 4 (a) (ii), 4 (e), 4 (f) and 4 (g); and the following supporting evidence:*

To demonstrate compliance with sub-criteria 4 (a), 4 (b) and 4 (c), the applicant shall provide:

(i) *SDS of any substance/mixture and their concentration in the final product;*

(ii) *a written confirmation that sub-criteria 4 (a), 4 (b) and 4 (c) are fulfilled.*

For substances exempted from sub-criterion 4 (a) (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to demonstrate compliance.

For mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in sub-criterion 4 (b), compliance with the recommendations[7] by Cosmetic Europe for mineral oils shall be demonstrated.

For sub-criterion 4 (c), reference to the latest list of substances of very high concern shall be made on the date of application ([12]).

To demonstrate compliance with sub-criterion 4 (d), the applicant shall provide a signed declaration of compliance, supported by a declaration of the fragrance manufacturer, as appropriate.

To demonstrate compliance with sub-criterion 4 (e), the applicant shall provide: copies of the SDS of any preservative added, and information on its BCF and/or log K_{ow} values.

To demonstrate compliance with sub-criterion 4 (f), the applicant shall provide: copies of the SDS of any colourant added together with information on its BCF and/or log K_{ow} value, or documentation to ensure that the colouring agent is approved for use in food.

([11]) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

([12]) http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

To demonstrate compliance with sub-criterion 4 (g), the applicant shall provide: copies of the SDS of any UV filters together with information on its BCF and/or log K_{ow} value, or lowest available NOEC/EC_x/EC/LC50 value. In addition, a declaration that, if used, nano TiO_2 fulfils the conditions laid down in Annex VI to Regulation (EC) No 1223/2009 shall be provided.

The above evidence may also be provided directly to competent bodies by any supplier in the applicant's product supply chain.

Criterion 5 – Packaging

The minimum volume for a rinse-off product to be certified other than toothpaste shall be 150 ml.

a) ***Primary packaging***

Primary packaging shall be in direct contact with the contents.

No additional packaging for the product as it is sold, e.g. cardboard over a bottle, shall be allowed, with the exception of secondary packaging which groups the product and its refill and products that include several elements for their use. For the rinse-off products for domestic use sold with pump that can be opened without compromising the design, a refilling option shall be provided in the same or higher primary packaging capacity.

Note: Cardboard boxes used to transport the products to the retail stores shall not be considered as secondary packaging.

Assessment and verification: *the applicant shall provide a signed declaration and relevant evidence (e.g. pictures of the products as marketed).*

(b) ***Packaging Impact Ratio (PIR)***

The Packaging Impact Ratio (PIR) shall be less than 0,20 g of packaging per gram of product for each of the packaging in which the product is sold. Products packed in metal aerosol containers shall be exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

$$PIR = (W + (W_{refill} \times F) + N + (N_{refill} \times F))/(D + (D_{refill} \times F))$$

Where:

W — weight of packaging (primary + proportion of secondary [1], including labels) (g)

W_{refill} — weight of refill packaging (primary + proportion of secondary [1], including labels) (g)

N — weight of non-renewable + non-recycled packaging (primary + proportion of secondary (1), including labels) (g)

N_{refill} — weight of non-renewable and non-recycled refill packaging (primary + proportion of secondary (1), including labels) (g)

D — weight of product contained in the 'parent' pack (g)

D_{refill} — weight of product delivered by the refill (g)

F — number of refills required to meet the total refillable quantity, calculated as follows:

$$F = V \times R/Vrefill$$

Where:

V — volume capacity of the parent pack (ml)

V_{refill} — volume capacity of the refill pack (ml)

R — the refillable quantity. This is the number of times that the parent pack can be refilled. Where F is not a whole number, it shall be rounded up to the next whole number.

In case no refill is offered PIR shall be calculated as follows:

$$PIR = (W + N)/D$$

The manufacturer shall provide the number of foreseen refillings, or use the default values of R = 5 for plastics and R = 2 for cardboard.

Primary packaging made of more than 80 % of recycled materials shall be exempted from this requirement.

For decorative cosmetics the following shall apply:

$$PIR = \Sigma(W_{packaging,i} + W_{not\text{-}recycled,i}) / 2 * W_{product,\ total} \leq 0{,}80$$

Where:

$W_{packaging,\ i}$ — the weight of the packaging component i

$W_{non\text{-}recycled,\ i}$ — the weight of non-recycled material in packaging component i (if it is not recycled material in the packaging is $W_{non\text{-}recycled} = W_{packaging}$)

$W_{product,\ total}$ — the weight of the end product (packaging plus content)

Note:[1] Proportional weight of the grouping packaging (e.g. 50 % of the total grouping packaging weight, if two products are sold together).

Assessment and verification: *the applicant shall provide the calculation of the PIR of the product. A spreadsheet for this calculation is available on the EU Ecolabel website. If the product is sold in different packaging (i.e. with different volumes), the calculation shall be submitted for each packaging size for which the EU Ecolabel shall be awarded. The applicant shall provide a signed declaration from the packaging manufacturer for the content of post-consumer recycled material or material from renewable origin in the packaging and a description of the refill system offered, if applicable (kinds of refills, volume). For approval of refill packaging, the applicant or retailer shall demonstrate that the refills shall be available for purchase on the market. The applicant shall provide third party verification and traceability for postconsumer recycled content. Certificates of recyclers pursuant a certification scheme following standard EN15343 may be used to support verification. Certificates of product production for converters pursuant a certification scheme following a controlled blending model as described in the ISO 22095 may be used to support verification.*

c) ***Information and design of primary packaging***

(i) Information on primary packaging

Dosage and refills:

Applicants shall indicate the correct dosage or the appropriate quantity to be used on the label of the primary packaging together with the following sentence:

'*using the correct dosage of the product minimises impacts on the environment and saves money.*'

In cases where the correct dosage cannot be defined for a specific product because it depends on consumer aspects (e.g. length of the hair), the following sentence shall be used instead:

'*dose the product with care so as not to over-consume it unnecessarily*'

If the product is refillable, the applicant shall complete the information with a reference to use refills in order to minimise impacts on the environment and save money.

End of life information:

Applicants shall include a sentence or a pictogram in relation to empty product disposal (e.g. '*when empty, the package/container should be disposed of in a dedicated container for recycling*')

Note: Products whose dimensions do not allow a proper display of information due to lack of space or text legibility reasons shall be exempted from this requirement.

(ii) Design of primary packaging

Rinse-off products:

The primary packaging shall be designed:

a) to make correct dosage easy by using a pump[1] or ensuring that the opening at the top is not too wide. Refills are exempted from this requirement.

b) to ensure that at least 95 % of the product can be easily removed from the container. The residual amount of the product in the container (R), which must be below 5 %, shall be calculated as follows:

$$R = ((m2 - m3)/(m1 - m3)) \times 100\ (\%)$$

Where:

m1 — Primary packaging and product (g)

m2 — Primary packaging and product residue in normal conditions of use (g)

m3 — Primary packaging emptied and cleaned (g)

Rinse-off products whose primary packaging can be manually opened and the residue product can be extracted with adding water shall be exempted from the requirement in b).

Leave-on products:

a) Leave-on conditioner bottles shall have an emptying level of 90 % or have a lid that can be removed without tools.

b) Cream bottles shall have an emptying level of 90 % or have a lid that can be removed without tools.

The residual amount for the specified leave-on products in the container (R), which must be below 10 %, shall be calculated according to the formula set out for rinse-off products.

Notes: [1] For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g (or 3 ml) soap per full press.

Assessment and verification: *the applicant shall submit a description of the dosage device (e.g. schematic illustration, pictures…), the test report with results of measuring the residual quantity of a rinse-off cosmetic product in the packaging and a high resolution image of the product packaging that clearly shows the sentences indicated in sub-criterion 5 (c) (i) (if applicable). Applicant shall provide documented evidence of which case under sub-criterion 5 (c) (i) applies for their product(s). The test procedure for measuring the residual quantity is described in the user manual available on the EU Ecolabel website.*

(d) ***Design for recycling of plastic packaging***

Plastic packaging shall be designed to facilitate effective recycling by avoiding potential contaminants and incompatible materials that are known to impede separation or reprocessing or to reduce the quality of recyclate. The label or sleeve, closure and, where applicable, barrier coatings shall not comprise, either singularly or in combination the materials and components listed in Table 8.

Toothpaste tubes, pumps and aerosol containers shall be exempted from this requirement.

Table 8

Materials and components excluded from packaging elements

Packaging element	Excluded material or component (*)
Label or sleeve	— PS label or sleeve in combination with a PET, PP or HDPE packaging — PVC label or sleeve in combination with a PET, PP or HDPE packaging — PETG label or sleeve in combination with a PET packaging. — PET label or sleeve (except LDPET (< 1 g/cm3)) in combination with a PET packaging. — Any other plastic materials for sleeves/labels with a density > 1 g/cm3 used with a PET packaging — Any other plastic materials for sleeves/labels with a density < 1 g/cm3 used with a PP or HDPE packaging — Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling). — PSL (pressure sensitive) label unless the adhesive is water releasable at washing conditions of the recycling process.

Packaging element	Excluded material or component (*)
	— PET PSL label, unless the adhesive is water releasable at washing conditions of the recycling process and has no reactivation.
Closure	— PS closure in combination a with a PET, PP or HDPE packaging — PVC closure in combination with a PET, PP or HDPE packaging — PETG closures and/or closure material with density of above 1 g/cm3 in combination with a PET packaging — Closures (or part of) made of metal, glass, EVA — Closures (or part of) made of silicone. Exempted are silicone closures with a density < 1 g/cm3 in combination with a PET packaging and silicone closures with a density > 1 g/cm3 in combination with PP or HDPE packaging — Metallic foils or seals which remain fixed to the bottle or its closure after the product has been opened
Barrier coatings	— Polyamide, EVOH provided with tie layers made by a polymer different that the one used for the packaging body, functional polyolefins, metallised and light blocking barriers

(*) EVA — Ethylene Vinyl Acetate, EVOH — Ethylene vinyl alcohol, HDPE — High-density polyethylene, LDPET – Low Density Polyethylene terephthalate, PET — Polyethylene terephtalate, PETC – crystalline polyethylene terephthalate, PETG — Polyethylene terephthalate glycol-modified, PP — Polypropylene, PS — Polystyrene, PSL – pressure sensitive label, PVC — Polyvinylchloride

Assessment and verification: *the applicant shall submit a signed declaration of compliance specifying the material composition, supported by manufacturer documentation, of the packaging including the container, label or sleeve, adhesives, closure and barrier coating, together with a sample of primary packaging.*

Criterion 6 – Sustainable sourcing of palm oil, palm kernel oil and their derivatives

In the specific case of renewable ingredients from palm oil or palm kernel oil, or derived from palm oil or palm kernel oil, 100 % w/w of the renewable ingredients used shall meet the requirements for sustainable production of a certification scheme that is a multi-stakeholder organisation with a broad membership, including non-governmental organisations (NGOs), industry, financial institutions and government and that addresses environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources.

Assessment and verification: *To demonstrate compliance, evidence through third-party chain of custody certificating that the raw materials used in the product or in its manufacturing originate from sustainably managed plantations shall be provided. For palm oil and palm kernel oil, Roundtable for Sustainable Palm Oil (RSPO) certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models shall be accepted:*

— *until 1st January 2025: identity preserved, segregated, and mass balance;*

— *after 1st January 2025: identity preserved and segregated.*

For palm oil and palm kernel oil derivatives, RSPO certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models shall be accepted: identity preserved, segregated, and mass balance.

For palm oil, palm kernel oil and their derivatives, a mass balance calculation and/or invoices/delivery notes from the raw material producer shall be provided, showing that the proportion of certified raw material corresponds to the amount of certified palm oil, palm kernel oil and/or their derivatives. Alternatively, a declaration from the producer of raw materials shall be provided, showing that all purchased palm oil, palm kernel oil and/or their derivatives are certified. Competent bodies shall annually check the validity of the certificates for each certified product/ingredient [1].

