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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: Position of the Council at first reading with a view to the adoption of a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE

COUNCIL on detergents and surfactants, and repealing

Regulation (EC) No 648/2004

REGULATION (EU) 2025/... OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of ...

on detergents and surfactants, and repealing Regulation (EC) No 648/2004

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee¹,

Acting in accordance with the ordinary legislative procedure²,

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¹ OJ C 349, 29.9.2023, p. 121.

² Position of the European Parliament of 27 February 2024 (OJ C, C/2025/1354, 17.3.2025, ELI: http://data.europa.eu/eli/C/2025/1354/oj) and position of the Council at first reading of ... (not yet published in the Official Journal). Position of the European Parliament of ... (not yet published in the Official Journal).

Whereas:

- (1) The conditions for placing on the market, and for making available on the market, detergents and surfactants for detergents have been harmonised through Regulation (EC) No 648/2004 of the European Parliament and of the Council³. That Regulation sets out requirements related to the biodegradability of surfactants, restrictions or bans on surfactants on grounds of biodegradability, limitations on the content of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents, information that manufacturers are to hold at the disposal of the Member States' competent authorities and medical personnel, and rules on the labelling of detergents, including regarding fragrance allergens.
- (2) The Commission's evaluation of Regulation (EC) No 648/2004 concluded that that Regulation has achieved its objectives to a large extent. However, that evaluation also identified a number of weaknesses and areas for further improvement. In recent years, the regulatory framework for chemicals has changed radically, creating duplications and a lack of coherence in the rules applicable to detergents and in particular the relevant information requirements. There is therefore a need to ensure consistency and to eliminate duplicated information requirements.

ELI: http://data.europa.eu/eli/reg/2004/648/oj).

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³ Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1,

(3) Certain new market developments, in particular the development of detergents containing micro-organisms and the refill sale of detergents, are either completely or partially not covered by Regulation (EC) No 648/2004. In addition, the number of products offered for sale via the Internet is increasing and such online sales pose particular enforcement issues in situations where there is neither a manufacturer established in the Union, nor an importer. On the other hand, digitalisation offers opportunities for simplification, burden reduction and increased ease of use and understandability of safety and use information that are currently being missed. It is therefore necessary to take account of new products and practices and step up digitalisation efforts in line with the overarching objectives of the Union, especially in terms of sustainability and green and digital transitions. In addition, refill sales should be encouraged as a specific waste-prevention measure necessary for meeting reuse and refill targets, in line with the European Green Deal set out in the Commission communication of 11 December 2019, and the new Circular Economy Action Plan for a cleaner and more competitive Europe, set out in the Commission communication of 11 March 2020. In order to further the Union's transition towards a circular economy, the reuse and refill of packaging should be encouraged and promoted. Economic operators should also endeavour to make detergents available on the market to consumers in other sustainable sales forms, for example in recyclable packaging that allows consumers to refill the appropriate packaging at home, while ensuring the safety of consumers.

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- (4) The Fitness Check of the most relevant chemicals legislation, which did not include Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁴, highlighted the complexity of the Union regulatory framework for chemicals and attributed that complexity to the large number of interconnected product-specific and sector-specific legal acts. The Fitness Check pointed out that enforcement issues are reported by market surveillance authorities concerning products entering the Union from third countries through online sales. It also pointed out that there is room for simplification in the communication of information through labels to product users and found that the use of innovative tools for communicating product information is currently not being taken advantage of. It is therefore necessary to simplify the current rules in order to reduce the burden on economic operators, improve consumer understanding and facilitate market surveillance. Regulation (EC) No 648/2004 should therefore be replaced.
- Decision No 768/2008/EC of the European Parliament and of the Council⁵ lays down (5) common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for a revision of that legislation. The new legal framework for detergents and surfactants should be aligned to the extent possible to those common principles and reference provisions.

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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, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

⁵ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82, ELI: http://data.europa.eu/eli/dec/2008/768(1)/oj).

- (6) In order to ensure legal certainty and a level playing field for economic operators, the existing definition of 'detergent' should be extended to cover the newly developed detergents containing intentionally added micro-organisms. That definition should also cover products that support the cleaning process when used together with a laundry detergent or an automatic dishwasher detergent, as well as products modifying the odour of fabrics, given the ancillary role those products have for fulfilling the cleaning function. References to surfaces include the surface of fruits and vegetables.
- (7) As surfactants are the main ingredients in detergents, the existing biodegradability requirements should be maintained. Since surfactants are primarily sold in business-to-business transactions in order to be used in the manufacturing of detergents, they do not need to be subject to the same requirements as detergents. Therefore, minimum rules for surfactants should be laid down, namely rules on labelling information and the obligation on manufacturers to draw up technical documentation. To avoid placing an unnecessary administrative burden, the manufacturer should be obliged to create a digital product passport and provide the ingredients data sheet for emergency health response only where surfactants are made available on the market directly to consumers or other end-users. In addition, provisions on refill sales should also apply to end-user surfactants.
- (8) The European Green Deal has set a goal to better protect human health and the environment as part of an ambitious approach to tackle pollution from all sources and move towards a toxic-free environment. As part of that approach, this Regulation should complement rules set out in existing legislative instruments.

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- (9) Since the Union already has one of the most comprehensive and protective regulatory frameworks for chemicals, supported by the most advanced knowledge base globally, this Regulation does not affect the application of existing Union law relating to aspects of protection of human health, of safety and of the environment not covered by this Regulation. This Regulation should, in particular, apply without prejudice to Regulations (EC) No 1907/2006, (EC) No 1272/2008⁶ and (EU) No 528/2012⁷ of the European Parliament and of the Council.
- (10) Surfactants are surface-active agents that help break down the interface between water and oils or dirt. They are one of the main ingredients used in detergents. Surfactants can, however, pose a risk to the environment as they are discharged into sewage systems or directly into surface waters. To prevent any adverse effects that surfactants might have on the environment, it is necessary to set requirements ensuring that surfactants are completely biodegradable, whether they are placed on the market on their own and intended for use in detergents or whether they are contained in detergents.

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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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

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, ELI: http://data.europa.eu/eli/reg/2012/528/oj).

(11)There are some substances used in detergents, other than surfactants, which can remain in wastewater after use and, if not removed by wastewater treatment plant operators through costly processes, persist and build up in the environment. In order to facilitate innovation and address potential risks to human health and the environment, and to support the objectives of Directive (EU) 2024/3019 of the European Parliament and of the Council⁸, ambitious targets should be set out for the introduction of biodegradability criteria and corresponding test methods for other ingredients in detergents, prioritising ingredients with potentially higher impacts on the environment. The Commission should, in a first stage, develop biodegradability criteria for water-soluble polymeric films used to encapsulate detergents and for all polymers within such films, and in a second stage should develop such criteria for other organic substances used in high concentration in detergents, representing at least 10 % of the product. To ensure an equal treatment between products irrespective of their liquid or solid form and to avoid dilution, that percentage should be calculated out of the total mass of substances, including various solvents, without taking into account the water content. The Commission should also determine suitable test methods, to ensure uniform implementation and effective market surveillance across the Union. In addition, for reasons of legal clarity and predictability, realistic timelines should be set for manufacturers to adapt their product formulations to meet the biodegradability criteria to be developed by the Commission for either the films or the polymers within films and the organic substances in high concentrations.

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Directive (EU) 2024/3019 of the European Parliament and of the Council of 27 November 2024 concerning urban wastewater treatment (OJ L, 2024/3019, 12.12.2024, ELI: http://data.europa.eu/eli/dir/2024/3019/oj).

To ensure flexibility of the rules in duly justified cases, the Commission should be empowered to introduce derogations from the biodegradability requirements to ensure that the efficiency, availability and affordability of detergents is not affected. Finally, to ensure a high degree of protection of the environment, the Commission should also assess the feasibility of introducing biodegradability criteria for organic substances present in lower concentrations or of lowering the minimum threshold. Such a comprehensive and staged approach towards biodegradability should ensure steady progress towards biodegradable products, within realistic timelines. To give manufacturers time to adapt product formulations, sufficient transitional periods should be provided and relevant test criteria should be established well in advance.

(12) Phosphorus is another key ingredient used in detergents. However, phosphorus and its compounds cause damage to ecosystems and aquatic environments as they contribute to eutrophication. Significant progress is expected to be made for the recovery of phosphorus from urban wastewater under Directive (EU) 2024/3019. It is nevertheless important to continue addressing the issue at source by limiting the content of phosphorus in the types of detergents which are used in the highest volumes. Therefore, to further ensure a high degree of protection of the environment, and to reduce the contribution of detergents to eutrophication, it is necessary to maintain the harmonised limits on the content of phosphates and phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents. Given the significant consequences eutrophication can have, the Commission should assess the feasibility of further reducing such limits and of introducing new limits for other categories of products and, where appropriate, adopt a proposal to amend such essential elements of this Regulation.

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- In recent years, novel cleaning products have been developed that contain living micro-organisms as active ingredients. Micro-organisms have their own biology and response to the environment. Due to their ability to proliferate, there is a clear difference between conventional and microbial detergents. Therefore, the inherent hazards and arising risks are not necessarily of the same nature as those presented by chemicals, especially in relation to the capacity of micro-organisms to survive and multiply in different environments and to produce a range of different metabolites and toxins of potential toxicological significance.
- (14) Since micro-organisms are not subject to registration pursuant to Regulation (EC) No 1907/2006 or to any other Union law requiring manufacturers to demonstrate that the intended use is safe, they should be eligible for use in detergents only to the extent that they have been clearly identified and supported by data demonstrating that their use is safe. Harmonised rules governing the safe use of micro-organisms in detergents should therefore be established. To ensure a high degree of protection of human health and the environment and a level playing field for economic operators, the Commission should set out a methodology for the risk assessment of detergents containing micro-organisms. Such methodology should be as comprehensive as possible and cover all known risks, including for specific categories of products such as those in a spray format or those to be used on surfaces in contact with food.

- In accordance with Directive 2010/63/EU of the European Parliament and of the Council⁹, it is necessary to replace, reduce or refine testing on animals, with a view to phasing out the use of animals for testing as soon as possible. The placing on the market of detergents and surfactants which have been the subject of animal testing in order to meet the requirements of this Regulation should therefore generally be prohibited while nevertheless allowing for the use of historic data. The Commission should provide for a derogation, where appropriate, to ensure a high degree of protection of human health and the environment, and should communicate any such decision granting a derogation to Member States and relevant economic operators.
- (16) To ensure a high degree of protection of public interest, and to guarantee fair competition on the internal market, economic operators should be responsible for the compliance of detergents and surfactants with this Regulation in relation to their respective roles in the supply chain. Whenever appropriate, manufacturers and importers should carry out sample testing of the detergents and surfactants that they have made available on the market, in order to protect the health and safety of consumers and the environment.

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Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33, ELI: http://data.europa.eu/eli/dir/2010/63/oj).

- (17) All economic operators intervening in the supply and distribution chain should take appropriate and effective measures to ensure that they make available on the Union market only detergents and surfactants which are in compliance with this Regulation. It is therefore necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (18) In order to enable economic operators to demonstrate, and the competent authorities to verify, that detergents and surfactants made available on the market comply with this Regulation, it is necessary to provide for a conformity assessment procedure.

 Decision No 768/2008/EC establishes modules for conformity assessment procedures, from the least stringent to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, that Decision specifies the conformity assessment procedures which can be chosen from among those modules.

- (19) The manufacturers, having detailed knowledge of the design and production process, are best placed to ensure compliance of the detergent or surfactant with this Regulation.

 Manufacturers should therefore be solely responsible for carrying out the conformity assessment procedure for detergents and surfactants. Module A set out in Annex II to Decision No 768/2008/EC should be applicable for the conformity assessment of detergents and surfactants. Manufacturers should also put together technical documentation demonstrating compliance of the detergent or surfactant with the relevant rules and test methods.
- Given that detergents and surfactants can have a long shelf life and to ensure coherence with the requirements to keep documentation under Regulation (EC) No 1272/2008 which are applicable to the majority of detergents, manufacturers should keep the technical documentation, the digital product passport and, where applicable, the digital label for a period of 10 years from the date on which the detergent or surfactant covered by that technical documentation, digital product passport or digital label has been placed on the market.

(21)To facilitate compliance of the manufacturers with their obligations under this Regulation, manufacturers established in the Union should be allowed to appoint an authorised representative to carry out specific tasks on their behalf. Such an appointment should be valid only when accepted in writing by the authorised representative. Moreover, to ensure a clear and proportionate distribution of responsibilities between the manufacturer and the authorised representative, it is necessary to set out the list of tasks with which manufacturers should entrust the authorised representative, as well as the list of tasks which cannot be delegated. Furthermore, to ensure the enforceability and effectiveness of the market surveillance requirements and ensure that only compliant detergents and surfactants are placed on the Union market, there should always be an entity established in the Union responsible for liaising with market surveillance authorities and for ensuring compliance with this Regulation. To that end, manufacturers established outside the Union should appoint an authorised representative established in the Union in respect of the detergents and surfactants which they place on the Union market via distance sale, including via online marketplaces. This Regulation should therefore set out a list of additional tasks with which such manufacturers are to entrust authorised representatives. That list should include an obligation to make best efforts to verify that the information and documentation supplied by the manufacturer demonstrate compliance with this Regulation. Such an obligation should be understood as being a document-based check, as the authorised representative should not be required to conduct detailed investigations or exhaustive analyses of compliance. It would ensure an appropriate protection of human health and the environment whilst respecting, in accordance with the principle of proportionality, the particular role and capacities of authorised representatives.

- (22) With a view to facilitating communication between economic operators, market surveillance authorities and consumers, economic operators should indicate and keep up-to-date their contact details, such as a telephone number in addition to postal and email addresses or other communication channels.
- (23) In order to safeguard the functioning of the internal market and to ensure that the objective of providing a high degree of protection of human health and the environment is achieved, it is necessary to establish that detergents and surfactants from third countries entering the Union market, including via online sales, also comply with this Regulation. In particular, it is necessary to ensure that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those products. It is also necessary to lay down rules for importers to ensure that the detergents and surfactants placed on the market comply with those requirements. Importers and authorised representatives should ensure that the documentation drawn up by manufacturers is available for inspection by the competent national authorities. Provision should be made for importers and, where applicable, authorised representatives to ensure that a digital product passport has been created for detergents and end-user surfactants.
- (24) Since importers play a key role in guaranteeing the compliance of imported detergents and surfactants in the Union market, when placing a detergent or surfactant on the market importers should indicate on the product label their name, registered trade name or registered trade mark, as well as their postal and electronic address and telephone number.

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- As distributors make a detergent or surfactant available on the market after it has been placed on the market by the manufacturer or importer, distributors should act with due care in relation to the applicable requirements. Distributors should also ensure that their handling of the detergent or surfactant does not adversely affect its compliance with this Regulation.
- (26) Since distributors, importers and, where applicable, authorised representatives are close to the marketplace and have an important role in ensuring product compliance, they should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the detergent or surfactant concerned.
- (27) Importers and distributors that either place a detergent or surfactant on the market under their own name or trademark or modify a detergent or surfactant in such a way that compliance with this Regulation could be affected should be considered to be manufacturers and should therefore assume the obligations of manufacturers. Similarly, importers and distributors making available on the market to end-users a surfactant which was not produced for supply to end-users but to producers of detergents should assume the role of manufacturers and, among others, create a digital product passport. In other cases, economic operators that only package or repackage a detergent or surfactant already placed on the market by other economic operators should be able to prove that compliance with this Regulation has not been affected, by indicating their identity on the package and by keeping a copy of the original labelling information. Packaging and repackaging activities should be understood as providing products to end-users in individual packaging and should not cover refill sales.

- (28) Since industrial and institutional detergents are used by specialised personnel outside the domestic sphere, they are subject to different requirements than consumer detergents. In order to avoid risks for the health of consumers or for the environment and to facilitate market surveillance activities, industrial and institutional detergents should be clearly identified by their label.
- (29)To ensure a high degree of protection of human health, given the wide availability of detergents and end-user surfactants and the high risk of accidental poisoning, in particular among children, the Member States' appointed bodies under Regulation (EC) No 1272/2008 supporting the emergency health response should have access to qualitative and quantitative information on the composition of detergents and end-user surfactants, even if not required under that Regulation. Therefore, before such products are placed on the market, manufacturers and, where applicable, their importer or authorised representative should provide an ingredients data sheet for detergents and end-users surfactants which are mixtures not hazardous for human health. In addition, distributors making available on the market the products in Member States other than those in which the products are already available, should also provide the ingredients data sheet. In order to optimise the communication of the information, the obligations in this Regulation should build upon the system related to emergency health response already established under Regulation (EC) No 1272/2008, as it is already familiar to many economic operators and poison centres. The Commission should be empowered to set out the technical requirements for fulfilling the obligation to provide the ingredients data sheet.

