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ANNEXES 1 to 4

ANNEXES

to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009, as regards simplification of certain requirements and procedures for chemical products

{SWD(2025) 531 final}

ANNEX I

Annexes I and II to Regulation (EC) No 1272/2008 are amended as follows:

(1) in Annex I, section 1.2.1.4 is replaced by the following:

‘1.2.1.4. The dimensions of the label and of each pictogram shall be as follows:

Table 1.3
Minimum dimensions of labels and pictograms

Capacity of the package	Dimensions of the label (in millimetres) for the information required by Article 17	Dimensions of each pictogram (in millimetres)
Not exceeding 3 litres:	If possible, at least 52 × 74	Not smaller than 10 × 10 If possible, at least 16 × 16
Greater than 3 litres but not exceeding 50 litres:	At least 74 × 105	At least 23 × 23
Greater than 50 litres but not exceeding 500 litres:	At least 105 × 148	At least 32×32
Greater than 500 litres:	At least 148 × 210	At least 46×46

’;

(2) in Annex I, section 1.2.1.5 is deleted;

(3) in Annex I, section 1.5.1.2 is replaced by the following:

‘1.5.1.2. Where section 1.5.1.1 applies, the label on any inner packaging shall contain at least the hazard pictograms, the signal words, the product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and the name and digital contact of the suppliers of the substance or mixture.’;

(4) the heading of section 1.5.2.4 is replaced by the following:

‘1.5.2.4 Labelling of packages where the contents do not exceed 10 ml ’;

(5) in Annex I, section 1.5.2.4.1 is replaced by the following:

‘1.5.2.4.1. The label elements set out in Article 17 may be omitted from the inner packaging where the contents of the inner packaging do not exceed 10 ml, the outer packaging meets the requirements set out in Article 17(1) and any of the following applies:

(a) the substance or mixture is placed on the market for scientific research and development or quality control analysis;

(b) the substance or mixture requires labelling in accordance with Part 1 or 2 of Annex II, except for section 2.8 of Part 2 of Annex II, and is not classified in any of the following hazard classes and categories:

(a) acute toxicity, any category;

(b) specific target organ toxicity – single exposure, categories 1 and 2;

(c) specific target organ toxicity – repeated exposure, any category;

(d) skin corrosion, category 1, any sub-category;

(e) serious eye damage, category 1;

(f) respiratory sensitisation, any category;

(g) aspiration hazard;

(h) germ cell mutagenicity, any category;

(i) carcinogenicity, any category;

(j) reproductive toxicity, any category;

(k) endocrine disruption for human health, any category.';

(6) in Annex I, section 1.5.2.4.2 is replaced by the following:

'1.5.2.4.2. Where section 1.5.2.4.1 applies, the label on the inner packaging shall contain the product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and, where applicable, the hazard pictograms 'GHS01', 'GHS05', 'GHS06' or 'GHS08'. Where more than two pictograms are assigned, 'GHS06' and 'GHS08' may take precedence over 'GHS01' and 'GHS05'.';

(7) in Annex I, section 1.5.2.4.3 is added:

'1.5.2.4.3. The label elements set out in Article 17(1) may be omitted from the package provided that the following conditions are met:

(a) the contents of the package do not exceed 10 ml;

(b) the substance or mixture does not require labelling in accordance with Part 1 or 2 of Annex II, except for section 2.8 of Part 2 of Annex II;

(c) the substance or mixture is not classified in any of the hazard classes and categories referred to in point (b) of section 1.5.2.4.1.';

(8) in Annex I, section 1.6 is replaced by the following:

'1.6. Label elements that may be provided on a digital label only

(a) Supplemental information referred to in Article 25(3);

(b) Where more than one supplier is indicated on the label in accordance with Article 17(1), point (a), the name, address and digital contact of the suppliers may be provided on a digital label only, as long as the supplier referred to in in Article 4(11) is indicated on the physical label.';

(9) in Annex II, Part 5 is replaced by the following:

'PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES

(a) Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.

(b) For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the copy of the label elements referred to in Article 17, points (c) to (h) shall be provided on a visible place on the respective pump. The unique formula identifier referred to in Article 25(7) does not need to be provided.

(c) When a vehicle fuel is supplied at a filling station through pumping into portable receptacles designed to be used for fuels, a copy of the label elements referred to in Article 17, points (c) to (h), shall be provided to be attached to the receptacle, unless the receptacle is already appropriately labelled. The unique formula identifier referred to in Article 25(7) does not need to be provided.'.

ANNEX II

In Annex I to Regulation (EC) No 1223/2009 Part A, point 2 is replaced by the following:

‘2. Physical/chemical characteristics and stability of the cosmetic product

The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product.

The stability of the cosmetics product under reasonably foreseeable storage conditions.

The specification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the preamble to Annexes II to VI, size of particles, physical and chemical properties.