Notes: [1] The verification can be done via RSPO website, where the status of the certificate is showed in real time: https://www.rspo.org/certification/search-for-supply-chain-certificate-holders

Criterion 7 – Fitness for use

The product's capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. anti-dandruff, colour protection, mild/sensitive) shall be demonstrated either through laboratory test(s) or a consumer test. The tests shall follow the 'Guidelines for the Evaluation of the Efficacy of Cosmetic Products' ([13]) and the instructions given in the user manual available on the EU Ecolabel website.

The tests shall be conducted on the dosage indicated by the applicant [1]. The tests shall be performed at least on the efficacy/performance of the product and its ease of application. If a recognised standardised laboratory test is available (for example Commission Recommendation 2006/647 ([14]) for sunscreen products), this shall be used, and consumer tests shall not be considered equivalent. The tests shall lead to a conclusion which clearly states how the results of the test demonstrate each individual parameter/property tested.

If national guidelines on fluorine content in toothpaste are available, these shall be followed. Fluorine-free toothpastes which have been evaluated as protective as fluorine-containing toothpastes by an independent party shall be exempted.

Laboratory tests shall include at least the following parameters:

— how/why the test method was chosen and how it can be used to document the product's performance/quality

— the parameters and/or properties that were tested and why they were chosen

In case laboratory tests are not available, consumer tests may be used. For consumer tests, the consumers shall be asked about the product's efficiency/performance compared to an equivalent market-leading product. The questions to the consumers shall cover at least the following aspects:

1) How well does the product perform in comparison with a market-leading product using the same dosage?

2) How easy is it to apply and rinse-off (for rinse-off products) the product to/from the hair and/or skin in comparison with a market-leading product?

Consumer tests shall include a minimum of 20 consumers, and at least 80 % of them shall be at least as satisfied with the product as with an equivalent market-leading product.

Notes: [1] The dosage used should be the same as the one identified in criterion 5 (c) (i). In the case a correct dosage could not be specified in criterion 5 (c) (i), the applicant shall indicate the dosage used for carrying out the test, substantiating the choice.

Assessment and verification: *The applicant shall document the test protocol (laboratory test(s) or consumer test) that has been followed in order to test the product's efficacy. Applicants shall present results from this protocol that demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging.*

Laboratory tests performed in compliance with Regulation (EC) No 1223/2009 and Commission Regulation (EU) No 655/2013 ([15]) *may be used to demonstrate that the product fulfils its primary function and any secondary claimed function. It is not necessary to perform new specific tests to demonstrate a function previously demonstrated.*

Criterion 8 – Information appearing on the EU Ecolabel for cosmetic products

The optional label with box shall contain the following information:

— 'Fulfils strict requirements on harmful substances';

— 'Tested performance';

— 'Less packaging waste'.

([13]) Available online under: https://www.cosmeticseurope.eu/files/4214/6407/6830/Guidelines_for_the_Evaluation_of_the_Efficacy_of_Cosmetic_Products_-_2008.pdf

([14]) Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto.

([15]) Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products (OJ L 190, 11.7.2013, p. 3).

The applicant shall follow the instructions on how to properly use the EU Ecolabel logo provided in the EU Ecolabel Logo Guidelines:

http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

Assessment and verification: *The applicant shall provide a declaration of compliance with this criterion, supported by a high resolution image of the product packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.*

Appendix

Detergents Ingredients Database (DID) list

The DID list (Part A) is a list containing information on the aquatic toxicity and biodegradability of ingredients typically used in detergent formulations. The list includes information on the toxicity and biodegradability of a range of substances used in washing and cleaning products. The list is not comprehensive, but guidance is given in Part B of the DID list concerning the determination of the relevant calculation parameters for substances not present on the DID list (e.g. the Toxicity Factor (TF) and degradation factor (DF), which are used for the calculation of the critical dilution volume). The list is a generic source of information and substances present on the DID list are not automatically approved for use in EU Ecolabel products.

Part A and Part B of the DID list can be found on the EU Ecolabel website at:

https://ec.europa.eu/environment/ecolabel/documents/DID%20List%20PART%20A%202016%20FINAL.pdf

https://ec.europa.eu/environment/ecolabel/documents/DID_List_PART_B_2016_FINAL.pdf

For substances with no data regarding aquatic toxicity and biodegradability, structure analogies with similar substances may be used to assess the TF and DF. Such structure analogies shall be approved by the competent body granting the EU Ecolabel license. Alternatively, a worst case approach shall be applied, using the parameters below:

Worst case approach:

	Acute toxicity			Chronic toxicity			Degradation		
Ingoing added substance	LC50/ EC50	SF (acute)	TF (acute)	NOEC (1)	SF (chronic) [1]	TF (chronic)	DF	Aerobic	Anaerobic
'Name'	1 mg/l	10 000	0,0001			0,0001	1	P	N

[1] If no acceptable chronic toxicity data is found, these columns are empty. In this case, TF (chronic) is defined as equal to TF (acute).

Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

(1) Until 1 December 2015:

The test methods for ready biodegradability provided for in Council Directive 67/548/EEC [1], in particular the methods detailed in Annex V.C4 to that Directive, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests.

The 10-day window principle shall not apply for surfactants. The pass levels shall be 70 % for the tests referred to in Annex V.C4-A and C4-B to Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents).

or

The test methods provided for in Regulation (EC) No 1272/2008.

(2) After 1 December 2015:

The test methods provided for in Regulation (EC) No 1272/2008

[1] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

Documentation of anaerobic biodegradability

The reference test for anaerobic biodegradability shall be EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent test method, with the requirement of 60 % ultimate biodegradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60 % ultimate biodegradability has been attained under anaerobic conditions.

Extrapolation for substances not listed in the DID-list

Where the ingoing substances are not listed in the DID-list, the following approach may be used to provide the necessary documentation of anaerobic biodegradability:

(1) Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic biodegradability of structurally related surfactants. Where anaerobic biodegradability has been confirmed for a surfactant (or a group of homologues) according to the DID-list, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g. C12-15 A 1-3 EO sulphate [DID No 8] is anaerobically biodegradable, and a similar anaerobic biodegradability may also be assumed for C12-15 A 6 EO sulphate). Where anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g. literature data confirming the anaerobic biodegradability of surfactants belonging to the group alkyl ester ammonium salts may be used as documentation for a similar anaerobic biodegradability of other quaternary ammonium salts containing ester-linkages in the alkyl chain(s)). Nevertheless, vice-versa if a structurally similar surfactant has been shown not to be anaerobically degradable, it can be assumed that a similar type of surfactant is also not anaerobically biodegradable.

(2) Perform screening test for anaerobic biodegradability. If new testing is necessary, perform a screening test by use of EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent method.

(3) Perform low-dosage biodegradability test. If new testing is necessary, and in the case of experimental problems in the screening test (e.g. inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by 14C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (August 2000) or an equivalent method.

Documentation of bioaccumulation

The following test methods for bioaccumulation shall be used:

(1) Until 1 March 2009:

The reference test for bioaccumulation shall be OECD 107 or 117 or equivalent. The pass levels shall be < 500 or log Kow is < 4,0.

The OECD 305 test on fish. For a BCF < 500 the substance is considered not bioaccumulative. If there is a measured BCF value, it is always the highest measured BCF that is used in assessing a substance's bioaccumulative potential.

(2) After 1 March 2009:

The reference test for bioaccumulation shall be OECD 107 or 117 or equivalent with the requirement of < 500 or log Kow is < 4,0

Documentation on aquatic toxicity

The lowest available NOEC/ECx/EC/LC50 value shall be used. If chronic values are available, they shall be used instead of acute ones.

For acute aquatic toxicity test methods Nos 201, 202 and 203 (*) in the OECD Guideline for the Testing of Chemicals or equivalent test methods shall be used.

For chronic aquatic toxicity test methods Nos 210 (*), 211, 215 (*)and 229 (*) in the OECD Guideline for the Testing of Chemicals or equivalent test methods shall be used. OECD 201 may be used as chronic test if chronic endpoints are chosen.

(*) The Commission prohibited animal testing of ingredients for cosmetic products from March 2009 onwards. To determine aquatic toxicity, however, the prohibition only concerns testing with fish (does not include invertebrates). As such, OECD test guideline No 203 (acute toxicity – fish), 210, 215 and 229 (chronic toxicity – fish) shall not be used to document acute/chronic toxicity. The results of acute/chronic toxicity testing using fish produced before March 2009 may still be used, however.

ANNEX II

EU Ecolabel criteria for awarding the EU Ecolabel to animal care products

FRAMEWORK

Aims of the criteria

The EU Ecolabel criteria target the best products on the market, in terms of environmental performance. The criteria focus on the main environmental impacts associated with the life cycle of these products and promote circular economy aspects.

In particular, the criteria aim to promote products that have limited impacts in terms of eco-toxicity and biodegradability, which may only contain a limited amount of hazardous substances, which are not animal tested and that use less packaging, which can be easily recycled. The use of recycled material and refillable packaging is promoted.

To this end, the criteria:

(1) set requirements to limit the overall aquatic toxicity;

(2) set requirements to ensure that the ingredients are biodegradable and will not persist in water;

(3) recognise and reward products with restricted use of hazardous substances;

(4) set requirements to allow the maximum usage of the product contained in a container and promotes the minimisation of use of packaging material and promote plastics recyclability;

(5) recognise and reward products with renewable ingredients from sustainable origin;

(6) guarantee that the product meets certain quality requirements;

(7) set a requirement to inform consumers on the environmental benefits associated with the product, in order to encourage its purchase;

(8) set a restriction on animal testing.

The criteria for awarding the EU Ecolabel to 'animal care products' are the following:

(1) toxicity to aquatic organisms: Critical Dilution Volume (CDV);

(2) biodegradability;

(3) excluded and restricted substances;

(4) packaging;

(5) sustainable sourcing of palm oil, palm kernel oil and their derivatives;

(6) fitness for use;

(7) information on EU Ecolabel.

Assessment and verification

a) Requirements

Specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or his/her supplier(s) and/or their supplier(s), etc. as appropriate.

Competent bodies shall preferentially recognise attestations which are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications or site inspections to check compliance with these criteria.

Changes in suppliers and production sites pertaining to products to which the EU Ecolabel has been granted shall be notified to competent bodies, together with supporting information to enable verification of continued compliance with the criteria.

As a prerequisite the product shall meet all applicable legal requirements of the country or countries in which the product is placed on the market. The applicant shall declare the product's compliance with this requirement.

The Appendix makes reference to the 'Detergent Ingredient Database' list (DID list) which contains the most widely used ingredients in detergents and cosmetics formulations. It shall be used for deriving the data for the calculations of the Critical Dilution Volume (CDV) (criterion 1) and for the assessment of the biodegradability (criterion 2) of the ingoing substances. For substances not included in the DID list, guidance is given on how to calculate or extrapolate the relevant data. The latest version of the DID list is available from the EU Ecolabel website ([1]) *or via the websites of the individual competent bodies.*

A list of all ingoing substances in the final product shall be provided to the competent body, indicating the trade name (if existing), the chemical name, the CAS No, International Nomenclature of Cosmetic Ingredients (INCI) designations, DID No ([2]) *(if existing), its function, form and concentration in mass percentage (including and excluding water), regardless of concentration in the final product formulation. All listed substances present in the form of nanomaterials shall be clearly indicated on the list with the word 'nano' written in brackets.*

For each substance listed, the Safety Data Sheets (SDS) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3])*shall be provided. Where an SDS is not available for a single substance because it is part of a mixture, the applicant shall provide the SDS of the mixture.*

A written confirmation from the applicant that all the criteria are fulfilled shall also be required for the assessment.