- (30) Labels communicate important use and safety information to users, for example the presence in detergents and surfactants of skin or respiratory sensitisers such as allergenic fragrances, preservatives or enzymes. By providing information on the content of those substances on the labels of detergents and surfactants, it is possible for users with allergies or allergic predispositions to make informed choices, and potential reactions related to the use of detergents and surfactants are thus reduced. It is therefore necessary to establish labelling requirements for detergents and surfactants.
- (31) Since the labelling of detergents and surfactants could fall under multiple Union legal acts, the information on detergents' and surfactants' labels needs to be streamlined so that when similar information stemming from different Union legal acts is required on detergents' and surfactants' labels, that information is provided only once in accordance with the stricter rules. That streamlining would, on the one hand, improve the readability and understandability of labels by end-users and, on the other, reduce the administrative burden on manufacturers.

- (32) Fragrance substances are organic compounds with characteristic, usually pleasant, odours, which are widely used in detergents as well as in many other products such as perfumes and other perfumed cosmetics. Those substances could cause an allergic reaction upon contact, especially for sensitised persons, even when contained in low concentrations. Therefore, it is important to provide information on the presence of individual allergens in detergents so that sensitised persons can avoid contact with the substance to which they are allergic. Specific labelling requirements should therefore be established that would apply only where the fragrance allergens are not to be labelled under Regulation (EC) No 1272/2008. This would not only prevent an unnecessary administrative burden being placed on economic operators but also ensure that consumers or other end-users receive that information presented in a clear manner, thereby providing a high degree of protection of human health for sensitised persons.
- (33) Additional labelling requirements are needed for certain substances, such as preservatives, in order to ensure a high degree of human health protection. The labelling requirements for preservatives should therefore cover not only those preservatives intentionally added by the manufacturer to the detergent, but also those that ensue from its constituent mixtures and which are often referred to as 'carry-over preservatives'.
- (34) Information on the correct amount of detergent that consumers need to use when undertaking cleaning activities, namely dosage information, should be included on the label of consumer laundry detergents, consumer automatic dishwasher detergents and consumer detergents for surfaces in order to prevent the potential over-use of detergents, thus reducing the total amount of detergent and surfactant entering the environment.

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- Oigital labelling could improve the communication of labelling information both by avoiding overcrowded physical labels and by allowing users to rely on various reading options available only for digital formats, such as increased font, automatic search, loudspeakers or translation into other languages. Digital labelling could therefore increase readability, ease of use and comprehension of labels for consumers, including vulnerable and visually impaired consumers. The provision of digital labels could also lead to a more efficient management of the labelling obligations by economic operators, by facilitating the update of labelling information, reducing labelling costs and permitting a more targeted provision of information to users. Therefore, economic operators should be allowed to provide certain labelling information for detergents only through the digital label, subject to certain conditions ensuring a high degree of protection for users.
- (36) To avoid imposing an unnecessary administrative burden on economic operators and since the digital label is complementary to the physical one, economic operators should be able to decide whether to use digital labels or to provide all the information on a physical label only. The choice to provide a digital label should rest with manufacturers and importers, who are responsible for providing an accurate set of labelling information.

- (37) Digital labelling could also create challenges for vulnerable population groups with no or insufficient digital skills and accentuate the digital divide. For that reason, the specific information to be provided on a digital label only should reflect the current level of digital readiness and the particular situation of users of detergents, as well as the readiness of the wireless and other technological infrastructure necessary for allowing unrestricted access to the information. In addition, all the labelling information concerning the protection of health and of the environment, as well as minimum-use instructions for detergents, should remain on the physical label, to enable consumers and other end-users to make informed choices before buying the detergent and to ensure its safe handling.
- (38) For detergents and surfactants sold to end-users through refill, it should be possible for a more extensive amount of information to be provided digitally only, in order to fully reap not only the benefits offered by digitalisation, but also the large environmental benefits in terms of reduction of packaging and related packaging waste that the practice of refill sales offers. Nevertheless, end-users should receive in a physical form at least simplified dosage instructions for consumer laundry detergents and information on fragrance allergens and preservatives, in order to avoid the risk of allergic reactions.
- (39) To ensure a level playing field among economic operators making detergents available on the market, and to protect consumers and other end-users, general requirements for digital labelling should be laid down. For example, economic operators should ensure free and easy access to digital labels and that mandatory labelling information required under this Regulation be separated from other information.

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- (40) Given the current development of digital skills, economic operators should also provide labelling information by alternative means to consumers and other end-users who are not able to access the digital label. That obligation should be imposed as a safety measure to reduce any potential risks caused by the unavailability of the labelling information, in particular as regards refilled detergents or end-user surfactants, where more labelling information may be provided on a digital label only.
- (41) Since detergents and end-user surfactants have the same use and present the same risks irrespective of the format in which they are made available on the market, economic operators making such products available on the market through refill should ensure that those products comply with the same requirements as products in individual packaging. In addition, consumers should receive the required labelling information when opting for refilled detergents, and minimum safety requirements should be set out for refill stations. The refill sale of detergents should therefore be explicitly covered by this Regulation in order to ensure a high degree of protection of human health and of the environment and a level playing field for economic operators.
- (42) In order to keep pace with technological developments and new means of sale, while ensuring good information for consumers and efficient market surveillance activities, the labelling information of detergents and surfactants should be indicated in the case of distance sales, including via online marketplaces.

- (43) Ensuring traceability of a detergent or surfactant throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who make non-compliant detergents or surfactants available on the market.
- Manufacturers should create a digital product passport to provide information on the (44)compliance of detergents and end-user surfactants with this Regulation. While this Regulation sets out the minimum content of the digital product passport, starting from the EU declaration of conformity, the inclusion of additional information, such as technical documentation, could be envisaged in the future. In order to facilitate checks on detergents or end-user surfactants by market surveillance authorities and to allow the actors in the supply chain, consumers and other end-users, as well as other relevant stakeholders such as civil society organisations and researchers, to access necessary information such as ingredients, the information on the digital product passport should be provided digitally and in a directly accessible and user-friendly manner through a data carrier. The data carrier should be clearly visible to the end-user before any purchase, including where the detergent or end-user surfactant is made available through an online advertisement. Market surveillance authorities, customs authorities, economic operators, consumers and other end-users should therefore have immediate access through the data carrier to the information relevant to them and based on their respective access rights.

- (45) To avoid placing costs on companies that are disproportionate to the wider benefits, the digital product passport should be specific to the model of a detergent or end-user surfactant. Detergents or end-user surfactants should be considered as belonging to the same model as long as there are no changes to the formula or to the production that would lead to modifications in the label of the products.
- (46) To avoid duplication of investment into digitalisation by all actors involved, including manufacturers, market surveillance authorities and customs authorities, where any other Union law requires a digital product passport for detergents or surfactants, a single digital product passport should be available containing the information required under this Regulation and that other Union law. In addition, the digital product passport established under this Regulation should be fully interoperable with any digital product passport required under other Union law.

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- In particular, Regulation (EU) 2024/1781 of the European Parliament and of the Council¹⁰ also lays down requirements and technical specifications for a digital product passport, the establishment by the Commission of a digital product passport registry (the 'registry') where digital product passport information is stored and the interconnection of the registry with the EU Customs Single Window Certificates Exchange System established by Regulation (EU) 2022/2399 of the European Parliament and of the Council¹¹. That Regulation could include detergents or surfactants within its scope in the medium term, thus requiring that a digital product passport be available for them.
- (48) The digital product passport for detergents and end-user surfactants created under this Regulation should therefore comply with the same requirements and technical elements as those set out in Regulation (EU) 2024/1781, including its technical, semantic and organisational aspects of end-to-end communication and data exchange.
- (49) It is crucial to make clear to both manufacturers and users that, by creating the digital product passport for a detergent or end-user surfactant, the manufacturer declares that the product is in compliance with all applicable requirements and that the manufacturer takes full responsibility for that compliance.

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Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1781/oj).

Regulation (EU) 2022/2399 of the European Parliament and of the Council of 23 November 2022 establishing the European Union Single Window Environment for Customs and amending Regulation (EU) No 952/2013 (OJ L 317, 9.12.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/2399/oj).

- (50) Where information is provided only digitally, it is necessary to clarify that such information should be provided through a single data carrier, but be provided separately and be clearly distinguishable from other information. This would facilitate the work of market surveillance authorities and also provide clarity to consumers or other end-users regarding the different pieces of information that are available to them in a digital format.
- (51) Chapter VII of Regulation (EU) 2019/1020 of the European Parliament and the Council¹², which establishes the rules regarding controls on products entering the Union market, applies to detergents and surfactants. The authorities in charge of those controls, which in almost all Member States are the customs authorities, are to perform them on the basis of risk analysis as referred to in Articles 46 and 47 of Regulation (EU) No 952/2013 of the European Parliament and of the Council¹³, its implementing acts and the corresponding guidance. This Regulation should therefore not modify in any way Chapter VII of Regulation (EU) 2019/1020 or the way in which the authorities in charge of controls on products entering the Union market organise themselves and perform their activities.

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Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/1020/oj).

Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1, ELI: http://data.europa.eu/eli/reg/2013/952/oj).

- (52) In addition to the framework of controls established by Chapter VII of Regulation (EU) 2019/1020, customs authorities should be able to automatically verify that a digital product passport exists for imported detergents and surfactants subject to this Regulation in order to strengthen the controls at the Union's external borders and prevent non-compliant detergents and surfactants from entering the Union market.
- Where detergents and end-user surfactants coming from third countries are placed under the customs procedure of release for free circulation, the reference to a digital product passport for those detergents and surfactants should be made available to the customs authorities by the economic operator. Such reference should correspond to a unique registration identifier communicated to the economic operator by the registry. Customs authorities should verify as a minimum that the unique registration identifier and the relevant commodity code for the detergent or end-user surfactant provided or made available to them correspond to the data that are stored in the registry. This would allow customs authorities to verify that a digital product passport for imported detergents and surfactants exists. To carry out that automatic verification, the interconnection between the registry and the EU Customs Single Window Certificates Exchange System should be used.

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- (54) The data included in the digital product passport are intended to allow customs authorities to enhance and facilitate risk management and enable the controls at the border to be better targeted. Therefore, customs authorities should be able to retrieve and use the data included in the digital product passport and the related registry for carrying out their tasks in accordance with Union law, including for risk management in accordance with Regulation (EU) No 952/2013.
- (55) The automatic verification by customs authorities of the digital product passport reference for detergents and surfactants entering the Union market should not replace or modify the responsibilities of the market surveillance authorities, but should instead complement the overall framework for controls on products entering the Union market. The market surveillance authorities should, in line with Regulation (EU) 2019/1020, carry out checks of the data contained in digital products passports, checks on products within the market and, in the case of suspension of release for free circulation by the authorities designated for controls at the Union's external borders, determine the compliance and serious risks of products pursuant to Chapter VII of Regulation (EU) 2019/1020.
- (56) Market surveillance is an essential instrument for ensuring the proper and uniform application of Union law. Regulation (EU) 2019/1020 sets out the framework for market surveillance of products that are subject to Union harmonisation law. Member States should therefore organise and carry out market surveillance of detergents and surfactants in accordance with that Regulation.

12331/25 27 COMPET.1 EN (57)Regulation (EC) No 648/2004 provides for a safeguard procedure which allows the Commission to examine the justification for a measure taken by a Member State in respect of detergents and surfactants considered to constitute a risk. In order to increase transparency, it is necessary to improve the previous safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States. The previous system should be replaced by a procedure under which interested parties are informed of measures intended to be taken with regard to detergents and surfactants posing a risk to health or the environment. Market surveillance authorities should be allowed, in cooperation with the relevant economic operators, to act at an early stage in respect of such detergents and surfactants. The Commission should, by means of implementing acts, with the application of the examination procedure laid down in Regulation (EU) No 182/2011 of the European Parliament and of the Council¹⁴, determine whether a provisional measure in respect of a detergent or surfactant posing a risk is justified. That specific safeguard procedure applies without prejudice to routine controls performed by market surveillance authorities in accordance with Regulation (EU) 2019/1020.

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Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

(58) Experience gained regarding the application of Regulation (EC) No 648/2004 has shown that detergents and surfactants which were compliant with the applicable requirements have nevertheless, in specific cases, posed a risk to health or the environment. Provisions should be made to ensure that market surveillance authorities take action against any detergent or surfactant posing a risk to health or the environment, even if the product is compliant with legal requirements. The Commission should, by means of implementing acts, with the application of the examination procedure laid down in Regulation (EU) No 182/2011, determine whether a provisional measure, taken in respect of compliant detergents or surfactants which a Member State finds to pose a risk to health and safety of persons or to the environment, is justified.

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(59)In order to take into account technical and scientific progress or new scientific evidence, and the level of digital readiness, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the Annexes to this Regulation to adapt them to technical progress; further supplementing the general requirements on digital labelling; amending the labelling information able to be provided in digital format only; amending the limit of the fragrance allergens when individual risk-based concentration limits for fragrance allergens are established under Regulation (EC) No 1223/2009 of the European Parliament and of the Council¹⁵ or adding new fragrance allergens; and amending the existing biodegradability requirements to introduce biodegradability requirements for substances and mixtures other than surfactants in detergents, including detergent capsules, when new scientific evidence so requires or allowing for derogation from such criteria in duly justified cases. The Commission should also be empowered to amend, by means of delegated acts, the specific information to be included in the digital product passport, as well as the information to be included in the registry. In addition, in order to facilitate the work of customs authorities in relation to detergents and surfactants and the requirements set out in this Regulation, the Commission should be empowered to adopt delegated acts amending the Annex to this Regulation containing the list of commodity codes, as set out in Annex I to Council Regulation (EEC) No 2658/87¹⁶, and product descriptions of detergents and surfactants.

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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, ELI: http://data.europa.eu/eli/reg/2009/1223/oj).

Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1, ELI: http://data.europa.eu/eli/reg/1987/2658/oj).

When adopting delegated acts under this Regulation, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making¹⁷. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(60)In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to establish the detailed technical requirements for the digital product passport for detergents and surfactants. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

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¹⁷ OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

(61) In view of the need to ensure a high degree of human health and environmental protection and the need to take into account new developments based on scientific facts, the Commission should submit to the European Parliament and to the Council a report on the application of this Regulation. The Commission should assess, inter alia, if this Regulation is achieving its objectives, taking into account the impact on small and medium-sized enterprises. As regards phosphorus, the report should contain an assessment of the feasibility of further reducing phosphorus limits, with a view to phasing out its use in future, if possible. As regards the most harmful substances, the Commission should, while taking into account the achievements under other relevant Union law, assess the need to include provisions in this Regulation on the presence of those substances in detergents and surfactants, for the purpose of ensuring fulfilment of the goals set in the European Green Deal concerning the generic approach to risk management for the most harmful substances in consumer products, and with a view to possibly phasing out the use of such substances, if appropriate. In addition, as regards biocidal active substances, the Commission should assess the need to introduce stricter rules to avoid the circumvention of the approval scheme established by Regulation (EU) No 528/2012. In order to ensure a high degree of protection of human health and the environment, foster innovation and boost competitiveness, the Commission should assess the safety requirements for detergents containing micro-organisms. In order to facilitate the transition to a fully circular economy, the Commission should assess the introduction of targets for renewable raw materials and recycled content for detergents.

- (62) This Regulation introduces the possibility of providing part of the mandatory labelling information only on digital labels in certain situations and requires the creation of a digital product passport for detergents and surfactants. It is therefore necessary to provide for sufficient time for economic operators to comply with their obligations under this Regulation, for Member States to set up the administrative infrastructure necessary for its application and for the Commission to prepare the implementation of the digital product passport's technical requirements. Consequently, the application of this Regulation should be deferred to a date by which those preparations can reasonably be finalised.
- (63) In order to ensure legal certainty and to prevent waste, economic operators need to be able to sell stock that is either in the distribution chain, or in storage, at the date of application of this Regulation. It is therefore necessary to provide for transitional arrangements that allow the making available on the market of detergents and surfactants that have been placed on the market in accordance with Regulation (EC) No 648/2004 before that date without those products having to comply with this Regulation. Distributors should therefore be able to supply such detergents and surfactants, namely stock that is already in the distribution chain, before the date of application of this Regulation.