The safety data of the nanomaterial (including its toxicological profile and exposure conditions) relating to the category of cosmetic product, as used in such products.’

ANNEX III

Annexes II to VI to Regulation (EC) No 1223/2009 are amended as follows:

(1) in the preamble to Annexes II to VI, point 2, the fifth indent is replaced by the following:

'- the name included in the internationally recognised nomenclature.';

(2) in the heading of tables in Annexes III to VI the title 'Name of Common Ingredients Glossary' is replaced by 'Name in the Internationally Recognised Nomenclature'.

ANNEX IV

Annexes I, II and IV to Regulation (EU) 2019/1009 are amended as follows:

(1) in Annex I, Part II, PFC 7: FERTILISING PRODUCT BLEND, point 4(c) is replaced by the following:

'(c) Article 8(8) (importers' obligation to keep the EU declaration of conformity at the disposal of the market surveillance authorities).';

(2) in Annex II, Part II, is amended as follows:

(a) in CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES, point 2 is deleted;

(b) in CMC 3: COMPOST, point 1(d) is replaced by the following:

'(d) composting additives which are necessary to improve the process performance or the environmental performance of the composting process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or';

(c) CMC 4: FRESH CROP DIGESTATE is amended as follows:

(i) point 1(b) is replaced by the following:

'(b) digestion additives which are needed to improve the process performance or the environmental performance of the digestion process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or';

(ii) point 3d is replaced by the following:

'3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used provided that the concentration of the additives needed in each of the processes does not exceed 5 % of the weight of the digestate or fraction used as input in the respective process.';

(d) CMC 5: DIGESTATE OTHER THAN FRESH CROP DIGESTATE is amended as follows

(i) point 1(d) is replaced by the following:

'(d) digestion additives which are necessary to improve the process performance or the environmental performance of the digestion process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or';

(ii) point 3d is replaced by the following:

‘3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used, provided that the concentration of the additives needed in each of the processes does not exceed 5% of the weight of the digestate or fraction used as input in the respective process.’;

(e) in CMC 6: FOOD INDUSTRY BY-PRODUCTS, point 2 is deleted;

(f) in CMC 8: NUTRIENT POLYMERS, point 1 is replaced by the following:

‘1. An EU fertilising product may contain polymers exclusively made up of monomer substances complying with the criteria set out in point 1 of CMC 1, where the purpose of the polymerisation is to control the release of nutrients from one or more of the monomer substances.’;

(g) in CMC 10: DERIVED PRODUCTS WITHIN THE MEANING OF REGULATION (EC) No 1069/2009, the table, point 1.3 is replaced by the following:

‘1.3. Additives needed in the processing referred to in points 1.1 and 1.2 may be used, provided that the concentration of the additives needed in each of the processes does not exceed 5% of the weight of the processed manure or fraction used as input in the respective process.’;

(h) in CMC 11: BY-PRODUCTS WITHIN THE MEANING OF DIRECTIVE 2008/98/EC, point 2 is deleted;

(i) in CMC 12: PRECIPITATED PHOSPHATE SALTS AND DERIVATES, point 13 is deleted;

(j) in CMC 13: THERMAL OXIDATION MATERIALS OR DERIVATES, point 8 is deleted;

(k) in CMC 14: PYROLYSIS AND GASIFICATION MATERIALS, point 7 is deleted;

(l) in CMC 15: RECOVERED HIGH PURITY MATERIALS, point 10 is deleted;

(3) in Annex IV, Part II is amended as follows:

(a) MODULE A – INTERNAL PRODUCTION CONTROL is amended as follows:

(i) in point 4.2, the first sentence is replaced by the following:

‘The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product or type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.’;

(ii) point 4.3. is replaced by the following:

‘4.3. The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.’;

(b) MODULE A1 - INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING is amended as follows:

(i) point 2.2.(f) is replaced by the following:

‘(f) the names, postal addresses and digital contacts of the sites, and of the operators of the sites, at which the product and its principal components were manufactured,’;

(ii) in point 5.2., the first sentence is replaced by the following:

‘The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.’;

(iii) point 5.3. is replaced by the following:

‘5.3. The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.’;

(c) MODULE B – EU-TYPE EXAMINATION is amended as follows:

(i) point 3.2.(a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his or her name, postal address and digital contact as well,’;

(ii) in point 6.1., the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(d) MODULE C – CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL is amended as follows:

(i) in point 3.2., the first sentence is replaced by the following:

‘The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.’;

(ii) point 3.3. is replaced by the following:

‘3.3. The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.’;

(e) MODULE D1 - QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:

(i) in point 5.2., the first indent is replaced by the following:

‘the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his or her name, postal address and digital contact as well,’;

(ii) in point 7.2., the first sentence is replaced by the following:

‘The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product or type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.’;

(iii) point 7.3. is replaced by the following:

‘The manufacturer shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.’