Note: Label, claims and/or instructions information accompanying the product shall be used to categorise the product. Where a product is marketed for different uses, the category for which stricter criteria apply shall be assigned to the product.

b) Measurement thresholds

Compliance with the ecological criteria is required for all substances as specified in Table 1.

([1]) http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf, http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf

([2]) DID No is the number of the ingoing substance on the DID list

([3]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)

Table 1

Threshold levels applicable to substances for animal care products (% weight by weight, % w/w), shown by criterion. Abbreviations: CLP: Classification, Labelling and Packaging; CMR: carcinogenic, mutagenic, toxic for reproduction; N/A: not applicable

Criterion name		Preservatives	Colorants	Fragrances	Impurities	Other substances (e.g. surfactants, enzymes)
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)
Criterion 2. Biodegradability		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)
Criterion 3. Excluded and restricted substances	Criterion 3 (a) (i): Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4])	≥ 0,0100 (*2)	≥ 0,0100 (*2)	≥ 0,0100	≥ 0,0100	≥ 0,0100
	Criterion 3 (a) (ii) : Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 (carcinogenic, mutagenic, toxic for reproduction)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (a) (iii): product classification	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (b): Specified excluded substances	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (c): Restrictions on Substances of Very High Concern	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (d): Fragrances	N/A	N/A	no limit (*1)	≥ 0,0100	N/A
	Criterion 3 (e): Preservatives	no limit (*1)	N/A	N/A	≥ 0,0100	N/A
	Criterion 3 (f): Colorants	N/A	no limit (*1)	N/A	≥ 0,0100	N/A
Criterion 5. Sustainable sourcing of palm oil, palm kernel oil and their derivatives		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)

(*1) "no limit" means: regardless of the concentration (analytical limit of detection) for all substances, with the exception of impurities, which can be present up to a concentration of 0,0100 % w/w in the final formulation.

(*2) for preservatives and colorants classified as H317 and H334 the threshold is 'no limit'.

([4]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

For the purpose of this Annex, the following definitions shall apply:

1) 'active content' (AC) means the sum of organic ingoing substances in the product excluding the water content of the ingredients (expressed in grams), calculated on the basis of the complete formulation of the final product. Inorganic rubbing/abrasive agents are not included in the calculation of the active content;

2) 'ingoing substances' means all substances in the product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde from preservatives and arylamine from azodyes and azopigments) shall also be regarded as ingoing substances. Residuals, pollutants, contaminants, by-products, etc. from production, incl. production of raw materials, that remain in the raw materials ≥ 1 000 ppm (≥ 0.1000 % w/w ≥ 1 000 mg/kg) are always regarded as ingoing substances, regardless of the concentration in the final product;

3) 'impurities' means residuals, pollutants, contaminants, by products, etc. from production, incl. production of raw materials that remain in the raw material/ingredient and/or in the in the final product in concentrations less than 100 ppm (0.0100 % w/w, 100 mg/kg) in the rinse-off product;

4) 'microplastics' means particles with a size of below 5 mm of insoluble macromolecular plastic, obtained through one of the following processes: a) a polymerisation process such as polyaddition or polycondensation or a similar process using monomers or other starting substances; b) chemical modification of natural or synthetic macromolecules; c) microbial fermentation;

5) 'primary packaging' means packaging in direct contact with the content conceived so as to constitute the smallest sales unit of distribution to the final user or consumer at the point of purchase;

6) 'nanomaterial' means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm, in accordance with Regulation (EC) No 1223/2009 ([5]);

7) 'secondary packaging' means packaging which can be removed from the product without affecting its characteristics and is conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale;

8) 'substances identified to have endocrine disrupting properties' means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([6]) (candidate list of substances of very high concern for authorisation), or according to Regulations (EU) No 528/2012 ([7]) or (EC) No 1107/2009 ([8]) of the European Parliament and of the Council.

([5]) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)

([6]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

([7]) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

([8]) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

EU ECOLABEL CRITERIA FOR ANIMAL CARE PRODUCTS

Criterion 1 - Toxicity to aquatic organisms: Critical Dilution Volume (CDV)

This criterion applies to final products.

The total CDV toxicity of the product shall not exceed the limits in Table 2:

Table 2

CDV limits

Product	CDV (l/g AC)
Animal care products	12 000

The CDV shall be calculated using the following equation:

$$CDV = \sum CDV \text{ (ingoing substance i)} = \sum \text{weight (i)} \times DF \text{ (i)} \times 1\,000/TF \text{ chronic (i)}$$

Where:

weight (i) — is the weight of the ingoing substance (in grams) per 1 gram of AC (i.e. normalised weight contribution of the ingoing substance to the AC)

DF (i) — is the degradation factor of the ingoing added substance

TF chronic (i) — is the toxicity factor of the ingoing added substance (in milligrams/litre)

Assessment and verification: *the applicant shall provide the calculation of the CDV of the product. A spreadsheet for calculation of the CDV value is available on the EU Ecolabel website. The values of DF and TF chronic shall be as given in the DID list-part A. If the ingoing substance is not included in the DID list-part A, the applicant shall determine the values using the guidelines described in the DID list-part B and attaching the associated documentation (for more information see the Appendix).*

Criterion 2 - Biodegradability

a) ***Biodegradability of surfactants***

All surfactants shall be readily biodegradable under aerobic conditions and biodegradable under anaerobic conditions.

b) ***Biodegradability of organic ingoing substances***

The content of all organic ingoing substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNBO) or anaerobically non-biodegradable (anNBO) shall not exceed the limits in Table 3:

Table 3

aNBO and anNBO limits

Product	aNBO (mg/g AC)	anNBO (mg/g AC)
Animal care products	15	15

Assessment and verification: *the applicant shall provide documentation for the biodegradability of surfactants, as well as the calculation of aNBO and anNBO for the product. A spreadsheet for calculating aNBO and anNBO values is available on the EU Ecolabel website.*

For surfactants biodegradability values as well for aNBO and anNBO values for organic ingoing substances, reference shall be made to the DID list. For ingoing substances which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, together with a toxicologist declaration showing that they are aerobically and anaerobically biodegradable shall be provided as described in the Appendix.

In the absence of documentation in accordance with the above requirements, an ingoing substance other than a surfactant may be exempted from the requirement for anaerobic biodegradability if one of the following three conditions is fulfilled:

1. *the substance is readily degradable and has low adsorption (A < 25 %);*

2. *the substance is readily degradable and has high desorption (D > 75 %);*

3. *the substance is readily degradable and non-bioaccumulating.*

Testing for adsorption/desorption may be conducted in accordance with Guidelines 106 of the Organisation for Economic Co-operation and Development (OECD).

Criterion 3 - Excluded and restricted substances

3(a) ***Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008***

(i) Unless derogated in Table 5, the product shall not contain substances at or above the concentration of 0.0100 % weight by weight, that meet the criteria for classification with thehazard classes, categories and associated hazard statement codes listed in Table 4, in accordance with Regulation (EC) No 1272/2008.

Where stricter, the generic or specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008 shall prevail.

Table 4

Restricted hazard classes, categories and associated hazard statement codes

Acute toxicity	
Categories 1 and 2	Category 3
H300 Fatal if swallowed	H301 Toxic if swallowed
H310 Fatal in contact with skin	H311 Toxic in contact with skin
H330 Fatal if inhaled	H331 Toxic if inhaled
H304 May be fatal if swallowed and enters airways	EUH070 Toxic by eye contact
Specific target on organ toxicity	
Category 1	Category 2
H370 Causes damage to organs	H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure	H373 May cause damage to organs through prolonged or repeated exposure
Respiratory and skin sensitisation (*[1])	
Category 1A	Category 1B
H317 May cause allergic skin reaction	H317 May cause allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Hazardous to the aquatic environment	
Categories 1 and 2	Category 3 and 4
H400 Very toxic to aquatic life	H412 Harmful to aquatic life with long-lasting effects
H410 Very toxic to aquatic life with long-lasting effects	H413 May cause long-lasting effects to aquatic life
H411 Toxic to aquatic life with long-lasting effects	

Hazardous to the ozone layer	
H420 Harms public health and the environment by destroying ozone in the upper atmosphere	

(*1) Enzymes shall be exempt (including stabilisers and preservatives in the enzyme raw material) if they are in liquid form or as granulate capsules. In the case of colorants and preservatives with a H317 or H334 hazard class, the requirement shall apply regardless of the concentration.

Table 5

Derogations to restrictions on ingoing substances classified under Regulation (EC) No 1272/2008

Substance type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Surfactants	Animal care products	H412: Harmful to aquatic life with long-lasting effects	Total concentration < 20 % in the final product

(ii) Substances that meet the criteria for classification with the hazard statements listed in Table 6 shall not be contained in the final product or its ingredients, regardless of their concentration.

Table 6

Excluded hazard classes, categories and associated hazard statement codes

Carcinogenic, mutagenic or toxic for reproduction	
Categories 1A and 1B	Category 2
H340 May cause genetic defects	H341 Suspected of causing genetic defects
H350 May cause cancer	H351 Suspected of causing cancer
H350i May cause cancer by inhalation	
H360F May damage fertility	H361f Suspected of damaging fertility
H360D May damage the unborn child	H361d Suspected of damaging the unborn child
H360FD May damage fertility. May damage the unborn child	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child
H360Fd May damage fertility. Suspected of damaging the unborn child	H362 May cause harm to breast fed children
H360Df May damage the unborn child. Suspected of damaging fertility	

(iii) The final product shall not be classified and labelled as being acutely toxic, a specific target organ toxicant, a respiratory or skin sensitiser, carcinogenic, mutagenic or toxic for reproduction, or hazardous to the aquatic environment, as defined in Annex I to Regulation (EC) No 1272/2008 and in accordance with the list in Tables 4 and 6 of this Annex.

Criterion 3 (a) shall not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006 which sets out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any substance and mixture in the final product.

3(b) ***Specified excluded substances***

Substances listed under Annex II to Regulation (EC) No 1223/2009 shall not be present in the product, regardless of the concentration, neither as part of the formulation, as part of any mixture included in the formulation, nor as impurities. The following substances shall also not be included in the product, neither as part of the formulation, as part of any mixture included in the formulation, nor as impurities:

(i) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1];

(ii) Butylated Hydroxytoluene (BHT) and Butylated hydroxyanisole (BHA);

(iii) Cocamide DEA;

(iv) Deltamethrin;

(v) Diethylenetriaminepentaacetic acid (DTPA) and its salts;

(vi) Ethylenediaminetetraacetic acid (EDTA) and its salts and non-readily biodegradable phosphonates;

(vii) Microplastics and microbaeds;

(viii) Nanomaterials, unless used according to the conditions laid down for specific nanomaterials in Annexes III, IV and VI to Regulation (EC) No 1223/2009 ;

(ix) Nitromusks and polycyclic musks;

(x) Perfluorinated and polyfluorinated substances;

(xi) Phthalates;

(xii) Resorcinol;

(xiii) Sodium hypochlorite, chloramine and sodium chlorite;

(xiv) Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate [2];

(xv) Substances identified to have endocrine disrupting properties;

(xvi) The following fragrances: benzyl salicylate, butylphenyl metylpropional, tetramethyl acetyloctahydranophthalenes (OTNE);

(xvii) The following isoflavones: daidzein, genistein;

(xviii) The following preservatives: benzalkonium chloride, formaldehyde releasers, isothiazolinones, kojic acid, parabens, triclocarban, triclosan;

(xix) Triphenyl phosphate

Notes:

[1] Substance name = “Alkyl phenol”, under: https://echa.europa.eu/es/advanced-search-for-chemicals

[2] These substances may be allowed if present as impurities, but up to a total concentration of 500 ppm in the product formulation.