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- (64) To further ensure legal certainty and prevent waste, it is important that economic operators be able, for a limited period after the date of application of this Regulation, to sell stock that is not yet in the distribution chain. To that end, transitional arrangements should also be made that allow the placing on the market of detergents and surfactants that are not yet in the distribution chain at the date of application of this Regulation, without those products having to comply with this Regulation, provided that they comply with Regulation (EC) No 648/2004. Manufacturers and importers should therefore be able to place on the market such detergents and surfactants, namely stock that is not yet in the distribution chain, after the date of application of this Regulation. Given the objective of that transitional period, that possibility should be strictly limited in time to one year after that date and, in particular, it should not be possible to make such stock available on the market after that one-year period.
- (65) Since the objectives of this Regulation, namely to guarantee the functioning of the internal market while ensuring that detergents and surfactants on the market fulfil the requirements that provide for a high degree of protection of health and the environment, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

Chapter I

General provisions

Article 1

Subject matter

- 1. This Regulation establishes rules for the free movement of detergents and surfactants in the internal market, while ensuring a high degree of protection of human health and the environment.
- 2. This Regulation does not affect the application of Regulations (EC) No 1907/2006, (EC) No 1272/2008 and (EU) No 528/2012.

Article 2

Definitions

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

- (1) 'detergent' means a substance, mixture or micro-organisms, or a combination thereof, which are intended:
 - to clean fabrics, dishes or surfaces;
 - to soak (pre-wash), rinse or bleach fabrics, dishes or surfaces;

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- to modify the feel or odour of fabrics in processes which are to complement the washing of fabrics;
- to support the cleaning process when used together with a laundry detergent or an automatic dishwasher detergent;
- (2) 'consumer laundry detergent' means a detergent for laundry placed on the market for use by non-professionals, including in public laundrettes;
- (3) 'consumer automatic dishwasher detergent' means a detergent placed on the market for use in automatic dishwashers by non-professionals;
- (4) 'detergent containing micro-organisms' means a detergent to which one or more micro-organisms have been intentionally added, either on their own or via one of the components of the detergent;
- (5) 'industrial and institutional detergent' means a detergent placed on the market for use only outside the domestic sphere, carried out by specialised personnel;
- (6) 'cleaning' means the process by which an undesirable deposit is degraded or dislodged from a substrate or from within a substrate and brought into a state of solution or dispersion;
- (7) 'substance' means a substance as defined in Article 3, point (1), of Regulation (EC) No 1907/2006;
- (8) 'mixture' means a mixture as defined in Article 3, point (2), of Regulation (EC) No 1907/2006;

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- (9) 'micro-organism' means a micro-organism as defined in Article 3(1), point (b), of Regulation (EU) No 528/2012;
- (10) 'genetically modified micro-organisms' means micro-organisms in which the genetic material has been altered in a way that does not occur naturally by mating and/or by natural recombination; within the terms of this definition:
 - genetic modification occurs at least through the use of the techniques listed in Part 1 of Annex I A to Directive 2001/18/EC of the European Parliament and of the Council¹⁸;
 - the techniques listed in Part 2 of Annex I A to the same Directive are not considered to result in genetic modification;
- (11) 'surfactant' means any organic substance or mixture contained in or intended to be used in detergents which has surface-active properties, and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of performing all of the following actions:
 - reduce the surface tension of water below 45 mN/m;
 - form spreading or adsorption monolayers at the water-air interface;

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Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj).

- form emulsions, microemulsions or micelles, or combinations thereof;
- adsorb at water-solid interfaces;
- (12) 'end-user surfactant' means a surfactant made available on the market to professional users or consumers;
- 'ultimate aerobic biodegradation' means the level of biodegradation achieved when the substance or mixture is totally used by micro-organisms in the presence of oxygen, resulting in its breakdown to carbon dioxide, water and mineral salts of any other elements present, as measured by test methods listed in Part A of Annex I, and new microbial cellular constituents (biomass);
- (14) 'films' means water-soluble polymeric films used as detergents capsules;
- 'making available on the market' means any supply for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (16) 'placing on the market' means the first making available on the Union market;
- 'manufacturer' means any natural or legal person that manufactures or has a detergent or a surfactant designed or manufactured, and that places that detergent or surfactant on the market under their name or trade mark;

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- 'authorised representative' means any natural or legal person established within the Union that has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks;
- (19) 'importer' means any natural or legal person established within the Union that places a detergent or surfactant from a third country on the Union market;
- (20) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or importer, that makes a detergent or surfactant available on the market;
- (21) 'economic operator' means the manufacturer, authorised representative, importer or distributor:
- (22) 'market surveillance' means the activities carried out and measures taken by market surveillance authorities to ensure that products comply with this Regulation;
- (23) 'market surveillance authority' means a market surveillance authority as defined in Article 3, point (4), of Regulation (EU) 2019/1020;
- (24) 'recall' means a recall as defined in Article 3, point (22), of Regulation (EU) 2019/1020;
- (25) 'withdrawal' means a withdrawal as defined in Article 3, point (23), of Regulation (EU) 2019/1020;
- (26) 'corrective action' means a corrective action as defined in Article 3, point (16), of Regulation (EU) 2019/1020;

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- (27) 'release for free circulation' means the procedure laid down in Article 201 of Regulation (EU) No 952/2013;
- 'data carrier' means a data carrier as defined in Article 2, first paragraph, point (29), of Regulation (EU) 2024/1781;
- 'unique product identifier' means a unique product identifier as defined in Article 2, first paragraph, point (30), of Regulation (EU) 2024/1781;
- (30) 'unique formula identifier' means a unique formula identifier as referred to in Part A, point 5, of Annex VIII to Regulation (EC) No 1272/2008;
- (31) 'unique operator identifier' means a unique operator identifier as defined in Article 2, first paragraph, point (31), of Regulation (EU) 2024/1781;
- 'digital product passport' means a set of data specific to a product that contains the information set out in Part A of Annex VI and that is accessible via electronic means through a data carrier in accordance with Article 21(4);
- (33) 'digital product passport service provider' means a digital product passport service provider as defined in Article 2, first paragraph, point (32), of Regulation (EU) 2024/1781;
- (34) 'customs authorities' means customs authorities as defined in Article 5, point (1), of Regulation (EU) No 952/2013;

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- (35) 'EU Customs Single Window Certificates Exchange System' means the system established by Regulation (EU) 2022/2399;
- (36) 'individual packaging' means packaging in which the detergent or end-user surfactant is made available on the market and which is intended to accompany the content to the place of use;
- 'refill' means the on-site operation by which a detergent or surfactant offered by an economic operator to end-users in the course of a commercial activity, whether in return for payment or free of charge, is filled in a packaging;
- 'refill station' means a place where an economic operator offers to end-users a detergent or surfactant that can be acquired through refill, either manually or through automatic or semi-automatic equipment;
- (39) 'model' means a type of detergent or surfactant all of whose units meet the following conditions:
 - having the same manufacturer and placed on the market under the same trade name;
 - having the same content, in accordance with Part A, point 1(h), of Annex V to this
 Regulation, and manufactured using the same manufacturing processes;

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- where applicable, being subject to the same classification under Regulation (EC) No 1272/2008; and
- being defined by a type number or other element allowing them to be identified as a group;
- (40)'end-user' means any natural or legal person residing or established in the Union to whom a detergent or surfactant has been made available on the market, either as a consumer outside of any trade, business, craft or profession or as a professional end-user in the course of its industrial or professional activities.

Chapter II

Product requirements

Article 3

Making available on the market and free movement

- 1. Detergents and surfactants shall only be made available on the market if they comply with this Regulation.
- 2. Member States shall not prohibit, restrict or impede the making available on the market of detergents or surfactants which comply with this Regulation.

Biodegradability

- 1. Surfactants and surfactants contained in detergents shall comply with the biodegradability requirements set out in Part A of Annex I.
- 2. Paragraph 1 of this Article shall not apply to surfactants and surfactants contained in detergents that are active substances within the meaning of Article 3(1), point (c), of Regulation (EU) No 528/2012 and that are used as disinfectants, provided that they meet one of the following conditions:
 - (a) they are included in the Union list of approved active substances as referred to in Article 9(2) of Regulation (EU) No 528/2012, or included in Annex I to that Regulation;
 - (b) they are included in the review programme as set out in Commission Delegated Regulation (EU) No 1062/201419; or
 - (c) they are constituents of disinfectants which can be made available on the market or used in accordance with Article 55 of Regulation (EU) No 528/2012.
- 3. By... [6 years from the date of entry into force of this Regulation], films or polymers within films shall comply with the biodegradability requirements set out in Part B of Annex I.

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¹⁹ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1, ELI: http://data.europa.eu/eli/reg_del/2014/1062/oj).

4. By...[8 years from the date of entry into force of this Regulation], organic substances intentionally added in detergents in concentration of at least 10 %w/w (weight by weight) of the total mass of substances, excluding water, other than surfactants, films and polymers within films, shall comply with the biodegradability criteria set out in Part C of Annex I, unless a derogation is granted in Part D of that Annex.

Article 5

Detergents containing micro-organisms

Detergents containing micro-organisms shall comply with the requirements set out in Annex II.

Article 6

Limitations on the content of phosphates and other phosphorus compounds

Detergents listed in Annex III shall comply with the limitations on the content of phosphates and other phosphorus compounds set out in that Annex.

Article 7

Animal testing

1. The compliance of detergents and surfactants with this Regulation shall be established by using non-animal testing methods validated at Union or international level.

- 2. Without prejudice to Article 1(1), the placing on the market of detergents and surfactants for which the final formulation or ingredients or combinations of ingredients have been the object of animal testing with a view to meeting the requirements of this Regulation shall be prohibited.
- 3. Paragraphs 1 and 2 shall be applicable without prejudice to relevant Union law and shall not prevent the use of data acquired before [the date of entry into force of this Regulation].
- 4. In exceptional circumstances, where concerns arise as regards the safety of an ingredient in a detergent or surfactant, the Commission may adopt an implementing decision granting a derogation from paragraphs 1 and 2, on its own initiative or on the basis of a reasoned request from an economic operator or a Member State.
- 5. Where the Commission acts on the basis of a reasoned request from an economic operator or a Member State, as referred to in paragraph 4, that request shall contain an evaluation of the situation and indicate the necessary measures. On that basis, the Commission may consult the European Centre for the Validation of Alternative Methods (ECVAM).

- 6. A decision granting a derogation, as referred to in paragraph 4, shall lay down the conditions associated with that derogation in terms of specific objectives, duration and reporting of the results. A derogation shall only be granted where:
 - (a) the ingredient is widely used and cannot be replaced by another ingredient capable of performing a similar function; and
 - (b) the human health or environmental problem is substantiated and the need to conduct animal testing is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.

The Commission shall address its decision granting a derogation to all Member States and shall immediately communicate it to them and to the relevant economic operators.

Chapter III

Obligations of economic operators

Article 8

Obligations of manufacturers

1. When placing detergents or surfactants on the market, manufacturers shall ensure that those detergents or surfactants have been designed and manufactured in accordance with this Regulation.

- 2. Manufacturers shall draw up the technical documentation set out in Annex IV and carry out the conformity assessment procedure set out in that Annex.
 - Where compliance of a detergent or end-user surfactant with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, before placing the product on the market manufacturers shall:
 - (a) create a digital product passport in accordance with Article 21;
 - (b) ensure that the data carrier is available in accordance with Article 21(4); and
 - (c) include a reference of the digital product passport in the registry referred to in Article 24(1) (the 'registry').
- 3. Manufacturers shall keep and, where necessary, update the technical documentation and the digital product passport for 10 years from the date on which the detergent or the surfactant has been placed on the market.
- 4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in product design or in characteristics, as well as changes in the test methods by reference to which the conformity of a product is declared, shall be adequately taken into account.

When deemed appropriate with regard to the performance of, or the risks presented by, a detergent or surfactant, manufacturers shall carry out sample testing of such detergent or surfactant, investigate, and, if necessary, keep a register of complaints, of non-compliant detergents or surfactants and of recalls of such detergents or surfactants, and shall keep distributors informed of any such monitoring.

- 5. Manufacturers placing on the market detergents or surfactants shall ensure that those detergents or surfactants comply with Article 17(1), (3), (4) and (5), Article 18(1) and Article 19(1) and (2) and, where applicable, Article 17(2), Article 18(2) and Article 19(3).
- 6. Before placing on the market detergents or end-user surfactants which are mixtures for which there is no obligation to provide information in accordance with Article 45 of Regulation (EC) No 1272/2008, the manufacturers established within the Union shall provide to the bodies appointed by Member States in accordance with that Article (the 'appointed bodies') the ingredient data sheet referred to in point 2.2 (e) of Annex IV to this Regulation (the 'ingredients data sheet'). Where the detergent or end-user surfactant for which an ingredients data sheet has already been submitted no longer corresponds to the information included in that ingredients data sheet, the manufacturers shall submit an updated ingredients data sheet. The ingredients data sheet shall be submitted by electronic means in the format provided by the European Chemicals Agency and made available free of charge for notifications in accordance with Part A, Section 3.1, second paragraph, of Annex VIII to Regulation (EC) No 1272/2008. The submission shall be in a language easily understood by the appointed bodies, as determined by the Member State in which the product is made available on the market.

- 7. Manufacturers established outside the Union shall provide the authorised representative or the importer with all the information and documentation necessary to demonstrate the compliance with this Regulation of the detergent or surfactant.
- 8. Where manufacturers consider or have reason to believe that a detergent or surfactant which they have placed on the market is not in compliance with this Regulation, they shall immediately take the corrective action necessary to bring the detergent or surfactant into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where manufacturers consider or have reason to believe that a detergent or surfactant which they have placed on the market poses a risk to human health or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made it available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective action taken.
- 9. Manufacturers shall ensure that other economic operators in the supply chain concerned are kept informed without undue delay regarding any non-compliance or risk to human health or the environment that they have identified and of any consequent corrective action, recall or withdrawal.
- 10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in electronic format and, on request, in paper format, necessary to demonstrate the compliance with this Regulation of a detergent or surfactant which they have placed on the market, in a language which can be easily understood by that authority. Manufacturers shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by that detergent or surfactant.

11. Manufacturers shall make their communication channels, such as a telephone number, an electronic address or a dedicated section of their website, publicly available on their website, taking into account the accessibility needs of persons with disabilities and enabling end-users to submit complaints about potential non-compliance of products or safety issues.

Article 9

Authorised representative

- Manufacturers may, by a written mandate, appoint an authorised representative. That
 mandate shall only be valid when accepted in writing by the authorised representative.
 The authorised representative shall provide a copy of the mandate to the competent
 authority, upon request.
- 2. Manufacturers established outside the Union, placing a detergent or surfactant on the Union market, shall appoint an authorised representative pursuant to the conditions laid down in paragraph 1.
- 3. The authorised representative shall perform the tasks specified in the mandate referred to in paragraph 1.

The mandate shall require the authorised representative to do at least the following:

- (a) verify that, in accordance with Article 8(2), the digital product passport has been created, the relevant information on the digital product passport has been included in the registry, the technical documentation has been drawn up and the conformity assessment procedure has been carried out;
- (b) keep the technical documentation at the disposal of national market surveillance authorities, and the digital product passport available, for 10 years from the date on which the detergent or surfactant covered by those documents has been placed on the market;
- further to a reasoned request from a competent national authority, provide that (c) authority with all the information and documentation necessary to demonstrate the compliance with this Regulation of the detergent or surfactant, in a language that can be easily understood by that authority;
- where it has reason to believe that a detergent or surfactant covered by the mandate (d) poses a risk to human health or to the environment, inform the manufacturer and the market surveillance authorities thereof:
- cooperate with the competent national authorities, at their request, on any action (e) taken to eliminate the risks posed by a detergent or surfactant covered by the mandate: and

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- (f) terminate the mandate and inform the competent national authorities of such termination if the manufacturer does not comply with its obligations under this Regulation.
- 4. In addition to the tasks referred to in paragraph 3 of this Article, the mandate of the authorised representative appointed in accordance with paragraph 2 of this Article shall require that authorised representative to do the following as regards detergents and surfactants covered by that mandate:
 - (a) provide and, where needed, update the ingredients data sheet in accordance with Article 8(6);
 - (b) keep the information contained in the ingredients data sheet confidential;
 - (c) verify that detergents and surfactants comply with the labelling requirements set out in Article 17(1), (3), (4) and (5), Article 18(1), Article 19(1) and (2) and, where applicable, Article 17(2), Article 18(2) and Article 19(3); and
 - (d) make best efforts to verify that the documentation and information provided by the manufacturer in accordance with Article 8(7) demonstrates compliance of the products with this Regulation.
- 5. The obligations laid down in Article 8(1) and the obligation to draw up technical documentation referred to in Article 8(2) shall not form part of the authorised representative's mandate.

Obligations of importers

- 1. Importers shall only place compliant detergents or surfactants on the market.
- 2. Before placing a detergent or surfactant on the market, importers shall ensure that:
 - (a) the manufacturer has carried out the conformity assessment procedure and drawn up the technical documentation referred to in Article 8(2);
 - (b) the information and documentation provided by the manufacturer in accordance with Article 8(7) demonstrate compliance with this Regulation; and
 - (c) the manufacturer has created the digital product passport referred to in Article 8(2), point (a), the data carrier is available in accordance with Article 21(4) and the relevant information on the digital product passport has been included in the registry.
- 3. Importers shall provide the ingredients data sheet before placing detergents or end-users surfactants on the market and, where needed, update the ingredients data sheet, in accordance with Article 8(6). The importer shall keep the information contained in the ingredients data sheet confidential.

- 4. Where importers consider or have reason to believe that a detergent or surfactant is not in compliance with this Regulation, they shall not place it on the market until it has been brought into conformity. Furthermore, where the detergent or surfactant poses a risk to human health or to the environment, importers shall inform the manufacturer and the market surveillance authorities to that effect.
- 5. Importers shall ensure that detergents and surfactants that they place on the market comply with Article 17(1), (3), (4) and (5), Article 18(1), Article 19(1) and (2) and, where applicable, Article 17(2), Article 18(2) and Article 19(3).
- 6. Importers shall ensure that, while a detergent or surfactant is under their responsibility, its storage or transport conditions do not jeopardise its compliance with this Regulation.
- 7. Where deemed appropriate with regard to the performance of a detergent or surfactant or to the risks presented by them, importers shall carry out sample testing of such detergent or surfactant, investigate, and, if necessary, keep a register of complaints, of non-compliant detergents and surfactants and of recalls of such detergents and surfactants, and shall keep distributors informed of any such monitoring.

- 8. Where importers consider or have reason to believe that a detergent or surfactant which they have placed on the market is not in compliance with this Regulation, they shall inform immediately and cooperate with the manufacturer and the competent authorities and shall immediately take the corrective action necessary to bring the detergent or surfactant into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where importers consider or have reason to believe that a detergent or surfactant which they have placed on the market poses a risk to human health or the environment, they shall immediately inform the manufacturer and the competent national authorities of the Member States in which they made it available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective action taken.
- 9. Importers shall ensure that other economic operators in the supply chain concerned are kept informed without delay regarding any non-compliance or risk to human health or the environment that they have identified and of any consequent corrective action, recall or withdrawal.
- 10. Importers shall keep the reference to the unique product identifier and the technical documentation referred to in Article 8(2) at the disposal of the market surveillance authorities for a period of 10 years from the date on which the detergent or surfactant has been placed on the market.

- 11. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in electronic format and, on request, in paper format, necessary to demonstrate the compliance with this Regulation of a detergent or surfactant, in a language which can be easily understood by that authority. Importers shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by a detergent or surfactant which they have placed on the market.
- 12. Importers shall verify whether the communication channels referred to in Article 8(11) are publicly available to consumers and other end-users. Where they are not available, importers shall provide for such channels, taking into account the accessibility needs of persons with disabilities.

Obligations of distributors

- 1. Where making a detergent or surfactant available on the market, distributors shall act with due care in relation to the requirements of this Regulation.
- 2. Before making a detergent or surfactant available on the market, distributors shall verify that:
 - (a) the detergent or surfactant is accompanied by the required documents and by a label containing the information referred to in Article 17(3) and (4), in the conditions set out in Article 17(5);

- (b) where a digital label is provided, the requirements in Article 19(1), points (a), (d), (e) and (h), Article 19(2) and, where applicable, Article 17(2), Article 18(2) and Article 19(3) are met; and
- (c) the data carrier is available in accordance with Article 21(4).
- 3. Distributors making available on the market in another Member State detergents or end-user surfactants for which an ingredients data sheet is to be provided in accordance with Article 8(6) shall submit to the appointed body in that Member State the ingredients data sheet before making the product available therein, and update the ingredients data sheet where needed, unless they can demonstrate that the appointed body already received the same information from another economic operator. Distributors shall keep the information contained in the ingredients data sheet confidential.
- 4. Where distributors consider or have reason to believe that a detergent or surfactant is not in compliance with this Regulation, they shall not make it available on the market until it has been brought into conformity. Furthermore, where the detergent or surfactant poses a risk to human health or the environment, distributors shall inform the market surveillance authorities, the manufacturer and, where relevant, the authorised representative or the importer to that effect.
- 5. Distributors shall ensure that, while a detergent or surfactant is under their responsibility, its storage or transport conditions do not jeopardise its compliance with this Regulation.

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- 6. Where distributors consider or have reason to believe that a detergent or a surfactant which they have made available on the market is not in compliance with this Regulation, they shall inform immediately and cooperate with the manufacturer or importer, as applicable, and the competent national authorities and shall ensure that the corrective action necessary to bring the detergent or surfactant into conformity, to withdraw it or to recall it, as appropriate, is taken. Furthermore, where distributors consider or have reason to believe that a detergent or surfactant which they have made available on the market poses a risk to human health or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made it available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective action taken.
- 7. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in electronic format and, on request, in paper format, necessary to demonstrate the compliance with this Regulation of a detergent or surfactant. Distributors shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by a detergent or surfactant which they have made available on the market.

Supply through refill

Without prejudice to Regulations (EU) 2023/988²⁰ and (EU) 2025/40²¹ of the European Parliament and of the Council as regards safety and hygiene requirements for refill including the risk of confusion with foodstuff, where detergents or end-user surfactants are made available on the market through refill, the economic operator making the product available to end-users shall ensure that:

- (a) risk mitigation measures are applied to minimise the exposure of humans, especially of children, including by preventing children from using the refill station unsupervised and by training appropriately their staff; and
- (b) the detergents or end-user surfactants provided through a refill station do not react with each other in a way that could endanger human health.

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Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p. 1, ELI: http://data.europa.eu/eli/reg/2023/988/oj).

Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC (OJ L, 2025/40, 22.1.2025, ELI: http://data.europa.eu/eli/reg/2025/40/oj).

Cases in which obligations of manufacturers apply to importers and distributors

Importers or distributors shall be considered manufacturers for the purposes of this Regulation and shall be subject to the obligations of the manufacturer under Article 8 where they:

- place a detergent or surfactant on the market under their name or trade mark; (a)
- (b) modify a detergent or surfactant already placed on the market in such a way that compliance with this Regulation could be affected; or
- make a surfactant that is not an end-user surfactant available on the market to end-users. (c)

Article 14

Packaging and repackaging by importers and distributors

- 1. Where importers or distributors package or repackage a detergent or surfactant and those importers or distributors are not subject to the obligations of the manufacturer pursuant to Article 13, they shall, as applicable and in addition to their obligations under Article 10 or 11:
 - (a) ensure that the package bears the importer's or distributor's name, registered trade name or registered trade mark, postal and electronic address and telephone number, preceded by the words 'packaged by' or 'repackaged by';

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- (b) keep a specimen of the original information referred to in Article 17(3) or (4) at the disposal of the market surveillance authorities for 10 years from the date on which the detergent or surfactant has been placed on the market; and
- keep the reference to the unique product identifier at the disposal of the market (c) surveillance authorities for 10 years from the date on which the detergent or end-user surfactant has been placed on the market.
- 2. The making available on the market of detergents or end-user surfactants at refill stations is not considered as packaging or repackaging for the purposes of this Article.

Identification of economic operators

- 1. Economic operators shall, on request from a market surveillance authority, identify the following:
 - any economic operator who has supplied them with a detergent or a surfactant; and (a)
 - any economic operator to whom they have supplied a detergent or a surfactant. (b)
- 2. Economic operators shall be able to provide the information referred to in paragraph 1 for 10 years after they have been supplied with the detergent or surfactant and for 10 years after they have supplied the detergent or surfactant.

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Confidentiality of the ingredients data sheet

Appointed bodies and medical personnel shall keep confidential the information included in the ingredients data sheet. They may only use such information:

- (a) to meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency; or
- (b) where requested by a Member State, the Commission or the European Chemicals Agency, to undertake a statistical analysis to identify where improved risk management measures might be needed.

Chapter IV

Labelling

Article 17

General labelling requirements

1. Detergents and surfactants that are made available on the market in individual packaging or through refill shall be accompanied by a label.

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- 2. An economic operator making a detergent or surfactant available on the market directly to an end-user through refill shall provide to the end-user the physical label and the data carrier referred to in Article 21(2), point (h), and shall ensure that the physical label and the data carrier are available for every packaging that is refilled with a detergent or surfactant.
- 3. The label of detergents and surfactants shall contain the information specified in Part A of Annex V.
- 4. In addition to the information referred to in paragraph 3, the label of consumer laundry detergents, consumer automatic dishwasher detergents and consumer detergents for surfaces shall contain dosage information in accordance with Part B of Annex V.
- 5. The information referred to in paragraphs 3 and 4 shall be in one or more languages which can be easily understood by end-users, as determined by the Member State concerned, and shall be legible, clear, understandable and intelligible. The label shall be accessible for inspection purposes where the detergent or surfactant is made available on the market.

Forms of labelling

- 1. The labelling information referred to in Parts A and B of Annex V shall be provided:
 - (a) on a physical label; or
 - (b) on a digital label and duplicated on a physical label.

- 2. Notwithstanding paragraph 1, point (b):
 - the labelling information referred to in Part C of Annex V may be provided on a (a) digital label only;
 - (b) the labelling information referred to in Part A, points 1(a), (c) and (d), of Annex V may be provided on a physical label only.

Requirements for digital labelling

- 1. Where detergents and surfactants carry a digital label in accordance with Article 18, the following rules shall apply to that label:
 - (a) all labelling information referred to in Part A of Annex V and, where applicable, Part B of that Annex, are provided together in one place and separated from other information;
 - (b) the information on the digital label is searchable;
 - the information on the digital label is accessible to all users in the Union; (c)
 - (d) the information on the digital label is accessible via the data carrier referred to in Article 21(2), point (h);

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- (e) the information on the digital label is presented in a way that also addresses the needs of vulnerable groups, including persons with disabilities, and supports, as relevant, the necessary adaptations to facilitate access to the information by those groups;
- (f) the digital label is accessible through digital technologies widely used and compatible with all major operating systems and browsers;
- (g) the digital label remains available for a period of 10 years from the date on which the detergent or surfactant is placed on the market, including in cases of insolvency, liquidation or cessation of activity in the Union of the economic operator that created it, or for a longer period as required under other Union law covering the information that it contains;
- (h) where the information on the digital label is accessible in more than one language, the choice of language is not to be conditioned by the geographical location from which it is accessed by the end-user.
- 2. Economic operators providing a digital label shall not track, analyse or use any usage information other than as absolutely necessary for the purposes of providing online the information on the digital label.

- 3. Economic operators making a detergent or surfactant available on the market to end-users shall provide the information present on the digital label by other means in the following cases:
 - (a) upon oral or written request by the end-user; or
 - (b) where the digital label is temporarily unavailable, including at the time of purchase.

Economic operators shall provide the information referred to in the first subparagraph independently of a purchase of a detergent or surfactant and free of charge.

Article 20

Distance sales

Where detergents or surfactants are made available on the market through distance sales, the offer shall clearly and visibly indicate the label information referred to in Article 17, and a digital copy of the data carrier or the unique product identifier.

Chapter V

Digital product passport

Article 21

Digital product passport

- 1. Before placing a detergent or end-user surfactant on the market, the manufacturer shall create a digital product passport for that product. The digital product passport shall meet the requirements set out in this Article and Article 22.
- 2. The digital product passport shall:
 - correspond to a specific model of detergent or end-user surfactant; (a)
 - state that compliance of the detergent or end-user surfactant with this Regulation has (b) been demonstrated;
 - (c) contain at least the data set out in Part A of Annex VI;
 - be accurate, complete and up-to-date; (d)
 - (e) be available in the language or languages required by the Member State in which the detergent or end-user surfactant is made available on the market;

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- (f) be accessible to consumers or other end-users, market surveillance authorities, customs authorities, the Commission and other economic operators in accordance with the access rights laid down pursuant to paragraph 10, point (d);
- (g) be available for a period of 10 years from the date on which the detergent or end-user surfactant is placed on the market, including in cases of insolvency, liquidation or cessation of activity in the Union of the economic operator that created the digital product passport;
- (h) be connected through a data carrier to a persistent unique product identifier; and
- (i) fulfil the specific and technical requirements laid down pursuant to paragraph 10.
- 3. In addition to the data set out in Part A of Annex VI, the digital product passport may contain the data set out in Part B of that Annex.
- 4. The data carrier referred to in paragraph 2, point (h), shall be:
 - (a) printed or otherwise physically present on the label or the packaging of the detergent or end-user surfactant, or on the documents accompanying the detergent or end-user surfactant if transported in bulk, in accordance with the Commission implementing act referred to in paragraph 10;

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- (b) indelible;
- (c) positioned in such a way to be processed automatically by digital devices;
- (d) present on the refill station, for detergents and end-user surfactants made available on the market through refill;
- (e) accompanied by the statement 'Please scan for more comprehensive information on the product' or by a similar statement; and
- (f) visible to the consumer or other end-users before any purchase and to market surveillance authorities, including, where applicable, in cases where the detergent or end-user surfactant is made available on the market through distance sales.
- 5. Where other Union law requires information on the detergent or end-user surfactant to be available via a data carrier, a single data carrier shall be used to provide the information required under this Regulation and other Union law.
- 6. Where other Union law applying to detergents and end-user surfactants requires a digital product passport, a single digital product passport shall be created for detergents and end-user surfactants, containing the data required under this Regulation as well as any other data required for the digital product passport by other Union law.

- 7. By way of derogation from paragraph 2, point (a), where other Union law requires that the digital product passport correspond to a batch or an item level, the digital product passport for the purposes of this Regulation may be issued to that level.
- 8. Economic operators may, in addition to the data referred to in paragraphs 5 and 6, make other information accessible through the data carrier referred to in paragraph 5. In such cases, those data shall be clearly separated from the data required under this Regulation and, where relevant, under other Union law.
- 9. By creating the digital product passport, the manufacturer shall assume the responsibility for the compliance of the detergent or end-user surfactant with this Regulation.
- 10. The Commission shall adopt an implementing act determining the basic technical requirements related to the digital product passport for detergents and end-user surfactants. The date of application of such implementing act shall not be earlier than 18 months from its entry into force, except in duly justified cases relating to the whole implementing act or to certain provisions thereof, or except in the event of partial repeal or amendment of the implementing act, where an earlier date of application may be set. Those technical requirements shall include at least the following:
 - one or more data carriers to be used; (a)
 - (b) the layout in which the data carrier is to be presented and its positioning;

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- (c) the technical elements of the digital product passport for which defined European or international standards are to be used;
- (d) the actors that are to have access to the data in the digital product passport and to what data they are to have access;
- (e) the actors that are to create a digital product passport or update the data in a digital product passport, and what data they may introduce or update; and
- (f) the detailed arrangements for introducing or updating data referred to in point (e).

The implementing act referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 32(2).