3(c) ***Restrictions on Substances of Very High Concern (SVHCs)***

Substances meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of that Regulation and included in the candidate list of substances of very high concern for authorisation shall not be present the product, regardless of their concentration.

3(d) ***Fragrances***

(i) Substances listed under Table 13-1 of the SCCS opinion on ‘Fragrance allergens in cosmetic products’ ([9]) shall not be present in EU Ecolabel products in concentrations higher than 0,0100 %.

([9]) https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

(ii) Any substance or mixture added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on the IFRA website: http://www.ifrafragrance.org/. The manufacturer shall follow the recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials.

3(e) ***Preservatives***

(i) Preservatives classified as H317 or H334 shall be prohibited regardless of the concentration.

(ii) Preservatives in the product shall not release or degrade to substances that are classified in accordance with the requirements of criterion 3(a).

(iii) The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if BCF < 500 or log K_{ow} < 4. If both BCF and log K_{ow} values are available, the highest measured value shall be used.

3(f) ***Colorants***

(i) Colorants classified as H317 or H334 shall be prohibited regardless of the concentration.

(ii) Colorants in the product shall not be bioaccumulating. A colorant is considered not bioaccumulating if BCF < 500 or log K_{ow} < 4. If both BCF and log K_{ow} values are available, the highest measured value shall be used. In the case of colouring agents approved for use in food, it is not necessary to submit documentation of bioaccumulation potential.

Assessment and verification: *The applicant shall provide a signed declaration of compliance with all above sub-criteria, supported by declarations from suppliers for criteria 3 (a) (ii), 3 (e), and 3 (f); and the following supporting evidence:*

To demonstrate compliance with sub-criteria 3(a), 3(b) and 3(c) the applicant shall provide:

(i) *SDS of any substance/mixture and their concentration in the final product.*

(ii) *a written confirmation that sub-criteria 3(a), 3(b) and 3(c) are fulfilled.*

For substances exempted from requirement sub-criterion 3(a) (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to demonstrate compliance.

For requirement sub-criterion3(c), reference to the latest list of substances of very high concern ([10]) *shall be made on the date of application.*

To demonstrate compliance with sub-criterion 3(d), the applicant shall provide a signed declaration of compliance, supported by a declaration of the fragrance manufacturer, as appropriate.

To demonstrate compliance with sub-criterion 3(e), the applicant shall provide: copies of the SDS of any preservative added, and information on its BCF and/or log K_{ow} values.

To demonstrate compliance with sub-criterion 3(f), the applicant shall provide: copies of the SDS of any colorant added together with information on its BCF and/or log K_{ow} value, or documentation to ensure that the colouring agent is approved for use in food.

The above evidence may also be provided directly to competent bodies by any supplier in the applicant's product supply chain.

Criterion 4 - Packaging

The minimum volume for an animal care product to be certified shall be 150ml.

(a) ***Primary packaging***

Primary packaging shall be in direct contact with the contents.

No additional packaging for the product as it is sold, e.g. cardboard over a bottle, shall be allowed, with the exception of secondary packaging which groups the product and its refill and products that include several elements for their use. For the products for domestic use sold with pump that can be opened without compromising the design, a refilling option shall be provided in the same or higher primary packaging capacity.

([10]) http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Note: Cardboard boxes used to transport the products to the retail stores shall not be considered as secondary packaging.

Assessment and verification: *the applicant shall provide a signed declaration and relevant evidence (e.g. pictures of the products as marketed).*

(b) ***Packaging Impact Ratio (PIR)***

The Packaging Impact Ratio (PIR) shall be less than 0,20 g of packaging per gram of product for each of the packaging in which the product is sold. Products packed in metal aerosol containers shall be exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

$$PIR = (W + (W_{refill} \times F) + N + (N_{refill} \times F))/(D + (D_{refill} \times F))$$

Where:

W — weight of packaging (primary + proportion of secondary (1), including labels)(g)

W_{refill} — weight of refill packaging (primary + proportion of secondary (1), including labels) (g)

N — weight of non-renewable + non-recycled packaging (primary + proportion of secondary (1), including labels) (g)

N_{refill} — weight of non-renewable and non-recycled refill packaging (primary + proportion of secondary (1), including labels) (g)

D — weight of product contained in the 'parent' pack (g)

D_{refill} — weight of product delivered by the refill (g)

F — number of refills required to meet the total refillable quantity, calculated as follows:

$$F = V \times R/Vrefill$$

Where:

V — volume capacity of the parent pack (ml)

V_{refill} — volume capacity of the refill pack (ml)

R — the refillable quantity. This is the number of times that the parent pack can be refilled. Where F is not a whole number, it shall be rounded up to the next whole number.

In case no refill is offered PIR shall be calculated as follows:

$$PIR = (W + N)/D$$

The manufacturer shall provide the number of foreseen refillings, or use the default values of R = 5 for plastics and R = 2 for cardboard.

Primary packaging made of more than 80% of recycled materials shall be exempted from this requirement.

Note: [1] Proportional weight of the grouping packaging (e.g. 50 % of the total grouping packaging weight, if two products are sold together).

Assessment and verification: *the applicant shall provide the calculation of the PIR of the product. A spreadsheet for this calculation is available on the EU Ecolabel website. If the product is sold in different packaging (i.e. with different volumes), the calculation shall be submitted for each packaging size for which the EU Ecolabel shall be awarded. The applicant shall provide a signed declaration from the packaging manufacturer for the content of post-consumer recycled material or material from renewable origin in the packaging and a description of the refill system offered, if applicable (kinds of refills, volume). For approval of refill packaging, the applicant or retailer shall demonstrate that the refills shall be available for purchase on the market. The applicant shall provide third party verification and traceability for postconsumer recycled content. Certificate of recyclers pursuant a certification scheme following standard EN15343 may be used to support verification. Certificates of product production for converters pursuant a certification scheme following a controlled blending model as described in the ISO 22095 may be used to support verification.*

(c) ***Information and design of primary packaging***

(i) Information on primary packaging

Dosage and refills: Applicants shall indicate the correct dosage or the appropriate quantity to be used on the label of the primary packaging together with the following sentence:

"*using the correct dosage of the product minimises impacts on the environment and saves money*."

In cases where the correct dosage cannot be defined for a specific product because it depends on consumer aspects (e.g. length of the hair), the following sentence shall be used instead:

"*dose the product with care so as not to over-consume it unnecessarily*"

If the product is refillable, the applicant shall complete the information with a reference to use refills in order to minimise impacts on the environment and save money.

End of life information: Applicants shall include a sentence or a pictogram in relation to empty product disposal (e.g. *"when empty, the package/container should be disposed of in a dedicated container for recycling"*)

Note: Products whose dimensions do not allow a proper display of information due to lack of space or text legibility reasons shall be exempted from this requirement.

(ii) Design of primary packaging

Applicants shall indicate the correct dosage or the appropriate quantity on the label of the primary packaging and a sentence which underlines the importance of using the correct dosage in order to minimise energy and water consumption, reduce water pollution and save money.

The primary packaging shall be designed:

a) to make correct dosage easy by using a pump [1] or ensuring that the opening at the top is not too wide. Refills are exempted from this requirement.

b) to ensure that at least 95% of the product can be easily removed from the container. The residual amount of the product in the container (R), which must be below 5%, shall be calculated as follows:

$$R = ((m2 - m3)/(m1 - m3)) \times 100\ (\%)$$

Where:

m1 — Primary packaging and product (g)

m2 — Primary packaging and product residue in normal conditions of use (g)

m3 — Primary packaging emptied and cleaned (g)

Rinse-off products whose primary packaging can be manually opened and the residue product can be extracted with adding water shall be exempted from the requirement in b).

Notes: [1] For liquid soap no pump or dispenser sold with the product may provide more than 2 g (or 3 ml) soap per full press.

Assessment and verification: *the applicant shall submit a description of the dosage device (e.g. schematic illustration, pictures…), the test report with results of measuring the residual quantity of the product in the packaging and a high resolution image of the product packaging that clearly shows the sentences indicated in sub-criterion 5 (c) (i) (if applicable). Applicant shall provide documented evidence of which case under sub-criterion 5 (c) (i) applies for their product(s). The test procedure for measuring the residual quantity is described in the user manual available on the EU Ecolabel website.*

(d) **Design for recycling of plastic packaging**

Plastic packaging shall be designed to facilitate effective recycling by avoiding potential contaminants and incompatible materials that are known to impede separation or reprocessing or to reduce the quality of recyclate. The label or sleeve, closure and, where applicable, barrier coatings shall not comprise, either singularly or in combination the materials and components listed in Table 7.

Pumps and aerosol containers are exempted from this requirement.

Table 7

Materials and components excluded from packaging elements

Packaging element	Excluded material or component (*)
Label or sleeve	— PS label or sleeve in combination with a PET, PP or HDPE packaging — PVC label or sleeve in combination with a PET, PP or HDPE packaging — PETG label or sleeve in combination with a PET packaging. — PET label or sleeve (except LDPET (< 1 g/cm³)) in combination with a PET packaging. — Any other plastic materials for sleeves/labels with a density > 1 g/cm3 used with a PET packaging — Any other plastic materials for sleeves/labels with a density < 1 g/cm3 used with a PP or HDPE packaging — Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling). — PSL (pressure sensitive) label shall demonstrate that the adhesive is water releasable at washing conditions of the recycling process. — PET PSL label, unless the adhesive is water releasable at washing conditions of the recycling process and has no reactivation.
Closure	— PS closure in combination a with a PET, PP or HDPE packaging — PVC closure in combination with a PET, PP or HDPE packaging — PETG closures and/or closure material with density of above 1 g/cm³ in combination with a PET packaging — Closures (or part of) made of metal, glass, EVA — Closures (or part of) made of silicone. Exempted are silicone closures with a density < 1 g/cm³ in combination with a PET packaging and silicone closures with a density > 1g/cm³ in combination with PP or HDPE packaging — Metallic foils or seals which remain fixed to the bottle or its closure after the product has been opened
Barrier coatings	— Polyamide, EVOH provided with tie layers made by a polymer different that the one used for the packaging body, functional polyolefins, metallised and light blocking barriers

(*) EVA — Ethylene Vinyl Acetate, EVOH — Ethylene vinyl alcohol, HDPE — High-density polyethylene, LDPET – Low Density Polyethylene terephthalate, PET — Polyethylene terephtalate, PETC – crystalline polyethylene terephthalate, PETG — Polyethylene terephthalate glycol-modified, PP — Polypropylene, PS — Polystyrene, PSL – pressure sensitive label, PVC — Polyvinylchloride

Assessment and verification: *the applicant shall submit a signed declaration of compliance specifying the material composition, supported by manufacturer documentation, of the packaging including the container, label or sleeve, adhesives, closure and barrier coating, together with a sample of primary packaging.*

Criterion 5 - Sustainable sourcing of palm oil, palm kernel oil and their derivatives

In the specific case of renewable ingredients from palm oil or palm kernel oil, or derived from palm oil or palm kernel oil, 100 % w/w of the renewable ingredients used shall meet the requirements for sustainable production of a certification scheme that is a multi-stakeholder organisation with a broad membership, including non-governmental organisations (NGOs), industry, financial institutions and government and that addresses environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources.

Assessment and verification: *To demonstrate compliance, evidence through third-party chain of custody certificating that the raw materials used in the product or in its manufacturing originate from sustainably managed plantations shall be provided. For palm oil and palm kernel oil, Roundtable for Sustainable Palm Oil (RSPO) certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models shall be accepted:*

— *until 1st January 2025: identity preserved, segregated, and mass balance;*

— *after 1st January 2025: identity preserved and segregated.*

For palm oil and palm kernel oil derivatives, RSPO certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models shall be accepted: identity preserved, segregated, and mass balance.