- 11. The actors that update data in the digital product passport shall be responsible for the accuracy of the data they provide, except in cases where they act on behalf of the manufacturer.
- 12. The economic operator placing the detergent or end-user surfactant on the market shall:
 - (a) provide distributors and providers of online marketplaces with a digital copy of the data carrier or the unique product identifier, as relevant, to allow them to make the data carrier or the unique product identifier accessible to potential customers who cannot physically access the product;

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- (b) provide the digital copy referred to in point (a) or a webpage link free of charge, promptly and in any event within five working days of receiving a request to do so; and
- (c) make available a back-up copy of the digital product passport through a digital product passport service provider.

Technical design and operation of the digital product passport

The technical design and operation of the digital product passport shall comply with all of the following requirements:

- (a) the digital product passport is fully interoperable with other digital product passports required by other Union law in relation to the technical, semantic and organisational aspects of end-to-end communication and data transfer;
- (b) all data included in the digital product passport is based on open standards, developed with an interoperable format, and is, as appropriate, machine readable, structured, searchable and transferable through an open interoperable data exchange network without vendor lock-in;

- (c) consumers or other end-users, economic operators, competent national authorities, customs authorities, the Commission and other relevant actors have access, on the basis of their respective access rights in accordance with Union law, to the digital product passport free of charge;
- (d) consumers and other end-users are not required to register or provide a password to access the digital product passport;
- (e) the digital product passport is stored by the economic operator responsible for its creation or by digital product passport service providers;
- (f) where a new digital product passport is created for a detergent or an end-user surfactant that already has one or more digital product passports, the new digital product passport is linked to those original digital product passports;
- (g) where the digital product passport is stored pursuant to point (e) of this Article or otherwise processed by digital product passport service providers pursuant to Article 21(12), point (c), those digital product passport service providers do not sell, reuse or process such data, in whole or in part, beyond what is necessary for the provision of the relevant storing or processing services, unless specifically agreed with the economic operator placing the detergent or end-user surfactant on the market;

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- (h) economic operators do not track, analyse or use any usage information other than as absolutely necessary for the purposes of providing the information on the digital product passport online; in particular, personal data related to the consumer or other end-user of the detergent or end-user surfactant is not stored in the digital product passport without its explicit consent given in compliance with Article 6 of Regulation (EU) 2016/679 of the European Parliament and of the Council²²;
- (i) data authentication, reliability and integrity are ensured;
- (j) digital product passports are designed and operated so that a high level of security and privacy is ensured and fraud is avoided.

Data carriers and unique identifiers

1. The data carrier, the unique product identifiers and the unique operator identifiers required pursuant to this Regulation shall comply with the standards applicable to data carriers, unique product identifiers and unique operator identifiers pursuant to Regulation (EU) 2024/1781.

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Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

- 2. Where a unique operator identifier is not yet available, Article 12(2) of Regulation (EU) 2024/1781 shall apply to economic operators that create or update a digital product passport under this Regulation. Any rules and procedures for the lifecycle management of unique identifiers and data carriers set out in delegated acts adopted pursuant to Article 12(4) of Regulation (EU) 2024/1781 shall also apply in respect of unique identifiers and data carriers under this Regulation.
- 3. Where a detergent or surfactant is subject to an obligation to provide for a digital product passport under a delegated act adopted pursuant to Article 4 of Regulation (EU) 2024/1781 or under other Union law, the unique product identifier, the unique operator identifier and the unique registration identifier referred to in Article 24(2), first subparagraph, of this Regulation shall be the same.
- 4. Any procedures for the issuing and verification of the digital credentials of economic operators and other relevant actors that have access rights to data included in the digital product passport, and which are established by implementing acts adopted pursuant to Article 11, fourth subparagraph, of Regulation (EU) 2024/1781, shall also be applicable for the purposes of this Regulation.
- 5. Any requirements that digital product passport service providers are to comply with in order to become such providers, and, where appropriate, in order to provide such services, set out in delegated acts adopted pursuant to Article 11, third subparagraph, of Regulation (EU) 2024/1781 shall also be applicable for the purposes of this Regulation.

Digital product passport registry

- Before placing a detergent or end-user surfactant on the market, the relevant economic operator shall upload, in the registry established under Article 13(1) of Regulation (EU) 2024/1781, the unique product identifier and the unique operator identifier for that detergent or end-user surfactant.
 - In the case of detergents or end-user surfactants intended to be placed under the customs procedure 'release for free circulation', the registry shall store the commodity code of that detergent or end-user surfactant.
- 2. Upon the uploading by the economic operator of the data referred to in paragraph 1 in the registry, the registry shall automatically communicate to that economic operator a unique registration identifier associated with the identifiers uploaded in the registry for a specific detergent or end-user surfactant ('unique registration identifier'). That communication by the registry shall not be deemed to be proof of compliance with this Regulation or other Union law.

The Commission may adopt an implementing act specifying the implementation arrangements for the registry, including for the communication of the unique registration identifier. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 32(2).

3. The Commission, competent national authorities and customs authorities shall have access to the registry for the purpose of carrying out their duties pursuant to this Regulation.

Article 25

Customs controls relating to the digital product passport

- 1. Detergents and end-user surfactants entering the Union market shall be subject to verifications and other measures laid down in this Article.
- 2. Any person intending to place a detergent or end-user surfactant under the customs procedure 'release for free circulation' shall provide or make available to customs authorities the unique registration identifier.
- 3. Customs authorities may release a detergent or end-user surfactant for free circulation only after having verified as a minimum that the unique registration identifier and the commodity code provided or made available to them corresponds to the data stored in the registry. The release for free circulation shall not be deemed to be proof of compliance with this Regulation or any other Union law.
- 4. The verification referred to in paragraph 3 shall take place electronically and automatically via the interconnection between the registry and the EU Customs Single Window Certificates Exchange System and shall apply from ... [the date of application of this Regulation] or from the date that interconnection is operational, whichever is later.

- 5. Customs authorities and the Commission may retrieve and use the data on the detergent or end-user surfactant included in the digital product passport and the registry for carrying out their duties pursuant to Union law, including risk management, customs controls and release for free circulation in accordance with Regulation (EU) No 952/2013.
- 6. The verifications and other measures laid down in this Article shall be carried out on the basis of the list of commodity codes and product description set out in Annex VII.
- 7. This Article is without prejudice to any other Union legal acts, in particular Regulation (EU) No 952/2013 and Chapter VII of Regulation (EU) 2019/1020.

Chapter VI

Market surveillance

Article 26

Procedure at national level for market surveillance of detergents and surfactants

 The market surveillance authorities of a Member State may carry out an evaluation in relation to a detergent or surfactant, covering the requirements laid down in this Regulation. Where there is reason to believe that a detergent or surfactant poses a risk to human health or the environment, the market surveillance authorities shall carry out that evaluation. The relevant economic operators shall cooperate with the market surveillance authorities.



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- 2. When carrying out tests for the purpose of the evaluation referred to in paragraph 1, market surveillance authorities shall use the reference methods set out in the Annexes, as applicable.
- 3. Where, in the course of the evaluation referred to in paragraph 1, the market surveillance authorities find that the detergent or surfactant does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the detergent or surfactant into compliance with those requirements, to withdraw it from the market or to recall it, within a reasonable period laid down by the market surveillance authorities and which is commensurate with the nature of the risk referred to in paragraph 1.
- 4. Where a market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the market surveillance authorities of the other Member States of the results of the evaluation and of the corrective action which it has required the economic operator to take.
- 5. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the detergents or surfactants concerned that it has made available on the market in the Union.

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- 6. Where the economic operator does not take adequate corrective action within the period referred to in paragraph 3, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the making available of the detergent or surfactant on their national market, to withdraw it from that market or to recall it.
 - The market surveillance authorities shall inform the Commission and the market surveillance authorities of the other Member States, without delay, of any measures they take under the first subparagraph. That information shall include all available details, in particular the data necessary for the identification of the non-compliant detergent or surfactant, the origin of that detergent or surfactant, the nature of the alleged non-compliance and the risk involved, the nature and duration of the measures taken and the arguments put forward by the relevant economic operator.
- 7. Market surveillance authorities of Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the market surveillance authorities of the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the detergent or surfactant concerned and, in the event of disagreement with those measures, of their objections.
- 8. Where, within three months of receipt of the information referred to in paragraph 6, second subparagraph, no objection has been raised by either a market surveillance authority or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

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- 9. Market surveillance authorities shall ensure that appropriate restrictive provisional measures, such as withdrawal of the detergent or surfactant from the market, are taken in respect of the detergent or surfactant concerned without delay.
- 10. For the purposes of paragraphs 4, 6, 7 and 8 of this Article, market surveillance authorities shall enter the information into the information and communication system referred to in Article 34(1) of Regulation (EU) 2019/1020.

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 26(3) and (6), objections are raised against a measure taken by a market surveillance authority, or where the Commission considers a national measure to be contrary to Union law, the Commission shall without delay enter into consultation with the market surveillance authorities and the relevant economic operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 32(2).

The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operators.

- 2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant detergent or surfactant is withdrawn from their market and shall inform the Commission accordingly.
- 3. If the national measure is considered unjustified, the Member State concerned shall withdraw it.

Compliant detergents and surfactants which pose a risk to human health or to the environment

- 1. Where, having carried out an evaluation under Article 26(1), a market surveillance authority finds that, although a detergent or surfactant is in compliance with this Regulation, it poses a risk to human health or to the environment, it shall require the relevant economic operator to take all appropriate measures to ensure that the detergent or surfactant, when placed on the market, no longer presents that risk, to withdraw it from the market or to recall it within a reasonable period laid down by the market surveillance authorities and which is commensurate with the nature of that risk.
- 2. The economic operator shall ensure that the measures referred to in paragraph 1 are taken in respect of all the detergents or surfactants concerned that it has made available on the market in the Union.

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- 3. The market surveillance authorities shall inform the Commission and the market surveillance authorities of the other Member States, without delay, of any measures as referred to in paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the detergents or surfactants concerned, the origin and the supply chain of those detergents or surfactants, the nature of the risk involved and the nature and duration of the national measures taken.
- 4. The Commission shall without delay enter into consultation with the market surveillance authorities and the relevant economic operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measures are justified and, where necessary, propose appropriate measures. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 32(2).

The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operators.

Formal non-compliance

- 1. Without prejudice to Article 26, where a market surveillance authority makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:
 - (a) the digital product passport has not been drawn up in accordance with Articles 21 and 22;
 - (b) the technical documentation referred to in Article 8(2) is either not available or incomplete;
 - the data carrier through which the digital product passport and, where relevant, the (c) digital label is accessible is not provided in accordance with Article 21(4), point (a) or (d), as applicable;
 - (d) the label has not been provided, or the label has not been provided in accordance with Articles 18 and 19, or the labelling information referred to in Annex V is false or incomplete;
 - the ingredients data sheet has not been communicated or updated in accordance with (e) Article 8(6), Article 9(4), point (a), Article 10(3) or Article 11(3), as applicable.

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2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the detergent or surfactant being made available on the market or ensure that it is recalled or withdrawn from the market.

Chapter VII

Delegated powers and committee procedure

Article 30

Delegated powers

- The Commission is empowered to adopt delegated acts in accordance with Article 31
 amending Annexes I and II, Annex III with the exception of phosphorus limit values and
 Annexes IV to VII, where such amendments are necessary to adapt them to technical or
 scientific progress.
- 2. The Commission is empowered to adopt delegated acts in accordance with Article 31 amending Annex VI, as regards the information to be provided in the digital product passport, for the purposes of adapting it to technical and scientific progress and to the level of digital readiness of market surveillance authorities and of end-users.
- 3. The Commission is empowered to adopt delegated acts in accordance with Article 31 amending Article 24(1) to require that additional information, drawn from the information listed in Annex VI, be stored in the registry.

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When adopting delegated acts in accordance with the first subparagraph, the Commission shall take into account the following criteria:

- (a) coherence with other relevant Union legal acts;
- (b) the need to allow for verification of the authenticity of the digital product passport;
- (c) the relevance of information for improving the efficiency and effectiveness of market surveillance checks and customs controls for detergents and end-user surfactants; and
- (d) the need to avoid imposing a disproportionate administrative burden on economic operators and national authorities.
- 4. The Commission is empowered to adopt delegated acts in accordance with Article 31 amending Annex I and, where appropriate, Article 4 to:
 - (a) amend the biodegradability criteria and corresponding test methods for surfactants or surfactants contained in detergents;
 - (b) set out biodegradability criteria and corresponding test methods for intentionally added organic substances other than surfactants; or
 - (c) set out exceptions authorising the limited use in detergents of specific organic substances that do not comply with the biodegradability criteria laid down in accordance with point (b), where duly justified.

- By ... [3 years from the date of entry into force of this Regulation], the Commission shall adopt delegated acts setting out biodegradability criteria and test methods for films and polymers within films.
- By ... [5 years from the date of entry into force of this Regulation], the Commission shall adopt delegated acts setting out biodegradability criteria and test methods for organic substances intentionally added in concentration of at least 10 % w/w of the total mass of substances, excluding water, in detergents, other than surfactants, films and polymers within films.
- 5. The purpose of the delegated acts referred to in paragraph 4 shall be to ensure a high degree of protection of human health and the environment. When adopting such delegated acts, the Commission shall take into account:
 - (a) the impact on human health and the environment, including scientific evidence pointing to the existence of a risk;
 - (b) manufacturing practices;
 - the availability of technically and economically feasible alternatives; (c)
 - (d) the consequence on wastewater treatment plants; and
 - the impact on small and medium-sized enterprises. (e)

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6. By ... [30 months from the date of entry into force of this Regulation] the Commission shall adopt a delegated act in accordance with Article 31 amending point 7 in Annex II to set out a methodology for a risk assessment at strain level and product level under all foreseeable use conditions as claimed by the manufacturer.

The methodology referred to in the first subparagraph shall contain the rules for the identification and characterisation of micro-organisms and the criteria for determining that the detergent is safe for human health and the environment, including the skin and respiratory sensitisation potential of products in a spray format, and potential risks in the event of ingestion of detergents used on surfaces in contact with food.

The methodology referred to in the first subparagraph shall be established by using non-animal testing methods, without prejudice to any other relevant Union law, and shall not prevent the use of historical data.

7. The Commission is empowered to adopt delegated acts in accordance with Article 31 amending Annex IV to set out harmonised requirements, including a harmonised format, on how the ingredients data sheet is to be provided in accordance with Article 8(6), Article 9(4), point (a), Article 10(3) and Article 11(3), and to set out the details of that communication and the conditions that necessitate an update of the ingredients data sheet. When developing those requirements, details and conditions, the Commission shall take into account the need to ensure effective access to the ingredients data sheet by appointed bodies, as well as the need to limit the administrative burden.

- 8. Where individual risk-based concentration limits for fragrance allergens are introduced or amended in Regulation (EC) No 1223/2009, the Commission shall adopt delegated acts in accordance with Article 31 of this Regulation amending Annex V to this Regulation in order to adapt it to the concentration limits for the fragrance allergens listed in Annex III to Regulation (EC) No 1223/2009.
- 9. Where new fragrance allergens are listed in Annex II or III to Regulation (EC) No 1223/2009, the Commission shall adopt delegated acts in accordance with Article 31 of this Regulation in order to add those fragrance allergens in Part D of Annex V to this Regulation.
- 10. By ... [the first day of the month following 30 months from the date of entry into force of this Regulation], the Commission shall adopt delegated acts in accordance with Article 31 to supplement this Regulation by determining the specific requirements for the digital labelling of detergents. Those requirements shall at least establish which types of IT solutions economic operators can use, and the alternative means for providing the information on the digital label referred to in Article19.

When adopting the delegated acts referred to in the first subparagraph, the Commission shall take into account the following criteria:

- (a) the need for the digital labelling not to compromise the safety of end-users and the environment:
- (b) coherence with other relevant Union acts;
- (c) the need to encourage innovation;

- (d) technological neutrality characterised by absence of constraints or prescriptions on the choice of technology or equipment, within the bounds of compatibility and avoidance of interference; and
- (e) the level of digital readiness among all population groups in the Union, as well as the readiness of the wireless and other technological infrastructure necessary for allowing unrestricted access to the information on detergents and surfactants.
- 11. The Commission is empowered to adopt delegated acts in accordance with Article 31 amending Annex V as regards the labelling information that economic operators are allowed to provide digitally only, in accordance with Article 18(2), in order to adapt that Annex to technical and scientific progress and to the level of digital readiness among endusers of detergents and surfactants. When adopting those delegated acts, the Commission shall take into account the need to ensure a high degree of protection of human health and environment.
- 12. The Commission is empowered to adopt delegated acts in accordance with Article 31 amending Annex VII in order to update the list of commodity codes and product descriptions of detergents and surfactants. Those amendments shall be based on the list set out in Annex I to Regulation (EEC) No 2658/87.

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Exercise of the delegation

- 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2. The power to adopt delegated acts referred to in Article 30 shall be conferred on the Commission for a period of five years from ... [the date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
- 3. The delegation of power referred to in Article 30 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
- 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State acting in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

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- 5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
- 6. A delegated act adopted pursuant to Article 30 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Committee procedure

- 1. The Commission shall be assisted by the Committee on detergents. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Chapter VIII

Transitional and final provisions

Article 33

Penalties

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

Article 34

Reports and reviews

- 1. By ... [7 years from the date of entry into force of this Regulation], the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation. That report shall contain an assessment of how this Regulation is achieving its objectives, including the impact on small and medium-sized enterprises, and shall include at least the following elements:
 - (a) as regards detergents containing micro-organisms, the suitability of the requirements set out in Annex II to ensure the safety of those products for human health and the environment;

- (b) as regards biodegradability, an assessment of the feasibility of introducing biodegradability criteria for organic substances intentionally added in detergents in concentrations lower than 10 % w/w of the total mass of substances, excluding water, other than surfactants, films and polymers within films, including with a view to examining the feasibility of revising the 10 % threshold downwards;
- (c) as regards the protection of human health and the environment from the most harmful substances, an assessment of the need to include provisions in this Regulation on the presence of those substances in detergents and surfactants, taking into account the interaction of this Regulation with other relevant Union law;
- (d) as regards detergents containing biocidal active substances, other than those listed in Annex I to Regulation (EU) No 528/2012, an assessment of the need to introduce stricter rules;
- (e) as regards detergents containing phosphates and other phosphorus compounds, the possibility to limit further the phosphorus content or add limitations of phosphorus content on other products categories to Annex III, with a view to examining the feasibility of phasing out phosphorus, taking into account the impact on the environment, the availability of alternatives and the socio-economic impact of substitution;

- (f) the need to introduce additional rules on labelling of consumer laundry detergents sold in bottles with lids, where such lids are intended to be used as measuring cups, taking into account both the feasibility and the potential of improving the correct and safe use of detergents; and
- (g) the necessity, feasibility, technical consequences and benefits for human health, the climate and the environment of the introduction of mandatory targets for renewable raw materials and recycled content in detergents and surfactants, taking into account the socio-economic impact, competitiveness of economic operators in the Union, sustainable sourcing and use of renewable feedstock, climate change mitigation potential and the potential for using food waste in detergents and surfactants.

The report referred to in the first subparagraph shall be accompanied, where appropriate, by a legislative proposal.

2. By ... [2 years from the date of entry into force of this Regulation], the Commission shall assess the feasibility of further reducing the existing limit values for phosphorus and phosphorus compounds for consumer automatic dishwasher detergents and consumer laundry detergents and of setting limit values for consumer hard surface cleaning products, consumer hand dishwashing detergents, industrial and institutional laundry detergents and industrial and institutional automatic dishwasher detergents. That assessment shall take into account the impact on the environment, the availability of suitable alternatives with less or no phosphorus and the socio-economic impact of substitution.

The Commission shall present a report on the main conclusions of the assessment referred to in the first subparagraph of this paragraph to the European Parliament and to the Council, which may be accompanied, if appropriate, by a legislative proposal for the amendment of Annex III.

Article 35 Repeal of Regulation (EC) No 648/2004

Regulation (EC) No 648/2004 is repealed with effect from ... [42 months from the date of entry into force of this Regulation].

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VIII.

Article 36

Transitional provisions

Detergents and surfactants placed on the market before ... [42 months from the date of entry into force of this Regulation] and which are in compliance with Regulation (EC) No 648/2004 as applicable on ... [one day before 42 months from the date of entry into force of this Regulation] may continue to be made available on the market indefinitely.

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2. Detergents and surfactants placed on the market after ... [one day before 42 months from the date of entry into force of this Regulation] and before ... [54 months from the date of entry into force of this Regulation] and which are in compliance with Regulation (EC) No 648/2004 as applicable on ... [one day before 42 months from the date of entry into force of this Regulation] may be made available on the market until ... [54 months from the date of entry into force of this Regulation].

Article 37

Entry into force and application

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

This Regulation, with the exception of Article 4(3) and (4), shall apply from ... [42 months from the date of entry into force of this Regulation].

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

Done at ...,

For the European Parliament	For the Council
The President	The President

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ANNEX I

BIODEGRADABILITY CRITERIA AND TEST METHODS, REFERRED TO IN ARTICLE 4

- A. Surfactants and surfactants contained in detergents
- 1. Surfactants and surfactants contained in detergents shall be biodegradable as determined in accordance with the criteria set out in point 2.
- 2. Surfactants and surfactants contained in detergents shall be considered as achieving ultimate aerobic biodegradation if they meet one of the following criteria:
 - (a) the level of biodegradability (mineralisation) is at least 60 % within 28 days measured in accordance with one of the following test methods:
 - (i) method C.4.-C CO₂ evolution test, described in Part C, Part IV, of the Annex to Commission Regulation (EC) No 440/2008¹;
 - (ii) method C.4-D Manometric respirometry test, described in Part C, Part V, of the Annex to Regulation (EC) No 440/2008;
 - (iii) method C.4-E Closed bottle test, described in Part C, Part VI, of the Annex to Regulation (EC) No 440/2008;
 - (iv) method C.4-F M.I.T.I. test, described in Part C, Part VII, of the Annex to Regulation (EC) No 440/2008;

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Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/440/oj).

- (b) the level of biodegradability (mineralisation) is at least 70 % within 28 days measured in accordance with one of the following test methods:
 - (i) method C.4-A DOC die-away test, described in Part C, Part II, of the Annex to Regulation (EC) No 440/2008;
 - (ii) method C.4-B Modified OECD screening test described in Part C, Part III, of the Annex to Regulation (EC) No 440/2008.

Pre-adaptation shall not be used and the 10-day window principle shall not be applied in any of the test methods referred to in this point.

- 3. The tests referred to in point 2 shall be conducted by laboratories meeting at least one of the following conditions:
 - (a) they comply with the principles of good laboratory practice provided for in Directive 2004/10/EC of the European Parliament and of the Council² or with international standards recognised as being equivalent;

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Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44, ELI: http://data.europa.eu/eli/dir/2004/10/oj).

- (b) they are accredited in accordance with the standard for laboratories referred to in Regulation (EC) No 765/2008 of the European Parliament and of the Council³.
- B. Films and polymers within films
- C. Other organic substances
- D. Derogations for specific organic substances

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30, ELI: http://data.europa.eu/eli/reg/2008/765/oj).

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ANNEX II

REQUIREMENTS FOR DETERGENTS CONTAINING MICRO-ORGANISMS, REFERRED TO IN ARTICLE 5

- 1. All micro-organisms intentionally added in detergents shall:
 - (a) belong to or be deposited in a collection of an International Depository Authority (IDA);
 - (b) be identified and characterised using whole genome sequence analysis in accordance with the methodology to be established by the Commission in accordance with Article 30(6);
 - (c) be identified with the following taxonomic information, taking into consideration the latest published information in the International Codes of Nomenclature: genus, species and strain name or code.
- 2. The following pathogenic micro-organisms shall not be present in any of the microbial formulations intentionally added in the finished product, in accordance with European or international standards or test methods:
 - (a) Escherichia coli;
 - (b) Streptococcus spp (Enterococcus spp);
 - (c) Staphylococcus aureus;

- (d) Bacillus cereus;
- (e) Salmonella spp;
- (f) Pseudomonas aeruginosa;
- (g) Candida albicans.
- 3. Intentionally added micro-organisms shall not be genetically modified micro-organisms.
- 4. Intentionally added micro-organisms shall be, with the exception of intrinsic resistance, susceptible to each of the major antibiotic classes, namely aminoglycoside, macrolide, beta-lactam, tetracycline and fluoroquinolones, in accordance with the European Committee on Antimicrobial Susceptibility Testing disk diffusion method or equivalent.
- 5. When placed on the market, detergents containing micro-organisms shall have a standard plate count equal to or greater than $1x10^5$ colony-forming units (CFUs) per millilitre or gram of product in accordance with European or international standards or test methods.
- 6. The minimum shelf life of a detergent containing micro-organisms shall not be shorter than 18 months and the detergent shall have a standard plate count equal to or greater than 1×10^4 CFUs per millilitre or gram of product at the end of shelf life in accordance with European or international standards or test methods.

- 7. Detergents containing micro-organisms shall be placed on the market only if safe use for human health and the environment is demonstrated based on a risk assessment performed in accordance with the methodology to be established by the Commission in accordance with Article 30(6).
- 8. The manufacturer shall substantiate all claims regarding the actions or performance of the micro-organisms intentionally added in the product with appropriate tests.
- 9. It is prohibited to claim or suggest on the label or by any other communication that the detergent has an antimicrobial or disinfecting effect, unless the detergent complies with Regulation (EU) No 528/2012.
- 10. The tests referred to in points 1, 2, 4, 5, 6 and 8 shall be conducted by laboratories meeting at least one of the following conditions:
 - (a) they comply with the principles of good laboratory practice provided for in

 Directive 2004/10/EC or with international standards recognised as being equivalent;
 - (b) they are accredited in accordance with the standard for laboratories referred to in Regulation (EC) No 765/2008.

ANNEX III

LIMITATIONS ON THE CONTENT OF PHOSPHATES AND OTHER PHOSPHORUS COMPOUNDS, REFERRED TO IN ARTICLE 6

Detergent	Limitations
Consumer laundry detergents	The total content of phosphorus shall be lower than 0,5 grams in the recommended quantity of the detergent to be used in the main cycle of the washing process for a standard washing machine load as defined in Part B of Annex V for hard water: (i) for 'normally soiled' fabrics in the case of heavy-duty detergents, (ii) for 'lightly soiled' fabrics in the case of detergents for delicate fabrics.
Consumer automatic dishwasher detergents	The total content of phosphorus shall be lower than 0,3 grams in the standard dosage as defined in Part B of Annex V.

ANNEX IV

CONFORMITY ASSESSMENT PROCEDURE, REFERRED TO IN ARTICLE 8(2)

Module A – Internal production control

1. Description of the module

Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations set out in points 2, 3 and 4, and ensures and declares on its sole responsibility that the detergent or surfactant concerned is in conformity with this Regulation.

- 2. Technical documentation
- 2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess compliance of the detergent or surfactant with the relevant requirements and shall include an adequate analysis and assessment of the risks.
- 2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the detergent or surfactant. The technical documentation shall contain at least the following elements:
 - (a) a general description of the detergent or surfactant;
 - (b) where applicable, the test reports demonstrating compliance with Annexes I and II and the report of the risk assessment referred to in point 7 of Annex II;
 - (c) where applicable, a list of test methods used to demonstrate compliance with this Regulation;

- (d) results of calculations made, including to demonstrate compliance with the limit values set out in Annexes II and III, where applicable, and examinations carried out;
- (e) an ingredients data sheet which contains:
 - (i) the name or trade name of the detergent or surfactant, the unique formula identifier, the name, registered trade name or registered trade mark of the manufacturer and the intended use of the detergent or surfactant;
 - (ii) the list of all intentionally added substances; for the purposes of such a list, a perfume, an essential oil or a colouring agent shall be considered to be a single component, and preservatives and fragrance allergens shall also be listed if they must be labelled in accordance with Regulation (EC) No 1272/2008 or (EU) No 528/2012 or with Part A, points 1 (h)(iii) and (iv), of Annex V to this Regulation.

All substances shall be identified in accordance with Article 18(2) of Regulation (EC) No 1272/2008. However, an International Nomenclature of Cosmetic Ingredients name, a colour index name or another international chemical name may be used, provided the chemical name is well known and unambiguously defines the substance identity. The chemical name of substances for which an alternative chemical name has been allowed in accordance with Article 24 of that Regulation shall also be provided. However, the generic component identifiers 'perfumes' or 'colouring agents' may be used for ingredients used exclusively to add perfume or colour, provided that the following conditions are met:

the ingredients are not classified for any health hazard;

 the concentration of ingredients identified with a given generic component identifier does not exceed, in total, 5 % for the sum of perfumes and 25 % for the sum of colouring agents.

All substances shall be listed in order of decreasing abundance by weight, and the list is sub-divided into the following weight percentage ranges, unless the manufacturer opts for providing the exact concentration:

- (1) $\geq 25 < 100$;
- (2) $\geq 10 \langle 25;$
- $(3) \geq 1 < 10;$
- $(4) \geq 0, 1 < 1;$
- (5) > 0 < 0,1.
- (iii) where applicable, a list of all intentionally added micro-organisms providing their taxonomic classification (genus, species and strain name or code), the deposition accession number of each microbial strain at an IDA, and the standard plate count of the micro-organisms in the detergent, expressed in CFUs per millilitre or gram of product;

- (iv) the pH, if available, of the mixture, or where the product is a solid, the pH of an aqueous liquid or solution at a given concentration; the concentration of the test mixture in water shall be indicated; if the pH is not available, the reasons shall be given;
- (v) a specimen of the label of the detergent or surfactant in accordance with Article 17.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the detergent or surfactant with the technical documentation referred to in point 2.

4. Digital product passport

The manufacturer shall create the digital product passport for each model of detergent or end-user surfactant and ensure that, together with the technical documentation, it remains available for 10 years after the detergent or end-user surfactant has been placed on the market. The digital product passport shall identify the detergent or end-user surfactant for which it has been drawn up. The manufacturer shall also ensure that the technical documentation of other surfactants remains available for 10 years, where applicable.

ANNEX V

LABELLING REQUIREMENTS

Part A

GENERAL LABELLING REQUIREMENTS

- 1. The label of detergents and surfactants made available on the market shall contain the following information:
 - (a) a type number, batch number or other element ensuring the product's traceability;
 - (b) the unique formula identifier for detergents or end-user surfactants preceded by the acronym 'UFI' in capital letters followed by a colon ('UFI:');
 - (c) the manufacturer's and, where applicable, the importer's name, registered trade name or registered trade mark, the postal and electronic address and telephone number at which they can be contacted; the postal address shall indicate a single point in the Union;
 - (d) the name and trade name of the product;
 - (e) instructions for use and special precautions, where necessary and relevant;

- (f) where applicable, an indication that the product is an industrial and institutional detergent for professional use only;
- (g) for surfactants, an indication that the product is suitable for use in detergents;
- (h) the content of the detergent or surfactant in accordance with the following rules:
 - (i) the weight percentage ranges 'less than 5 %', '5 % or over but less than 15 %', '15 % or over but less than 30 %' and '30 % and more' shall be used to indicate the content of the constituents listed below where they are added in a concentration above 0,2 % by weight:
 - phosphates,
 - phosphonates,
 - anionic surfactants,
 - cationic surfactants,
 - amphoteric surfactants,
 - non-ionic surfactants,
 - oxygen-based bleaching agents,
 - chlorine-based bleaching agents,

	-	EDTA (ethylenediaminetetraacetic acid) and salts thereof,
	_	NTA (nitrilotriacetic acid) and salts thereof,
	_	phenols and halogenated phenols,
	_	paradichlorobenzene,
	_	aromatic hydrocarbons,
	-	aliphatic hydrocarbons,
	_	halogenated hydrocarbons,
	_	soap,
	_	zeolites,
	_	polycarboxylates;
(ii)	the f	following classes of constituents, if added, shall be listed irrespective of
	their	concentration:
	_	enzymes,
	_	micro-organisms,
	_	optical brighteners,
	_	perfumes;

- (iii) except when they are already labelled on the product in accordance with Article 18(3), point (b), of Regulation (EC) No 1272/2008 or Article 58 of Regulation (EU) No 528/2012, preservatives shall be listed, using where possible the system referred to in Article 33 of Regulation (EC) No 1223/2009, provided that they meet one of the following conditions:
 - they contribute to the qualification of the detergent or surfactant as a treated article as defined in Article 3(1), point (l), of Regulation
 (EU) No 528/2012, irrespective of their concentration; or
 - they are labelled as a constituent of the detergent or surfactant, unless the concentration of the preservative in the detergent or surfactant does not exceed the thresholds of 0,00015 % (w/w);
- (iv) if intentionally added in concentrations exceeding 0,01 % by weight, the fragrance allergens listed in Part D of this Annex shall be labelled using, where applicable, the system referred to in Article 33 of Regulation (EC) 1223/2009, except for fragrance allergens that are already labelled on the product in accordance with Article 18(3), point (b), of Regulation (EC) No 1272/2008;
- (v) Points (i) to (iv) shall not apply to industrial and institutional detergents and surfactants, provided that the equivalent information to that required in those points is provided in the safety data sheet drawn up in accordance with Article 31 of Regulation (EC) No 1907/2006;

- (vi) in addition to the information listed in points (i) to (iv), as applicable, the label of detergents containing micro-organisms shall bear the following information:
 - an indication or a precautionary statement that the product is not to be used on surfaces in contact with food, unless the product has been found safe for such applications on the basis of the risk assessment referred to in point 7 of Annex II;
 - an indication of the shelf life of the product;
 - use instructions or special precautions, where relevant.
- 2. For detergents and surfactants transported in bulk, the information referred to in points 1(a), (c) and (d), shall appear on transportation containers as well as on all documents accompanying them.