For palm oil, palm kernel oil and their derivatives, a mass balance calculation and/or invoices/delivery notes from the raw material producer shall be provided, showing that the proportion of certified raw material corresponds to the amount of certified palm oil, palm kernel oil and/or their derivatives. Alternatively, a declaration from the producer of raw materials shall be provided, showing that all purchased palm oil, palm kernel oil and/or their derivatives are certified. Competent bodies shall annually check the validity of the certificates for each certified product/ingredient [1].

Notes: [1] The verification can be done via RSPO website, where the status of the Certificate is showed in real time: https://www.rspo.org/certification/search-for-supply-chain-certificate-holders

Criterion 6 - Fitness for use

The animal care product's capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. colour protection, moisturizing) shall be supported by adequate and verifiable studies, data and information of ingredients.

Carrying out of animal testing of final formulations, ingredients or combinations of ingredients shall be strictly prohibited.

Assessment and verification: *The applicant shall present studies, data and information of ingredients or final formulation to demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging.*

Criterion 7 - Information appearing on the EU Ecolabel for animal care products

The optional label with box shall contain the following information:

— 'Fulfills strict requirements on harmful substances';

— 'Tested performance (not animal tested)';

— 'Less packaging waste'.

The applicant shall follow the instructions on how to properly use the EU Ecolabel logo provided in the EU Ecolabel Logo Guidelines:

http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

Assessment and verification: *The applicant shall provide a declaration of compliance with this criterion, supported by a high resolution image of the product packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.*

Appendix

Detergents Ingredients Database (DID) list

The DID list (Part A) is a list containing information on the aquatic toxicity and biodegradability of ingredients typically used in detergent formulations. The list includes information on the toxicity and biodegradability of a range of substances used in washing and cleaning products. The list is not comprehensive, but guidance is given in Part B of the DID list concerning the determination of the relevant calculation parameters for substances not present on the DID list (e.g. the Toxicity Factor (TF) and degradation factor (DF), which are used for the calculation of the critical dilution volume). The list is a generic source of information and substances present on the DID list are not automatically approved for use in EU Ecolabel products.

Part A and Part B of the DID list can be found on the EU Ecolabel website at:

https://ec.europa.eu/environment/ecolabel/documents/DID%20List%20PART%20A%202016%20FINAL.pdf

https://ec.europa.eu/environment/ecolabel/documents/DID_List_PART_B_2016_FINAL.pdf

For substances with no data regarding aquatic toxicity and biodegradability, structure analogies with similar substances may be used to assess the TF and DF. Such structure analogies shall be approved by the competent body granting the EU Ecolabel license. Alternatively, a worst case approach shall be applied, using the parameters below:

Worst case approach:

	Acute toxicity			Chronic toxicity			Degradation		
Ingoing added substance	LC50/ EC50	SF (acute)	TF (acute)	NOEC (1)	SF (chronic) [1]	TF (chronic)	DF	Aerobic	Anaerobic
'Name'	1mg/l	10 000	0,0001			0,0001	1	P	N

[1] If no acceptable chronic toxicity data is found, these columns are empty. In this case, TF (chronic) is defined as equal to TF (acute).

Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

(1) Until 1 December 2015:

The test methods for ready biodegradability provided for in Council Directive 67/548/EEC [1], in particular the methods detailed in Annex V.C4 to that Directive, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests.

The 10-day window principle shall not apply for surfactants. The pass levels shall be 70 % for the tests referred to in Annex V.C4-A and C4-B to Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents).

or

The test methods provided for in Regulation (EC) No 1272/2008.

(2) After 1 December 2015:

The test methods provided for in Regulation (EC) No 1272/2008

[1] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

Documentation of anaerobic biodegradability

The reference test for anaerobic biodegradability shall be EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent test method, with the requirement of 60 % ultimate biodegradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60 % ultimate biodegradability has been attained under anaerobic conditions.

Extrapolation for substances not listed in the DID-list

Where the ingoing substances are not listed in the DID-list, the following approach may be used to provide the necessary documentation of anaerobic biodegradability:

(1) Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic biodegradability of structurally related surfactants. Where anaerobic biodegradability has been confirmed for a surfactant (or a group of homologues) according to the DID-list, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g., C12-15 A 1-3 EO sulphate [DID No 8] is anaerobically biodegradable, and a similar anaerobic biodegradability may also be assumed for C12-15 A 6 EO sulphate). Where anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g., literature data confirming the anaerobic biodegradability of surfactants belonging to the group alkyl ester ammonium salts may be used as documentation for a similar anaerobic biodegradability of other quaternary ammonium salts containing ester-linkages in the alkyl chain(s)). Nevertheless, vice-versa if a structurally similar surfactant has been shown not to be anaerobically degradable, it can be assumed that a similar type of surfactant is also not anaerobically biodegradable.

(2) Perform screening test for anaerobic biodegradability. If new testing is necessary, perform a screening test by use of EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent method.

(3) Perform low-dosage biodegradability test. If new testing is necessary, and in the case of experimental problems in the screening test (e.g. inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by 14C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (August 2000) or an equivalent method.

Documentation of bioaccumulation

The following test methods for bioaccumulation shall be used:

(1) Until 1 March 2009:

The reference test for bioaccumulation shall be OECD 107 or 117 or equivalent. The pass levels shall be < 500 or log Kow is < 4,0.

The OECD 305 test on fish. For a BCF < 500 the substance is considered not bioaccumulative. If there is a measured BCF value, it is always the highest measured BCF that is used in assessing a substance's bioaccumulative potential.

(2) After 1 March 2009:

The reference test for bioaccumulation shall be OECD 107 or 117 or equivalent with the requirement of < 500 or log Kow is < 4,0

Documentation on aquatic toxicity:

The lowest available NOEC/ECx/EC/LC50 value shall be used. If chronic values are available, they shall be used instead of acute ones.

For acute aquatic toxicity test methods nos. 201, 202 and 203 (*) in the OECD Guideline for the Testing of Chemicals or equivalent test methods shall be used.

For chronic aquatic toxicity test methods nos. 210 (*), 211, 215 (*) and 229 (*) in the OECD Guideline for the Testing of Chemicals or equivalent test methods shall be used. OECD 201 may be used as chronic test if chronic endpoints are chosen.

(*) The Commission prohibited animal testing of ingredients for cosmetic products from March 2009 onwards. To determine aquatic toxicity, however, the prohibition only concerns testing with fish (does not include invertebrates). As such, OECD test guideline no. 203 (acute toxicity – fish), 210, 215 and 229 (chronic toxicity – fish) shall not be used to document acute/chronic toxicity. The results of acute/chronic toxicity testing using fish produced before March 2009 may still be used, however.

COMMISSION DECISION (EU) 2021/1871

of 22 October 2021

amending Decision 2014/312/EU establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes

(notified under document C(2021) 7514)

(Text with EEA relevance)

THE EUROPEAN COMMISSION

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

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel ([1]), and in particular Article 8(2) thereof,

After consulting the European Union Ecolabelling Board,

Whereas:

(1) Regulation (EC) No 66/2010 provides that the EU Ecolabel may be awarded to products with a reduced environmental impact during their entire life cycle. Specific EU Ecolabel criteria are to be established for each product group.

(2) Commission Decision 2014/312/EU ([2]) establishes the criteria, and related assessment and verifications requirements, for indoor and outdoor paints and varnishes.

(3) In line with the conclusions of the EU Ecolabel Fitness check (REFIT) of 30 June 2017 ([3]), the Commission services, assessed the relevance of an amendment to guarantee a high uptake of the scheme for that product group. Public stakeholders have also been consulted.

(4) That assessment confirmed that a derogation for the pigment titanium dioxide (TiO2), CAS No 13463-67-7, and to the pigment additive trimethylolpropane (TMP), CAS No 77-99-6, is necessary to ensure the criteria remain fully operational.

(5) Following the adoption of Commission Delegated Regulation (EU) 2020/217 ([4]), the pigment TiO2, in dry powder form, has been set the harmonised classification of carcinogen category 2 by inhalation, with the associated hazard code H351 and hazard statement 'suspected of causing cancer', if 1 % or more of the TiO2 particles have an aerodynamic diameter less than or equal to 10 μm. This classification will enter in force on 1 October 2021 and from that date it will no longer be possible to use titanium dioxide in EU Ecolabel paint and varnish products, in concentrations exceeding 0,010 % w/w, unless expressly derogated from the requirements of criterion 5(a)(i) set out in the Annex to Commission Decision 2014/312/EU.

(6) Based on information provided by industry stakeholders, members of the EU Ecolabelling Board and EU Ecolabel license holders, TiO2 is currently used in at least 91 % of paint and varnish products bearing the EU Ecolabel, (typical content of TiO2 is 3-30 % weight/weight (w/w) in paints and varnishes, and up to 65 % in tinting pastes). Other ISO 14024 Type I ecolabels in the Union already derogate TiO2 use regardless of concentration in liquid paints and varnishes not bearing the H351 hazard code.

([1]) OJ L 27, 30.1.2010, p. 1.

([2]) Commission Decision 2014/312/EU establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes (OJ L 164, 3.6.2014, p. 45).

([3]) Report from the Commission to the European Parliament and the Council on the review of implementation of Regulation (EC) No 122/2009 of the European Parliament and of the Council on 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) and the Regulation (EC) No 66/2010 of the parliament and of the Council of 25 November 2009 on the EU Ecolabel (COM(2017) 355 final).

([4]) Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation (OJ L 44, 18.2.2020, p. 1).

(7) TiO2 is a superior performing pigment to all other known alternatives because of its high brightness and high refractive index. In order to provide a given opacity to a coating, paints and varnishes with alternative pigments, such as zirconium oxide, zinc oxide, barium sulphate or zinc sulphate, would need to contain higher pigment contents or be applied in denser coatings, with a higher environmental impact.

(8) The derogation request for the use of TiO2 in EU Ecolabel paints and varnishes should apply only to mixtures where the presence of TiO2 does not trigger the classification of the final product with the hazard code H351. According to Delegated Regulation (EU) 2020/217, however, the label on the packaging of liquid mixtures containing 1 % or more of TiO2 particles with aerodynamic diameter equal to or below 10 μm, shall bear the EUH211 statement: 'Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.' as set out in Annex II, Part 2, to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([5]).

(9) In March 2020, as part of a joint submission to the classification and labelling inventory managed by the European Chemicals Agency, the pigment additive TMP has been set the classification of reprotoxicant category 2, with the associated hazard code H361fd and hazard statement 'suspected of damaging fertility or the unborn child'. TMP is not directly used by paint producers, but can be present in pigments, as an additive, in concentrations up to 1,0 % w/w of pigment (most commonly up to 0,6 %). TMP-treated pigments cannot be used in EU Ecolabel paint and varnish products if the concentration of TMP in the paint and varnish product exceeds 0,010 % w/w. To facilitate the use of TMP-treated pigments, the presence of TMP needs to be expressly derogated from the requirements of criterion 5(a) 'Overall restrictions to hazard classifications and risk phrases' of Decision 2014/312/EU.

(10) Based on information provided by industry stakeholders, members of the EU Ecolabelling Board and EU Ecolabel license holders, pigments are treated with TMP in order to improve their bulk flow during dosing and to improve dispersion during mixing. TMP-treated pigments facilitate superior dispersion levels and lower mixing times (estimated 30 % reduction), resulting in energy savings and increased plant productivity rates. Currently there are no known alternatives that provide the bulk flow and dispersion benefits of TMP. It is estimated that research and development efforts into non-hazardous or less hazardous alternatives to TMP would take at least two years with no guarantee of success. The continued use of TMP-treated pigments in paint and varnish products has already been permitted in several other ISO 14024 Type I ecolabels in the Union.

(11) The need for derogations for TiO2 and TMP after the validity period of Decision 2014/312/EU should be carefully assessed during the revision process of the related criteria. Industry is encouraged to find safer alternatives to those substances in the meantime.

(12) For clarity, in the Appendix to the Annex to Decision 2014/312/EUin point 1.(iii), it is necessary to replace the 0,0200 % threshold indicated for 2-methyl-2H-isothiazol-3one (MIT), CAS No 2682-20-4; EC No 220-239-6, with 0,0015 %, in order to harmonize the content of Criterion 5(a) of that Annex with the 13th adaptation to technical and scientific progress (ATP) to Regulation (EC) No 1272/2008 ([6]), which entered into force on 1 May 2020.

(13) The 13th ATP has in fact lowered to 0,0015 % the MIT threshold concentration that would trigger the classification of the mixture as a skin sensitiser, category 1A with the associated hazard code H317 and hazard statement 'may cause an allergic skin reaction'. Criterion 5(a) does not permit the final EU Ecolabel paint or varnish product to be classified with the hazard code H317 unless explicitly derogated. Therefore the 0,0200 % threshold indicated for MIT in the EU Ecolabel Appendix to the Annex to Decision 2014/312/EU is contradictory and should be substituted with 0,0015 %.

([5]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([6]) Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776 (OJ L 251, 5.10.2018, p. 1).

(14) For clarity, in the Appendix to the Annex to Decision 2014/312/EU, in point 1.(iii), it is necessary to replace the 0,0500 % threshold indicated for substance 2-octyl-2H-isothiazol-3-one (OIT), CAS No 26530-20-1; EC No 247-761-7, with 0,0015 %, in order to harmonize the content of Criterion 5(a) of that Annex with the 15th ATP to Regulation (EC) No 1272/2008, which is to enter into force on 1 March 2022.

(15) The 15th ATP is to lower to 0,0015 % the OIT threshold concentration that would trigger the classification of the mixture as a skin sensitiser, category 1A with the associated hazard code H317 and hazard statement 'may cause an allergic skin reaction'. Criterion 5(a) does not permit the final EU Ecolabel paint or varnish product to be classified with the hazard code H317 unless explicitly derogated. Therefore the 0,0500 % threshold indicated for OIT in the EU Ecolabel Appendix would be contradictory from 1 March 2022 and should be substituted with 0,0015 %, effective from that date onwards.

(16) Decision 2014/312/EU should therefore be amended accordingly.

(17) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010,

HAS ADOPTED THIS DECISION:

Sole Article

The Annex to Decision 2014/312/EU is amended in accordance with the Annex to this Decision.

This Decision is addressed to the Member States.

Done at Brussels, 22 October 2021.

For the Commission
Virginijus SINKEVIČIUS
Member of the Commission

ANNEX

The Appendix to the Annex to Decision 2014/312/EU is amended as follows:

(1) the section headed '1. Preservatives added to colorants, binders and the final product, (iii) Permitted sum totals of isothiazolinone substances and compounds in the ready to use product' is amended as follows:

(a) the limit of 0,0200 % for 2-methyl-2H-isothiazol-3one is replaced by the following:

'2-methyl-2H-isothiazol-3-one: 0,0015 %';

(b) the limit of 0,0500 % for 2-octyl-2H-isothiazol-3-one is replaced by the following:

'2-octyl-2H-isothiazol-3-one: 0,0500 % (until 28 February 2022); 0,0015 % (from 1 March 2022 onwards)';

(2) in the section headed '5. Miscellaneous functional substances with general application', point (f) (Pigments) is replaced by the following:

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
'(f) Pigments Applicability: All products	Restriction: Pigments containing metals shall only be used where laboratory testing of the pigment shows that the metal chromophore is bonded within a crystal lattice and is insoluble. Derogation: The following metal containing pigments are derogated for use without the need for testing: — Barium sulphate — Antimony nickel within an insoluble TiO_2 lattice — Cobalt aluminate blue spinel — Cobalt chromite blue-green spinel	n/a	Verification: Test results demonstrating that the pigment chromophore is bonded within a crystal lattice and is insoluble. Test method: DIN 53770-1 or equivalent
	Derogation to criterion 5(a): Carc. Cat. 2, H351 (inhalation): — For titanium dioxide (TiO2) only, and only in cases where the presence of TiO2 does not trigger Carc. 2, H351 classification of the paint or varnish product to be licensed	n/a	Verification: The applicant shall demonstrate that both they and the TiO2 supplier have systems in place to minimise worker exposure to dry TiO2 powder in the workplace (e.g. closed dosing systems, ventilated dosing and mixing areas, personal protective equipment).
	Derogation to criterion 5(a): Repr. Cat. 2, H361fd: — For trimethylolpropane (TMP), and only when used as an additive in pigments	0,50 %	Verification: The pigment supplier shall declare that the TMP content does not exceed 0,50 % w/w of the pigment.'

COMMISSION IMPLEMENTING DECISION (EU) 2021/1872

of 25 October 2021

amending the Annex to Implementing Decision (EU) 2021/641 concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza in certain Member States

(notified under document C(2021) 7728)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ([1]), and in particular Article 259(1), point (c) thereof,

Whereas:

(1) Highly pathogenic avian influenza (HPAI) is an infectious viral disease in birds and may have a severe impact on the profitability of poultry farming causing disturbance to trade within the Union and exports to third countries. HPAI viruses can infect migratory birds, which can then spread these viruses over long distances during their autumn and spring migrations. Therefore, the presence of HPAI viruses in wild birds poses a continuous threat for the direct and indirect introduction of these viruses into holdings where poultry or captive birds are kept. In the event of an outbreak of HPAI, there is a risk that the disease agent may spread to other holdings where poultry or captive birds are kept.

(2) Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases that are transmissible to animals or humans. HPAI falls within the definition of a listed disease in that Regulation, and it is subject to the disease prevention and control rules laid down therein. In addition, Commission Delegated Regulation (EU) 2020/687 ([2]) supplements Regulation (EU) 2016/429 as regards the rules for the prevention and control of certain listed diseases, including disease control measures for HPAI.

(3) Commission Implementing Decision (EU) 2021/641 ([3]) has been adopted within the framework of Regulation (EU) 2016/429, and it lays down disease control measures in relation to outbreaks of HPAI.

(4) More particularly, Implementing Decision (EU) 2021/641 provides that the protection and surveillance zones established by the Member States following outbreaks of HPAI, in accordance with Delegated Regulation (EU) 2020/687, are to comprise at least the areas listed as protection and surveillance zones in the Annex to that Implementing Decision.

(5) The Annex to Implementing Decision (EU) 2021/641 was recently amended by Commission Implementing Decision (EU) 2021/1766 ([4]) following an outbreak of HPAI in poultry or captive birds in Czechia that needed to be reflected in that Annex.

([1]) OJ L 84, 31.3.2016, p. 1.

([2]) Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

([3]) Commission Implementing Decision (EU) 2021/641 of 16 April 2021 concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza in certain Member States (OJ L 134, 20.4.2021, p. 166).

([4]) Commission Implementing Decision (EU) 2021/1766 of 7 October 2021 amending the Annex to Implementing Decision (EU) 2021/641 concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza in certain Member States (OJ L 358, 8.10.2021, p. 1).

(6) Since the date of adoption of Implementing Decision (EU) 2021/1766, Italy has notified the Commission of an outbreak of HPAI of subtype H5N1 in an establishment where poultry or captive birds were kept in the Veneto region of that Member State.

(7) The outbreak in Italy is located outside the areas currently listed in the Annex to Implementing Decision (EU) 2021/641 and the competent authority of that Member State has taken the necessary disease control measures required in accordance with Delegated Regulation (EU) 2020/687, including the establishment of protection and surveillance zones around this outbreak.

(8) The Commission has examined the disease control measures taken by Italy in collaboration with that Member State and it is satisfied that the boundaries of the protection and surveillance zones established by the competent authority of Italy are at a sufficient distance from the establishment where the recent outbreak of HPAI has been confirmed.

(9) In order to prevent any unnecessary disturbance to trade within the Union and to avoid unjustified barriers to trade being imposed by third countries, it is necessary to rapidly describe at Union level, in collaboration with Italy, the new protection and surveillance zones established by that Member State in accordance with Delegated Regulation (EU) 2020/687.

(10) Therefore, protection and surveillance zones should be listed for Italy in the Annex to Implementing Decision (EU) 2021/641.

(11) The Annex to Implementing Decision (EU) 2021/641 should therefore be amended to update regionalisation at Union level to take account of the protection and surveillance zones duly established by Italy, in accordance with Delegated Regulation (EU) 2020/687, and the duration of the restrictions applicable therein.

(12) Implementing Decision (EU) 2021/641 should therefore be amended accordingly.

(13) Given the urgency of the epidemiological situation in the Union as regards the spread of HPAI, it is important that the amendments to be made to the Annex to Implementing Decision (EU) 2021/641 by this Decision take effect as soon as possible.

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

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2021/641 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, 25 October 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

'*ANNEX*

PART A

Protection zones as referred to in Articles 1 and 2:

Member State: Czechia

Area comprising:	Date until applicable in accordance with Article 39 of Delegated Regulation (EU) 2020/687
Region: Central Bohemian	
Bratkovice (609595); Drahlín (631604); Dubno (633682); Hluboš (639681); Kardavec (639699); Lhota u Příbramě (681211); Občov (708526); Pičín (720551); Sádek (745839); Liha (759198); Trhové Dušníky (768146); část katastrálního území Příbram (číslo KÚ 735426) – severní část katastrálního území Příbram po hranici silnice č. 18.	19.10.2021

Member State: Italy

Area comprising:	Date until applicable in accordance with Article 39 of Delegated Regulation (EU) 2020/687
Region: Veneto	
The area of the parts of Veneto Region (ADIS: IT-HPAI(P)-2021-00001) contained within a circle of radius of three kilometres, centred on WGS84 dec. coordinates N45.331231 E11.209306	12.11.2021

PART B

Surveillance zones as referred to in Articles 1 and 3:

Member State: Czechia

Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
Region: Central Bohemian	
Baština (990019); Běřín (603180); Běštín (603368); Bohutín (606685); Brod u Příbramě (612634); Březové Hory (735515); Buková u Příbramě (615811); Bytíz (633356); Čenkov u Příbramě (619451); Dlouhá Lhota u Dobříše (626392); Dominikální Paseky (609609); Drásov u Příbramě (632074); Dubenec u Příbramě (633364); Háje u Příbramě (636550); Hostomice pod Brdy (645885); Hrachoviště (990591); Jince (660281); Konětopy u Příbramě (669083); Kotenčice (671045); Kozičín (671576); Křešín (676101); Lazec (671584); Lešetice (680435); Milín (694975); Narysov (701629); Obecnice (708569);	28.10.2021

Obořiště (708682); Ohrazenice u Jinec (709310); Orlov (712272); Oseč (712698); Ostrov u Ouběnic (717037); Podlesí nad Litavkou (723886); Radětice (737585); Rejkovice (740047); Rosovice (741370); Stěžov (755486); Suchodol (759201); Tisová u Bohutína (606693); Višňová (782548); Vysoká Pec u Bohutína (606707); Zavržice (662704); Zdaboř (735566); Žežice (796689); část katastrálního území Příbram (číslo KÚ 735426) – jižní část katastrálního území od hranice tvoření silnicí č. 18.	
Bratkovice (609595); Drahlín (631604); Dubno (633682); Hluboš (639681); Kardavec (639699); Lhota u Příbramě (681211); Občov (708526); Pičín (720551); Sádek (745839); Liha (759198); Trhové Dušníky (768146); část katastrálního území Příbram (číslo KÚ 735426) – severní část katastrálního území Příbram po hranici silnice č. 18.	From 20.10.2021 until 28.10.2021

Member State: Italy

Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
Region: Veneto	
The area of the parts of Veneto Region (ADIS: IT-HPAI(P)-2021-00001) extending beyond the area described in the protection zone and within the circle of a radius of ten kilometres, centred on WGS84 dec. coordinates N45.331231 E11.209306	21.11.2021
The area of the parts of Veneto Region (ADIS: IT-HPAI(P)-2021-00001) contained within a circle of radius of three kilometres, centred on WGS84 dec. coordinates N45.331231 E11.209306	From 13.11.2021 until 21.11.2021’

RULES OF PROCEDURE

DECISION OF THE STEERING COMMITTEE OF THE EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY

on internal rules concerning restrictions of certain rights of data subjects in relation to the processing of personal data in the framework of activities carried out by the Agency

THE STEERING COMMITTEE,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 249(1) thereof,

Having regard to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC ([1]) ('the Regulation'), and in particular Article 25 thereof,

Having regard to Commission Implementing Decision (EU) 2021/173 of 12 February 2021 establishing the European Climate, Infrastructure and Environment Executive Agency, the European Health and Digital Executive Agency, the European Research Executive Agency, the European Innovation Council and SMEs Executive Agency, the European Research Council Executive Agency, and the European Education and Culture Executive Agency and repealing Implementing Decisions 2013/801/EU, 2013/771/EU, 2013/778/EU, 2013/779/EU, 2013/776/EU and 2013/770/EU ([2]),

Having consulted the European Data Protection Supervisor,

Whereas:

(1) The European Health and Digital Executive Agency (HaDEA) ('the Agency') was established by Implementing Decision (EU) 2021/173 in view to the performance of tasks linked to the implementation of Union programmes in the field of EU4Health, Single Market, Research and Innovation, Digital Europe, Connecting Europe Facility – Digital ([3]).