Part B

LABELLING OF DOSAGE INFORMATION

- 1. The label of consumer laundry detergents shall contain the following information:
 - (a) the recommended quantities or dosage instructions expressed in millilitres or grams or, where relevant, number of units appropriate to a standard washing machine load, for soft, medium and hard water hardness levels and making provision for one or two cycle washing processes;

- (b) for heavy-duty detergents, the number of standard washing machine loads of 'normally soiled' fabrics and, for detergents for delicate fabrics, the number of standard washing machine loads of 'lightly soiled' fabrics that can be washed with the contents of the package using water of medium hardness, corresponding to 2,5 millimoles CaCO₃/1; if the detergent is made available on the market through refill, the number of standard washing machine loads shall be expressed per 1 litre or 1 kg of product; if the detergent made available on the market through refill is in units, that requirement does not apply;
- (c) the capacity of any measuring cup, if provided, indicated in millilitres or grams, and clearly visible markings indicating the dose of detergent appropriate for a standard washing machine load for soft, medium and hard water hardness levels.
- 2. For the purposes of point 1, the standard washing machine loads shall be 4,5 kg dry fabric for heavy-duty detergents, 2,5 kg dry fabric for heavy duty detergents for short cycles and 2,5 kg dry fabric for light-duty detergents. A detergent shall be considered to be a heavy-duty detergent unless the claims of the manufacturer predominantly promote fabric care, namely low temperature wash, delicate fibres and colours.
- 3. The label of consumer automatic dishwasher detergents shall indicate the standard dosage expressed in millilitres or grams or number of units for the main washing cycle for normally soiled tableware in a fully loaded 12 place settings dishwasher, adjusting the standard dosage, where relevant, for soft, medium and hard water hardness.

4. The label of consumer detergents for surfaces shall contain the recommended dilution and quantity to be used per surface area or other relevant use instructions to ensure the product is not used in excess.

Part C

DIGITAL LABELLING

- 1. The following content information referred to in Part A may be provided on the digital label only, in accordance with Article 18(2):
 - (a) anionic surfactants;
 - (b) cationic surfactants;
 - (c) amphoteric surfactants;
 - (d) non-ionic surfactants;
 - (e) phosphates;
 - (f) phosphonates;
 - (g) soap.
- 2. For detergents and surfactants made available on the market through refill, the content information referred to in Part A may be provided on the digital label only, with the exception of points 1(h)(iii) and (iv) of that Part.

- 3. For consumer laundry detergents, the dosage information in accordance with Part B, points 1 and 2, may be provided on the digital label only, if a simplified dosage grid is provided on the physical label, containing the following information:
 - (a) basic instructions for use;
 - (b) the recommended quantities based on medium water hardness and different degrees of fabric soiling; and
 - (c) an indication of the washing machine load.

PART D

List of fragrance allergens referred to in point 1(h)(iv) of Part A

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
1	Benzyl alcohol	Benzyl Alcohol	100-51-6	202-859-9
2	6-Methylcoumarin	6-Methyl Coumarin	92-48-8	202-158-8
3	2-Benzylideneheptanal	Amyl cinnamal	122-40-7	204-541-5
4	Cinnamyl alcohol	Cinnamyl alcohol	104-54-1	203-212-3
5	3,7-Dimethyl-2,6-octadienal	Citral	5392-40-5	226-394-6
	(E)-3,7-dimethylocta-2,6-dienal	Geranial	141-27-5	205-476-5
	(Z)-3,7-dimethylocta-2,6-dienal	Neral	106-26-3	203-379-2
6	Phenol, 2-methoxy-4-(2-propenyl)	Eugenol	97-53-0	202-589-1
7	7-Hydroxycitronellal	Hydroxycitronellal	107-75-5	203-518-7

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
8	Phenol, 2-methoxy-4-(1-propenyl)	Isoeugenol	97-54-1	202-590-7
	(E)-2-methoxy-4-(prop-1-enyl)phenol;	Isoeugenol	5932-68-3	227-678-2
	(trans-Isoeugenol)			
	(Z)-2-methoxy-4-(prop-1-enyl)phenol;	Isoeugenol	5912-86-7	227-633-7
	(cis-Isoeugenol)			
9	2-Pentyl-3-phenylprop-2-en-1-ol	Amylcinnamyl alcohol	101-85-9	202-982-8
10	Benzyl salicylate	Benzyl salicylate	118-58-1	204-262-9
11	2-Propenal, 3-phenyl-	Cinnamal	104-55-2	203-213-9
12	2H-1-Benzopyran-2-one	Coumarin	91-64-5	202-086-7
13	2,6-Octadien-1-ol, 3,7-dimethyl-, (2E)-	Geraniol	106-24-1	203-377-1
14	4-Methoxybenzyl alcohol	Anise alcohol	105-13-5	203-273-6
15	2-Propenoic acid, 3-phenyl-, phenylmethyl ester	Benzyl cinnamate	103-41-3	203-109-3
16	2,6,10-Dodecatrien-1-ol, 3,7,11-trimethyl-	Farnesol	4602-84-0	225-004-1
17	1,6-Octadien-3-ol, 3,7-dimethyl-	Linalool	78-70-6	201-134-4
18	Benzyl benzoate	Benzyl benzoate	120-51-4	204-402-9
19	Citronellol/ (±)	Citronellol	106-22-9/	203-375-0/
	3,7-Dimethyl-6-octen-1-ol		26489-01-0	247-737-6
	(3R)-3,7-dimethyloct-6-en-1-ol	Citronellol	1117-61-9	214-250-5
	(3S)-3,7-dimethyloct-6-en-1-ol	Citronellol	7540-51-4	231-415-7
20	2-Benzylideneoctanal	Hexyl cinnamal	101-86-0	202-983-3

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
21	1-methyl-4-prop-1-en-2-yl-	Limonene	138-86-3/	205-341-0/
	cyclohexene; dl-limonene (racemic); Dipentene		7705-14-8	231-732-0
	(R)-p-mentha-1,8-diene; (d-limonene)	Limonene	5989-27-5	227-813-5
	(S)-p-mentha-1,8-diene; (l-limonene)	Limonene	5989-54-8	227-815-6
22	Methyl Oct-2-ynoate; Methyl heptine carbonate	Methyl 2-Octynoate	111-12-6	203-836-6
23	3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	alpha-Isomethyl ionone	127-51-5	204-846-3
24	Oak moss extract	Evernia prunastri extract	90028-68-5	289-861-3
25	Treemoss extract	Evernia furfuracea extract	90028-67-4	289-860-8
26	Pinus mugo leaf and twig oil and extract	Pinus Mugo Leaf Oil; Pinus Mugo Twig Leaf Extract; Pinus Mugo Twig Oil	90082-72-7	290-163-6
27	Pinus pumila leaf and twig oil and extract	Pinus Pumila Needle Extract;	97676-05-6	307-681-6
		Pinus Pumila Twig Leaf Extract;		
		Pinus Pumila Twig Leaf Oil		
28	Cedrus atlantica oil and extract	Cedrus Atlantica Bark Extract;	92201-55-3/	295-985-9/
		Cedrus Atlantica Bark Oil;	8023-85-6	-
		Cedrus Atlantica Bark Water;		
		Cedrus Atlantica Leaf Extract;		
		Cedrus Atlantica Wood Extract;		
		Cedrus Atlantica Wood Oil		
29	Turpentine gum (Pinus spp.);	Turpentine	9005-90-7;	232-688-5;
	Turpentine oil and rectified oil; Turpentine, steam distilled (<i>Pinus</i>		8006-64-2;	232-350-7;
	spp.)		8052-14-0	

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
30	p-Mentha-1,3-diene	Alpha-Terpinene	99-86-5	202-795-1
31	p-Mentha-1,4(8)-diene	Terpinolene	586-62-9	209-578-0
32	Myroxylon balsamum var. pereirae; extracts and distillates; Balsam Peru oil, absolute and anhydrol (Balsam Oil Peru); Exudation of Myroxylon pereirae (Royle) Klotzsch (Peru balsam, crude)	Myroxylon Balsamum Pereirae Balsam Extract; Myroxylon Balsamum Pereirae Balsam Oil; Myroxylon Pereirae Oil; Myroxylon Pereirae Resin Extract;	8007-00-9	232-352-8
		Myroxylon Pereirae Resin		
33	1-(2,6,6-trimethyl-2-cyclohexen-1-yl)-2-buten-1-one	Alpha-Damascone; cis-Rose ketone 1	43052-87-5/ 23726-94-5	-/ 245-845-8
		trans-Rose ketone 1	24720-09-0	246-430-4
	1-(2,6,6-Trimethylcyclohexa-1,3-dien-1-yl)-2-buten-1-one	Rose ketone 4 (Damascone)	23696-85-7	245-833-2
	1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one	Rose ketone 3 (delta- Damascone)	57378-68-4 71048-82-3	260-709-8 275-156-8
	(Z)-1-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2-buten-1-one	trans-Rose ketone 3 cis-Rose ketone 2 (cis-beta-Damascone)	23726-92-3	245-843-7
	(E)-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one	trans-Rose ketone 2 (trans-beta-Damascone)	23726-91-2	245-842-1

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
34	3-Propylidene-1(3H)- isobenzofuranone;	3-Propylidenephthalide	17369-59-4	241-402-8
	3-Propylidenephthalide			
35	Verbena absolute	Lippia citriodora absolute	8024-12-2/	
			85116-63-8	285-515-0
36	Verbena essential oils (Lippia citriodora Kunth.) and derivatives other than absolute	Lippia citriodora leaf; Lippia citriodora flower oil; Lippia citriodora oil	8024-12-2	285-515-0
37	Methyl 2-hydroxybenzoate	Methyl Salicylate	119-36-8	204-317-7
38	[3R-(3\alpha,3a\beta,7\beta,8a\alpha)]-1- (2,3,4,7,8,8a-hexahydro-3,6,8,8- tetramethyl-1H-3a,7- methanoazulen-5-yl)ethan-1-one	Acetyl Cedrene	32388-55-9	251-020-3
39	Pentyl-2-hydroxy-benzoate	Amyl Salicylate	2050-08-0	218-080-2
40	1-Methoxy-4-(1E)-1-propen-1-yl- benzene (trans-Anethole)	Anethole	104-46-1/ 4180-23-8	203-205-5/ 224-052-0
41	Benzaldehyde	Benzaldehyde	100-52-7	202-860-4
42	Bornan-2-one; 1,7,7-Trimethylbi-cyclo[2.2.1]-2-heptanone	Camphor	76-22-2/ 21368-68-3/ 464-49-3/ 464-48-2	200-945-0/ 244-350-4/ 207-355-2/ 207-354-7
43	(1R,4E,9S)-4,11,11-Trimethyl-8-methylenebicyclo[7.2.0]undec-4-ene	Beta-Caryophyllene	87-44-5	201-746-1

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
44	2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one;(5R)-2-Methyl-5-prop-1-en-2-ylcyclohex-2-en-1-one;(5S)-2-Methyl-5-prop-1-en-2-ylcyclohex-2-en-1-one	Carvone	99-49-0/ 6485-40-1/ 2244-16-8	202-759-5/ 229-352-5/ 218-827-2
45	2-Methyl-1-phenyl-2-propyl acetate; Dimethylbenzyl Carbinyl Acetate	Dimethyl Phenethyl Acetate	151-05-3	205-781-3
46	Oxacyclohepta-decan-2-one	Hexadecanolactone	109-29-5	203-662-0
47	1,3,4,6,7,8-Hexahydro- 4,6,6,7,8,8- hexamethylcyclopenta-γ-2- benzopyran	Hexamethylindanopyran	1222-05-5	214-946-9
48	3,7-Dimethyl octa-1,6-diene-3-yl acetate	Linalyl Acetate	115-95-7	204-116-4
49	Menthol; dl-menthol; l-menthol; d-menthol	Menthol	89-78-1 / 1490-04-6 / 2216-51-5 / 15356-60-2	201-939-0/ 216-074-4/ 218-690-9/ 239-387-8
50	3-Methyl-5-(2,2,3-Trimethyl-3- Cyclopentenyl)pent-4-en-2-ol	Trimethylcyclopentenyl Methylisopentenol	67801-20-1	267-140-4
51	o-Hydroxy-benzaldehyde	Salicylaldehyde	90-02-8	201-961-0
52	5-(2,3-Dimethyl- tricyclo[2.2.1.02,6]-hept-3-yl)-2- methylpent-2-en-1-ol (alpha- Santalol); (1S-(1a,2a(Z),4a))-2-Methyl-5-(2-	Santalol	11031-45-1/ 115-71-9/ 77-42-9	234-262-4/ 204-102-8/ 201-027-2
	methyl-3- methylenebicyclo[2.2.1]hept-2- yl)-2-penten-1-ol			
	(beta-Santalol)			

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
53	[1R-(1alpha)]-alpha- Ethenyldecahydro-2-hydroxy- a,2,5,5,8a-pentamethyl-1- naphthalenepropanol	Sclareol	515-03-7	208-194-0
54	2-(4-methylcyclohex-3-en-1-yl)propan-2-ol; p-Menth-1-en-8-ol (alpha-Terpineol); 1-methyl-4-(1-methylvinyl)cyclohexan-1-ol (beta-Terpineol); 1-methyl-4-(1-methylethylidene)cyclohexan-1-ol (gamma-Terpineol)	Terpineol	8000-41-7/ 98-55-5/ 138-87-4/ 586-81-2	232-268-1/ 202-680-6/ 205-342-6/ 209-584-3
55	1-(1,2,3,4,5,6,7,8-octahydro- 2,3,8,8-tetramethyl-2- naphthyl)ethan-1-one; 1- (1,2,3,4,5,6,7,8-octahydro- 2,3,5,5-tetramethyl-2- naphthyl)ethan-1-one; 1- (1,2,3,5,6,7,8,8a-octahydro- 2,3,8,8-tetramethyl-2- naphthyl)ethan-1-one; 1- (1,2,3,4,6,7,8,8a-octahydro- 2,3,8,8-tetramethyl-2- naphthyl)ethan-1-one	Tetramethyl acetyloctahydronaphthalenes	54464-57-2/ 54464-59-4/ 68155-66-8/ 68155-67-9/	259-174-3/ 259-175-9/ 268-978-3/ 268-979-9/
56	3-(2,2-Dimethyl-3- hydroxypropyl)toluene	Trimethylbenzenepropanol	103694-68-4	403-140-4
57	4-Hydroxy-3-methoxybenz- aldehyde	Vanillin	121-33-5	204-465-2
58	Cananga odorata flower oil and extract; Ylang Ylang flower oil and extract	Cananga Odorata Flower Extract; Cananga Odorata Flower Oil	83863-30-3/ 8006-81-3/ 68606-83-7/ 93686-30-7	281-092-1/ - / -/ 297-681-1