(2) Within the framework of its administrative and operational functioning, the Agency may conduct administrative inquiries, pre-disciplinary, disciplinary and suspension proceedings in accordance with the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68 ('Staff Regulations') ([4]) and with implementing provisions regarding the conduct of administrative inquiries and disciplinary proceedings. If required the Agency may carry out preliminary activities related to cases of potential fraud and irregularities and may notify cases to OLAF.

(3) Agency staff members are under an obligation to report potentially illegal activities, including fraud and corruption, which are detrimental to the interests of the Union. Staff members are also obliged to report conduct relating to the discharge of professional duties which may constitute a serious failure to comply with the obligations of officials of the Union. This is regulated by the internal rules or policies concerning whistleblowing.

([1]) OJ L 295, 21.11.2018, p. 39.
([2]) OJ L 50, 15.2.2021, p. 9.
([3]) Commission Decision C(2021)948 of 12 February 2021 delegating powers to the European Health and Digital Executive Agency with a view to the performance of tasks linked to the implementation of Union programmes in the field of EU4Health, Single Market, Research and Innovation, Digital Europe, Connecting Europe Facility – Digital, comprising, in particular, implementation of appropriations entered in the general budget of the Union and its Annexes.
([4]) Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Communities and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1).

(4) The Agency has put in place a policy to prevent and deal effectively with actual or potential cases of psychological or sexual harassment in the workplace, as provided for in implementing measures pursuant to the Staff Regulations establishing an informal procedure whereby the alleged victim of the harassment can contact the Agency's 'confidential' counsellors.

(5) The Agency can also conduct internal (IT) security investigations and on potential breaches of security rules for European Union classified information ('EUCI').

(6) The Agency is subject to both internal and external audits concerning its activities, including conducted by the Internal Audit Services of the European Commission and the European Court of Auditors.

(7) The Agency may handle requests from the European Public Prosecutors office (EPPO), requests for access to medical files of Agency staff members, carry out investigations by the Data Protection Officer in line with Article 45(2) of the Regulation.

(8) In the context of such administrative inquiries, audits, investigations or requests, the Agency cooperates with other Union institutions, bodies, offices and agencies.

(9) The Agency may cooperate with third countries' national authorities and international organisations, either at their request or on its own initiative.

(10) The Agency may also cooperate with EU Member States' public authorities, either at their request or on its own initiative.

(11) The Agency may be subject to complaints, proceeding or investigations via whistle- blowers or the European Ombudsman.

(12) The Agency may be involved in cases before the Court of Justice of the European Union when it either refers a matter to the Court, defends a decision it has taken and which has been challenged before the Court, or intervenes in cases relevant to its tasks.

(13) In the context of its activities, the Agency processes several categories of personal data, including identification data of natural persons, contact information, professional roles and tasks, information on private and professional conduct and performance, and financial data as well as in some specific cases sensitive data (e.g. health data). Personal data includes factual 'hard' data and 'soft' assessment data.

'Hard data' is objective factual data such as identification data, contact data, professional data, administrative details, metadata related to electronic communications and traffic data.

'Soft data' is subjective data and include in particular the description and assessment of situations and circumstances, opinions, observations related to data subjects, evaluation of the conduct and performance of data subjects and reasoning underpinning individual decisions related to or brought forward in connection with the subject matter of the procedure or activity carried out by the Agency in line with the applicable legal framework.

Assessments, observations and opinions are considered personal data in the meaning of Article 3(1) of the Regulation.

(14) Under the Regulation, the Agency is therefore obliged to provide information to data subjects on those processing activities and to respect their rights as data subjects.

(15) The Agency is committed to respect, to the maximum extent possible, the fundamental rights of the data subjects in particular, the right of provision of information, access and rectification, the right to erasure, restriction of processing, the right of communication of a personal data breach to the data subject or confidentiality of communication as enshrined in the Regulation. However, the Agency may also be required to restrict data subject's rights and obligations for the purpose of protecting its activities and the fundamental rights and freedoms of others.

(16) Therefore Article 25(1) and (5) of the Regulation, gives the Agency the possibility to restrict, under conditions, the application of Articles 14 to 22, 35 and 36, as well as Article 4 of the Regulation in so far as its provisions correspond to the rights and obligations provided for in Articles 14 to 20 shall be based on internal rules to be adopted at the highest level of management of the Agency and subject to publication in the *Official Journal of the European Union*, where they are not based on legal acts adopted on the basis of the Treaties.

(17) Restrictions may apply to different data subject rights, including the provision of information to data subjects, right of access, rectification, erasure, restriction of processing, communication of a personal data breach to the data subject or confidentiality of communication as enshrined in the Regulation.

(18) The Agency may be required to reconcile those rights with the objectives of administrative inquiries, audits, investigations and court proceedings. It may also be required to balance a data subject's rights against the fundamental rights and freedoms of other data subjects.

(19) The Agency may, for instance, need to restrict the information it provides to a data subject about the processing of his or her personal data during the preliminary assessment phase of an administrative inquiry or during the inquiry itself, prior to a possible dismissal of case or at the pre-disciplinary stage. In certain circumstances, providing such information may seriously affect the Agency's capacity to conduct the inquiry in an effective way, whenever, for example, there is a risk that the person concerned may destroy evidence or interfere with potential witnesses before they are interviewed. The Agency may also need to protect the rights and freedoms of witnesses as well as those of other persons involved.

(20) The Agency may need to protect the anonymity of a witness or whistle-blower who has asked not to be identified. In such a case, the Agency may decide to restrict access to the identity, statements and other personal data of such persons or the suspect, in order to protect their rights and freedoms.

(21) The Agency may need to protect confidential information concerning a staff member who has contacted Agency's confidential counsellors in the context of a harassment procedure. In such cases, the Agency may need to restrict access to the identity, statements and other personal data of the alleged victim, the alleged harasser and other persons involved, in order to protect the rights and freedoms of all concerned individuals.

(22) In relation to selection and recruitment procedures, staff evaluation and public procurement procedures the right to access, rectification, erasure and restriction can be exercised only at certain points in time and under the conditions as provided for in the relevant procedures in order to safeguard the rights of other data subjects and to respect the principles of equal treatment and the secrecy of deliberations.

(23) The Agency may also restrict access of individuals to their medical data for instance of psychological or psychiatric nature due to the potential sensitivity of these data, and the medical service of the Commission may want to give the data subjects only indirect access through their own practitioner. The data subject may exercise the right to rectification of assessments or opinions of the Commission's Medical service by providing their comments or a report of a medical practitioner of their choice.

(24) The Agency, represented by its Director, acts as the data controller irrespective of further delegations of the controller role within the Agency to reflect operational responsibilities for specific personal data processing activities to competent 'delegated data controllers'.

(25) The personal data are stored securely in an electronic environment compliant with Commission Decision (EU, Euratom) 2017/46 ([5]) or on paper, preventing unlawful access or transfer of data to persons who do not have a need to know. The personal data processed are retained for no longer than necessary and appropriate for the purposes for which the data are processed for the period specified in the data protection notices and records of the Agency.

([5]) Commission Decision (EU, Euratom) 2017/46 of 10 January 2017 on the security of communication and information systems in the European Commission (OJ L 6, 11.1.2017, p. 40).

(26) The Agency shall apply restrictions only when they respect the essence of fundamental rights and freedoms, are strictly necessary and are a proportionate measure in a democratic society. The Agency shall give reasons explaining the justification for those restrictions and inform accordingly the data subjects on those grounds and their right to lodge a complaint to the EDPS as provided for by Article 25(6) of the Regulation.

(27) In application of the principle of accountability, the Agency shall keep a record of its application of restrictions.

(28) When processing personal data exchanged with other organisations in the context of its tasks, the Agency and those organisations shall consult each other on potential grounds for imposing restrictions and the necessity and proportionality of those restrictions, unless this would jeopardise the activities of the Agency.

(29) These internal rules shall thus apply to all processing activities carried out by the Agency involving personal data in the performance of administrative inquiries, disciplinary proceedings, preliminary activities related to cases of potential irregularities reported to OLAF, investigations of the European Public Prosecutors office (EPPO), whistleblowing procedures, (formal and informal) procedures for cases of harassment, processing of internal and external complaints, requests of access to or rectification of own medical files, the investigations carried out by the Data Protection Officer in line with Article 45(2) of the Regulation, (IT) security investigations handled internally or with external involvement (e.g. CERT-EU), audits, proceedings before the Court of Justice of the European Union or national public authorities, selection and recruitment procedures, staff evaluation and public procurement, as listed above.

(30) These internal rules shall apply to processing activities carried out prior to the launch of the procedures referred to above, during these procedures and during the monitoring of the follow-up to the outcome of these procedures. It should also include assistance and cooperation provided by the Agency to other EU Institutions, national authorities and international organisations outside of its administrative investigations.

(31) Pursuant to Article 25(8) of the Regulation, the Agency is entitled to defer, omit or deny the provision of information on the reasons for the application of a restriction to the data subject if this would in any way cancel the effect of the restriction. The Agency shall assess on a case-by-case basis whether the communication of the restriction would cancel its effect.

(32) The Agency shall lift the restriction as soon as the conditions that justify the restriction no longer apply, and assess those conditions on a regular basis.

(33) To guarantee utmost protection of the rights and freedoms of data subjects and in accordance with Article 44(1) of the Regulation, the Data Protection Officer of the Agency shall be consulted in due time before any restriction may be applied or reviewed and verify its compliance with this Decision.

(34) Articles 16(5) and 17(4) of the Regulation provide for exceptions to data subjects' right to information and right of access. If these exceptions apply, the Agency does not need to apply a restriction under this Decision,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

1. This Decision lays down rules relating to the conditions under which the European Health and Digital Executive Agency (HaDEA) and any of its legal successor ('the Agency') may restrict the application of Articles 4, 14 to 22, 35 and 36, pursuant to Article 25 of the Regulation.

2. The Agency, as the Data controller, is represented by the Director of the Agency, who may delegate further the function of the Data controller.

Article 2

Applicable Restrictions

1. The Agency may restrict the application of Articles 14 to 22, 35 and 36, as well as Article 4 of the Regulation in so far as its provisions correspond to the rights and obligations provided for in Articles 14 to 20.