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
59	Cinnamomum cassia leaf Oil	Cinnamomum Cassia Leaf Oil	8007-80-5/	-/
			84961-46-6	284-635-0
60	Cinnamomum zeylanicum bark	Cinnamomum Zeylanicum Bark	8015-91-6/	-/
	oil	Oil	84649-98-9	283-479-0
61	Citrus aurantium amara and dulcis flower oil	Citrus Aurantium Amara Flower Oil	72968-50-4	277-143-2
		Citrus Aurantium Dulcis Flower Oil	8028-48-6/ 8016-38-4	232-433-8/
62	Citrus aurantium amara and dulcis peel oil	Citrus Aurantium Amara Peel	68916-04-1/	-/
		Oil	72968-50-4	277-143-2
	Citrus aurantium amara and dulcis peel oil	Citrus Aurantium Dulcis Peel	97766-30-8/ 8028-48-6/ 8008-57-9	307-891-8/
		Oil; Citrus Sinensis Peel Oil		232-433-8/
			0000 37 7	-
63	Citrus aurantium bergamia oil (Bergamot oil)	Citrus Aurantium Bergamia Peel Oil	8007-75-8	616-915-9
			89957-91-5	289-612-9
			68648-33-9/	-/
			8007-75-8/	616-915-9/
			85049-52-1	-
64	Citrus limon oil	Citrus Limon Peel Oil	84929-31-7/	284-515-8/
			8008-56-8	-
65	Cymbopogon citratus /	Cymbopogon Schoenanthus Oil	8007-02-1/	-/
	schoenanthus/flexuosus oils		89998-16-3	289-754-1
	Cymbopogon citratus / schoenanthus/flexuosus oils	Cymbopogon Flexuosus Oil	91844-92-7	295-161-9
	Cymbopogon citratus /	Cymbopogon Citratus Leaf Oil	8007-02-1/	295-161-9/
	schoenanthus/flexuosus oils		91844-92-7	295-161-9

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
66	Eucalyptus globulus oil	Eucalyptus Globulus Leaf Oil;	97926-40-4/ 8000-48-4/	308-257-3/ 616-775-9/
	Eucalyptus globulus oil	Eucalyptus Globulus Leaf/Twig Oil	8000-48-4	
67	Eugenia caryophyllus oil	Eugenia Caryophyllus Leaf Oil	8000-34-8 / 8015-97-2/ 84961-50-2	616-772-2/ - / 284-638-7
	Eugenia caryophyllus oil	Eugenia Caryophyllus Flower Oil	84961-50-2	284-638-7
	Eugenia caryophyllus oil	Eugenia Caryophyllus Stem oil	84961-50-2	284-638-7
	Eugenia caryophyllus oil	Eugenia Caryophyllus Bud oil	84961-50-2	284-638-7
68	Jasminum grandiflorum / officinale oil and extract	Jasminum Grandiflorum Flower Extract; Jasminum Officinale Oil; Jasminum Officinale Flower Extract	84776-64-7/ 90045-94-6/ 8022-96-6/ 8024-43-9 90045-94-6	283-993-5/ 289-960-1/- / - 289-960-1
69	Juniperus virginiana oil	Juniperus Virginiana Oil; Juniperus Virginiana Wood Oil	8000-27-9 / 85085-41-2	-/ 285-370-3
70	Laurus nobilis oil	Laurus Nobilis Leaf Oil	8002-41-3/ 8007-48-5/ 84603-73-6	-/ -/ 283-272-5

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
71	Lavandula hybrida oil/extract;	Lavandula Hybrida Oil;	91722-69-9/	294-470-6/
		Lavandula Hybrida Extract;	8022-15-9/	-/
		Lavandula Hybrida Flower	93455-96-0/	-/
		Extract;	93455-97-1/	-/
			92623-76-2	296-408-3
	Lavandula intermedia oil/extract;	Lavandula Intermedia	84776-65-8/	283-994-0/
		Flower/Leaf/Stem Extract; Lavandula Intermedia	8000-28-0/	-/
		Flower/Leaf/Stem Oil; Lavandula Intermedia Oil	90063-37-9	289-995-2
	Lavandula angustifolia oil/extract	Lavandula Angustifolia Oil; Lavandula Angustifolia Flower/Leaf/Stem Extract	84776-65-8/	283-994-0/
			8000-28-0/	-/
			90063-37-9	289-995-2
72	Mentha piperita oil	Mentha Piperita Oil	8006-90-4/	-/
			84082-70-2	282-015-4
73	Mentha spicata oil (spearmint oil)	Mentha Viridis Leaf Oil	8008-79-5/	616-927-4/
			84696-51-5	283-656-2
74	Narcissus	Narcissus Poeticus Extract	90064-26-9/	290-087-3/
	poeticus/pseudonarcissus/jonquill a/tazetta extract		68917-12-4	
	Narcissus poeticus/pseudonarcissus/jonquill a/tazetta extract	Narcissus Pseudonarcissus Flower Extract	90064-27-0	290-088-9
Ī	Narcissus poeticus/pseudonarcissus/jonquill a/tazetta extract	Narcissus Jonquilla Extract Narcissus Tazetta Extract	90064-25-8	290-086-8

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
75	Pelargonium graveolens oil	Pelargonium Graveolens Flower Oil	90082-51-2/ 8000-46-2	290-140-0/ -
76	Pogostemon cablin oil	Pogostemon Cablin Oil	8014-09-3/ 84238-39-1	-/ 282-493-4
77	Rosa damascena flower oil/extract;	Rosa Damascena Flower Oil; Rosa Damascena Flower Extract	8007-01-0/ 90106-38-0/	-/ 290-260-3
	Rosa alba flower oil/extract;	Rosa Alba Flower Oil; Rosa Alba Flower Extract	93334-48-6	297-122-1
	Rosa canina flower oil;	Rosa Canina Flower Oil	84696-47-9	283-652-0
	Rosa centifolia oil/extract;	Rosa Centifolia Flower Oil; Rosa Centifolia Flower Extract	84604-12-6	283-289-8
	Rosa gallica flower oil;	Rosa Gallica Flower Oil	84604-13-7	283-290-3
	Rosa moschata flower oil;	Rosa Moschata Flower Oil	-	-
	Rosa rugosa flower oil	Rosa Rugosa Flower Oil	92347-25-6	296-213-3
78	Santalum album oil	Santalum Album Oil	8006-87-9/ 84787-70-2	-/ 284-111-1
79	Phenol, 2-methoxy-4-(2-propenyl)-, acetate	Eugenyl Acetate	93-28-7	202-235-6
80	2,6-Octadien-1-ol, 3,7-dimethyl-,1-acetate, (2E)-	Geranyl Acetate	105-87-3	203-341-5
81	2-Methoxy-4-prop-1-enylphenyl acetate	Isoeugenyl Acetate	93-29-8	202-236-1
82	2,6,6-Trimethylbi- cyclo[3.1.1]hept-2-ene (alpha- Pinene); 6,6-Dimethyl- 2- methylenebicyclo[3.1.1]heptane	Pinene	80-56-8/ 7785-70-8/ 127-91-3/ 18172-67-3	201-291-9/ 232-087-8/ 204-872-5/ 242-060-2
	methylenebicyclo[3.1.1]heptane (beta-Pinene)		18172-67-3	

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
83	Allyl isothiocyanate		57-06-7	200-309-2
84	4-Benzyloxyphenol and 4-ethoxyphenol		103-16-2/ 622-62-8	203-083-3/ 210-748-1
85	4-Phenylbut-3-en-2-one (Benzylidene acetone)		122-57-6	204-555-1
86	Cyclamen alcohol		4756-19-8	225-289-2
87	Diethyl maleate		141-05-9	205-451-9
88	3,4-Dihydrocoumarin	Dihydrocoumarin	119-84-6	204-354-9
89	7,11-Dimethyl-4,6,10-dodecatrien-3-one	Pseudomethylionone	26651-96-7	247-878-3
90	6,10-Dimethyl-3,5,9-undecatrien- 2-one	Pseudoionone	141-10-6	205-457-1
91	Ethyl acrylate	Ethyl acrylate	140-88-5	205-438-8
92	Fig leaf absolute (Ficus carica L.)	Ficus carica extract	68916-52-9	
93	trans-2-Heptenal		18829-55-5	242-608-0
94	trans-2-Hexenal diethyl acetal		67746-30-9	266-989-8
95	trans-2-Hexenal dimethyl acetal		18318-83-7	242-204-4
96	Hydroabietyl alcohol	Hydroabietyl alcohol	13393-93-6	236-476-3
97	1-(4-Methoxyphenyl)-1-penten-3- one (alpha- Methylanisylideneacetone)		104-27-8	203-190-5
98	5-Methyl-2,3-hexanedione (Acetyl isovaleryl)		13706-86-0	237-241-8

Reference number	Chemical name/INN ^[1]	Name of Common Ingredients Glossary	CAS number	EC number
99	3,6,10-Trimethyl-3,5,9- undecatrien-2-one (Pseudo- Isomethyl ionone)		1117-41-5	214-245-8
100	7-Ethoxy-4-methylcoumarin		87-05-8	201-721-5
101	Hexahydrocoumarin		700-82-3	211-851-4
102	3- and 4-(4-Hydroxy-4- methylpentyl) cyclohex-3-ene-1- carbaldehyde (HICC)		51414-25-6/ 31906-04-4/	257-187-9/ 250-863-4/
103	2,6-Dihydroxy-4-methylbenzaldehyde (atranol)		526-37-4	_
104	3-Chloro-2,6-Dihydroxy-4- methyl-benzaldehyde (chloroatranol)		57074-21-2	_
105	2-(4-tert-butylbenzyl) propionaldehyde		80-54-6	201-289-8

The Non-proprietary Names (INN) for pharmaceutical products, WHO, Geneva, August 1975

ANNEX VI

DIGITAL PRODUCT PASSPORT

Part A

Information to be included in the digital product passport

The digital product passport shall include the following information:

- (a) the trade name, unique product identifier of the detergent or end-user surfactant and a colour image of the packaging or the label of the model of detergent or end-user surfactant of sufficient clarity to enable its identification;
- (b) the name, postal and electronic address and telephone number of the manufacturer and, where applicable, of the importer or the authorised representative, as well the manufacturer's unique operator identifier;
- (c) the reference to the digital product passport service provider hosting the back-up copy of the digital product passport;
- (d) the identification of the detergent or end-user surfactant allowing traceability;
- (e) an indication that the digital product passport is issued under the sole responsibility of the manufacturer;
- (f) where applicable, the commodity codes as set out in Annex I to Regulation
 (EEC) No 2658/87 under which the detergent or end-user surfactant is classified at the moment the digital product passport is created;

- (g) a statement that compliance of the detergent or end-user surfactant with this Regulation has been demonstrated, and, where relevant, references to other Union law with which the detergent or end-user surfactant complies;
- (h) a full list of substances intentionally added in the detergent or surfactant, identified in accordance with Article 18(3) of Regulation (EC) No 1272/2008; carry-over preservatives shall also be listed if they must be included in the label in accordance with Article 18(3), point (b), of Regulation (EC) No 1272/2008, Article 58 of Regulation (EU) No 528/2012 or Part A, point 1(h)(iii), of Annex V to this Regulation;
- (i) the list of all intentionally added micro-organisms providing their taxonomic classification (genus, species and strain name or code).

The obligation referred to in point (h) of this Part shall not apply to industrial and institutional detergents, or to surfactants, for which the equivalent information is provided by means of a safety data sheet as referred to in Article 31 of Regulation (EC) No 1907/2006.

Part B

Information which may be provided in the digital product passport

The digital product passport may include the labelling information referred to in Article 17(3) and (4).

ANNEX VII

LIST OF COMMODITY CODES AND DESCRIPTION OF DETERGENTS AND SURFACTANTS FOR THE PURPOSES OF ARTICLE 25(6)

	Commodity codes	Product descriptions
ex	3401 19 00	Other soap and organic surface-active products and preparations, including products for cleaning food, in the form of bars, cakes, moulded pieces or shapes, and paper, wadding, felt and nonwovens, impregnated, coated or covered with detergent
ex	3401 20	Soap in other forms intended for the cleaning, soaking, rinsing or bleaching of fabrics, dishes or surfaces, including products for cleaning food
	3402 31 00	Anionic organic surface-active agents, whether or not put up for retail sale: linear alkylbenzene sulphonic acids and their salts, including products for cleaning food
	3402 39	Other anionic organic surface-active agents, whether or not put up for retail sale, including products for cleaning food
	3402 41 00	Other cationic organic surface-active agents, whether or not put up for retail sale, including products for cleaning food
	3402 42 00	Other non-ionic organic surface-active agents, whether or not put up for retail sale, including products for cleaning food
	3402 49 00	Other organic surface-active agents, whether or not put up for retail sale, including products for cleaning food
	3402 50 10	Surface-active preparations put up for retail sale, including products for cleaning food

	Commodity codes	Product descriptions	
	3402 50 90	Washing preparations and cleaning preparations put up for retail sale, including products for cleaning food	
	3402 90 10	Other surface-active preparations, including products for cleaning food	
	3402 90 90	Other washing preparations and cleaning preparations, including products for cleaning food	
ex	3405 10 00	Polishes, creams and similar preparations, for footwear or leather with cleansing properties	
ex	3405 20 00	Polishes, creams and similar preparations, for the maintenance of wooden furniture, floors or other woodwork with cleansing properties	
ex	3405 30 00	Polishes and similar preparations for coachwork, other than metal polishes, with cleansing properties	
	3405 40 00	Scouring pastes and powders and other scouring preparations	
ex	3405 90	Other polishes and creams, for footwear, furniture, floors, coachwork, glass or metal, scouring pastes and powders and similar preparations with cleansing properties	
ex	3809 10	Finishing agents with a basis of amylaceous substances of a kind used in the textile or like industries to modify the feel or odour of fabrics and to stiffen the fabrics in processes which are to complement the washing of fabrics	
ex	3809 91 00	Other finishing agents of a kind used in the textile or like industries to modify the feel or odour of fabrics in processes which are to complement the washing of fabrics	
ex	3824 99 45	Anti-scaling and similar compounds, to be used together with a laundry detergent or an automatic dishwasher detergent	

Notes: in the first column, 'ex' indicates that the listed code covers more products than those described in the product description.

ANNEX VIII

CORRELATION TABLE

Regulation (EC) No 648/2004	This Regulation
Article 1(1)	Article 1(1)
Article 1(2)	_
Article 2, point (1)	Article 2, point (1)
Article 2, point (1a)	Article 2, point (2)
Article 2, point (1b)	Article 2, point (3)
Article 2, point (2)	_
Article 2, point (3)	Article 2, point (6)
Article 2, point (4)	Article 2, point (7)
Article 2, point (5)	Article 2, point (8)
Article 2, point (6)	Article 2, point (11)
Article 2, point (7)	_
Article 2, point (8)	Article 2, point (13)
Article 2, point (9)	Article 2, point (16)
Article 2, point (9a)	Article 2, point (15)
Article 2, point (10)	Article 2, point (17)
Article 2, point (11)	_
Article 2, point (12)	Article 2, point (5)
Article 3(1)	Article 3(1) and Article 4(2)
Article 3(2)	_
Article 3(3)	Article 8(1)
Article 4(1)	Article 4(1)

Regulation (EC) No 648/2004	This Regulation
Article 4(2)	_
Article 4(3)	_
Article 4a	Article 6
Article 5(1)	_
Article 5(2)	_
Article 5(3)	_
Article 5(4)	_
Article 5(5)	_
Article 5(6)	_
Article 6(1)	_
Article 6(2)	_
Article 6(3)	-
Article 6(4)	-
Article 7	_
Article 8(1)	-
Article 8(2)	_
Article 8(3)	_
Article 8(4)	_
Article 9(1)	_
Article 9(2)	_
Article 9(3)	Article 8(6) and Article 16
Article 10(1)	_
Article 10(2)	_
Article 11(1)	Article 1(2), point (b)
Article 11(2) and (3)	Article 17(3)
Article 11(4)	Article 17(4)
Article 11(5)	Article 17(5)

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Article 11(6)	-
Article 12	Article 32
Article 13	Article 30
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Article 13a(2)	Article 31(2)
Article 13a(3)	Article 31(3)
Article 13a(4)	Article 31(5)
Article 13a(5)	Article 31(6)
Article 14(1)	Article 3(2)
Article 14(2)	_
Article 14(3)	-
Article 14(4)	_
Article 14(5)	_
Article 15(1), first subparagraph	Article 28(1)
Article 15(1), second subparagraph	Article 28(3)
Article 15(2)	Article 28(4)
Article 16	Article 34(2)
Article 17	Article 35
Article 18	Article 33
Article 19	Article 37