2. This Decision applies to the processing of personal data by the Agency within the framework of its administrative and operational functioning:

(a) pursuant to Article 25(1)(b), (c), (f), (g) and (h) of the Regulation when conducting internal investigations, including based on external complaints, administrative inquiries, pre-disciplinary, disciplinary or suspension proceedings under Article 86 and Annex IX to the Staff Regulations and its implementing rules, security investigations or OLAF investigations;

(b) pursuant to Article 25(1)(h) of the Regulation, when ensuring that Agency's staff members may report facts confidentially where they believe there are serious irregularities, as set out in the internal rules or policies concerning whistleblowing;

(c) pursuant to Article 25(1)(h) of the Regulation, when ensuring that Agency's staff members are able to report to confidential counsellors in the context of a harassment procedure, as defined by internal rules;

(d) pursuant to Article 25(1)(c), (g) and (h) of the Regulation, when conducting internal or external audits in relation to activities or the functioning of the Agency;

(e) pursuant to Article 25(1)(d) and (h) of the Regulation, when ensuring security analyses, including cyber security and IT system abuses, handled internally or with external involvement (e.g. CERT-EU), ensuring internal security by means of video surveillance, access control and investigation purposes, securing communication and information systems and carrying out technical security counter measures;

(f) pursuant to Article 25(1)(g) and (h) of the Regulation, when the Data Protection Officer ('DPO') of the Agency investigates matters directly related to the his/her tasks;

(g) pursuant to Article 25(1)(b), (g) and (h) of the Regulation, in the context of investigations from the European Public Prosecutor Office (EPPO);

(h) pursuant to Article 25(1)(h) of the Regulation, when individuals request to access or rectify their medical data, including if they are held by the Commission's Medical Service;

(i) pursuant to Article 25(1)(c), (d), (g) and (h) of the Regulation, when providing or receiving assistance to or from other Union institutions, bodies, offices and agencies or cooperating with them in the context of activities under points (a) to (h) of this paragraph and pursuant to relevant service level agreements, memoranda of understanding and cooperation agreements of their respective establishment act;

(j) pursuant to Article 25(1)(c), (g) and (h) of the Regulation, when providing or receiving assistance to or from third countries national authorities and international organisations or cooperating with such authorities and organisations, either at their request or on its own initiative;

(k) pursuant to Article 25(1)(c), (g) and (h) of the Regulation, when providing or receiving assistance and cooperation to and from EU Member States' public authorities, either at their request or on its own initiative;

(l) pursuant to Article 25(1)(e) of the Regulation, when processing personal data in documents obtained by the parties or interveners in the context of proceedings before the Court of Justice of the European Union.

For the purpose of this Decision, the above activities shall include preparatory and follow-up actions directly related to the same activity.

3. The Agency may also apply restrictions on a case-by-case basis to data subjects' rights referred to in this Decision, in the following circumstances:

(a) where the Commission services or other Union institutions, bodies, agencies and offices are entitled to restrict the exercise of the listed rights and the purpose of such a restriction by that Commission Service, Union institution, body or agency would be jeopardised where the Agency does not apply an equivalent restriction in respect of the same personal data;

(b) where the competent authorities of Member States are entitled to restrict the exercise of the listed rights and the purpose of such a restriction by that Member State authority would be jeopardised where the Agency does not apply an equivalent restriction in respect of the same personal data;

(c) where the exercise of those rights and obligations would jeopardise the Agency's cooperation with third countries or international organisations in the conduct of its tasks, unless this need to cooperate is overridden by the interests or fundamental rights and freedoms of the data subject;

(d) Before applying restrictions under this paragraph, the Agency shall consult where necessary the relevant Commission services, other Union institutions, bodies, agencies, offices, international organisations or the competent authorities of Member States, unless it is clear that the restriction is provided for by one of the acts referred to above or such a consultation would jeopardise the Agency's activities.

4. The categories of personal data processed related to the above activities may contain factual 'hard' data and 'soft' assessment data.

5. Any restriction shall respect the essence of fundamental rights and freedoms and be necessary and proportionate in a democratic society.

Article 3

Recording and registering of restrictions

1. The Data controller shall draw up a record of the restriction describing:

(a) the reasons for any restriction applied pursuant to this Decision;

(b) which grounds among those listed in Article 2 apply;

(c) how the exercise of the right would present a risk for the data subject or would jeopardise the purpose of the Agency's tasks or would adversely affect the rights and freedoms of other data subjects;

(d) outcome of the assessment of the necessity and proportionality of the restriction, taking into account the relevant elements in Article 25(2) of the Regulation.

2. A necessity and proportionality test of a restriction shall be carried out on a case-by-case basis before restrictions are applied. The Data controller shall consider the potential risks to the rights and freedoms of the data subject. Restrictions shall be limited to what is strictly necessary to achieve their objective.

3. The record of the restriction and, where applicable, the documents containing underlying factual and legal elements shall be registered. They shall be made available to the European Data Protection Supervisor on request.

Article 4

Risks to the rights and freedoms of data subjects

1. Assessments of the risks to the rights and freedoms of data subjects of imposing restrictions and details of the period of application of those restrictions shall be registered in the record of processing activities maintained by the data controller based on Article 31 of the Regulation. They shall also be recorded in any data protection impact assessments regarding those restrictions conducted under Article 39 of the Regulation, when applicable.

2. Where the data controller considers applying a restriction, the risk to the rights and freedoms of the data subject shall be weighed, in particular, against the risk to the rights and freedoms of other data subjects and the risk of negatively impacting investigations or procedures, for example, by destroying evidence. The risks to the rights and freedoms of the data subject concern primarily, but are not limited to, reputational risks and risks to the right of defence and the right to be heard.

Article 5

Safeguards and storage periods

1. The Agency shall put in place specific safeguards to prevent abuse and unlawful access or transfer of personal data in respect of which restrictions apply or could be applied. Such safeguards shall include technical and organisational measures and be detailed as necessary in the Agency's internal decisions, procedures and implementing rules. These safeguards shall include:

(a) a clear definition of roles, responsibilities and procedural steps;

(b) if appropriate, a secure electronic environment which prevents unlawful and accidental access or transfer of electronic data to unauthorised persons;

(c) if appropriate, secure storage and processing of paper-based documents;

(d) ensure compliance with confidentiality obligations for all persons having access to the personal data.

2. The retention period of personal data under a restriction shall be defined in the related record under Article 31 of the Regulation taking into account the purpose of the processing and shall include the timeframe necessary for administrative and judicial review. At the end of the retention period, the personal data shall be deleted, anonymised or transferred to archives in accordance with Article 13 of the Regulation.

Article 6

Duration of restrictions

1. Restrictions referred to in Article 2 shall continue to apply as long as the reasons justifying them remain applicable.

2. Where the reasons for a restriction no longer apply, the Data controller shall lift the restriction if the exercise of the restricted right would no longer negatively impact the relevant applicable procedure or adversely affect the rights or freedoms of other data subjects.

3. In case the data subject has asked again for access to the personal data concerned, the Data controller shall provide the principal reasons for the restriction to the data subject. At the same time, the Agency shall inform the data subject of the possibility of lodging a complaint with the European Data Protection Supervisor at any time or of seeking a judicial remedy in the Court of Justice of the European Union.

4. The Agency shall review the application of the restrictions referred to in Article 2 every six months.

Article 7

Involvement of the Data Protection Officer

1. The data controller of the Agency shall inform the DPO of the Agency without undue delay and prior to any decision to restrict data subject rights in accordance with this Decision or to extend the application of the restriction. The data controller shall provide the DPO access to the associated records and any document concerning the factual or legal context.

2. The DPO may request the data controller to review the application of a restriction. The data controller shall inform the DPO in writing of the outcome of the requested review.

3. The data controller shall document the involvement of the DPO in the application of the restriction, including what information is shared. The documents under this Article shall be part of the record related to the restriction and made available to the EDPS on request.

Article 8

Information to data subject on restrictions of their rights

1. The data controller shall include in the data protection notices and records under Article 31 of the Regulation, published on its website and on the Intranet general information on the potential restrictions of data subjects' rights pursuant to Article 2(2) of this Decision. The information shall cover which rights and obligations may be restricted, the grounds on which restrictions may be applied and their potential duration.

2. The data controller shall inform data subjects individually, in writing and without undue delay of ongoing or future restrictions of their rights. The data controller shall inform the data subject of the principal reasons on which the application of the restriction is based, of their right to consult the DPO with a view to challenging the restriction and of their rights to lodge a complaint with the EDPS.

3. The data controller may defer, omit or deny the provision of information concerning the reasons for a restriction and the right to lodge a complaint with the EDPS for as long as it would cancel the effect of the restriction. The assessment of this justification shall take place on a case-by-case basis and the data controller shall provide the information to the data subject, as soon as this would no longer cancel the effect of the restriction.

Article 9

Right of access by data subject

1. In duly justified cases and under the conditions stipulated in this Decision, the right to access under Article 17 of the Regulation may be restricted by the data controller where necessary and proportionate with regards to the activities under this Decision.

2. Where data subjects request access to their personal data processed in the context of a specific processing activity referred to in Article 2(2) of this Decision, the Agency shall limit its response to the personal data processed for that activity.

3. The data subjects rights to directly access the documents of a psychological or psychiatric nature may be restricted. Neither indirect access, nor the right to rectification and communication of a personal data breach shall be limited with these internal rules. Therefore, an intermediary physician should be granted access on request of the concerned individual to all related information and discretionary power as to how and what access to provide to the data subject.

4. Where the data controller restricts, wholly or partly, the right of access to personal data, as referred to in Article 17 of the Regulation, it shall inform the data subject concerned in writing, in its reply to the request for access, of the restriction applied and of the principal reasons thereof and of the possibility of lodging a complaint with the EDPS or of seeking a judicial remedy in the Court of Justice of the European Union.

5. The information on the restriction of access may be deferred, omitted or denied if it would cancel the effect of the restriction in accordance with Article 25(8) of the Regulation.

6. A restriction under this Article shall be applied in accordance with this Decision.

Article 10

Right of rectification, erasure and restriction of processing

1. In duly justified cases and under the conditions stipulated in this Decision, the right to rectification, erasure and restriction of processing under Articles 18, 19(1) and 20(1) of the Regulation may be restricted by the data controller where necessary and appropriate, with regards to activities under Article 2(2) of this Decision.

2. In relation to medical data, data subjects may exercise the right to rectification of the assessment or opinion of the Commission' Medical Service by providing their comments or a report of a medical practitioner of their choice including, directly to the Commission's Medical Service.

3. A restriction under this Article shall be applied in accordance with this Decision.

Article 11

Communication of a personal data breach to the data subject

1. Where the data controller is under an obligation to communicate a data breach under Article 35(1) of the Regulation, he/she may, in exceptional circumstances, restrict such communication wholly or partly. He/she shall document in a note the reasons for the restriction, the legal ground for it under Article 2 and an assessment of its necessity and proportionality. The note shall be communicated to the EDPS at the time of the notification of the personal data breach.

2. Where the reasons for the restriction no longer apply, the Agency shall communicate the personal data breach to the data subject concerned and inform him or her of the principal reasons for the restriction and of his or her right to lodge a complaint with the EDPS.

Article 12

Confidentiality of electronic communications

1. In exceptional circumstances, the Agency may restrict the right to confidentiality of electronic communications provided for by Article 36 of the Regulation. Such restrictions shall comply with Directive 2002/58/EC of the European Parliament and of the Council.

2. Notwithstanding Article 8(3), where the Agency restricts the right to confidentiality of electronic communications, it shall inform the data subject concerned, in its reply to any request from the data subject, of the principal reasons on which the application of the restriction is based and of his or her right to lodge a complaint with the EDPS.

Article 13

Entry into force

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

Done at Brussels, 8 July 2021.

For the HaDEA Steering Committee
Pierre DELSAUX
The Chairperson

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