EUROPEAN
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Brussels, 19.10.2020
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COMMISSION DELEGATED REGULATION (EU) …/...

of 19.10.2020

amending Annexes II and III to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products[1] (hereinafter the BPR) aims to improve the functioning of the internal market for biocidal products, whilst ensuring a high level of protection of human and animal health and the environment. Annexes II and III to the BPR set out the information requirements for active substances and biocidal products, respectively.

According to Article 5(1)(d) of the BPR, active substances considered as having endocrine-disrupting properties on the basis of the scientific criteria specified in Commission Delegated Regulation (EU) 2017/2100[2] shall not be approved unless it is shown that at least one of the conditions in Article 5(2) of the BPR is met. Commission Delegated Regulation (EU) 2017/2100 applies since 7 June 2018. The European Chemical Agency (ECHA) and the European Food Safety Authority (EFSA) have developed, with the support of the Joint Research Centre (JRC), a common guidance document for implementing the criteria laid down in that Regulation, specifying an assessment strategy and information requirements supporting such an assessment[3].

Therefore, the information requirements in Annexes II and III to the BPR should be adapted to scientific and technical progress in relation to the determination of endocrine-disrupting properties. In addition, these Annexes should also be adapted to the current state of science, for example in relation to new test methods ensuring a better protection of human and animal health or reducing the number of tests conducted on vertebrate animals.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission has consulted an expert group (the 'Biocides CA meeting') in six meetings between September 2018 and September 2019, attended by representatives of Member States' competent authorities for biocidal products, ECHA and observers on possible amendments of Annexes II and III to the BPR. Draft versions of this Commission Delegated Regulation were discussed in February 2020 and May 2020.

In accordance with the Better Regulation agenda, a draft version of this Commission Delegated Regulation was open for feedback for a period of four weeks[4]. Eleven contributions[5] from NGOs, industry and industry associations were received. During this consultation concerns were raised pertaining to the prioritisation of non-animal methods over animal testing to minimise animal use, the complexity and costs of the proposed additional tests required to determine the endocrine-disrupting properties of

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1 OJ L 167, 27.6.2012, p. 1.

2 Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

3 The Guidance has been published in the EFSA Journal: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5311.

4 The contributions may be consulted here.

5 Four from animal welfare associations, one from a human health organization, two from European industry associations, three from individual companies, one from a testing laboratory.

active and non-active substances and the appropriateness of the wording of some testing requirements.

Although the received inputs contradicted occasionally each other depending on the respondents' objectives, those concerns were taken into account as far as possible in the final version of the Delegated Regulation as follows:

(1) The possibility to use *in vitro* and *in silico* methods for risk assessment purposes for some information requirements was already included in the draft version of the Delegated Regulation submitted for feedback. However, at the current state of science it is not possible to rely solely on non-animal testing strategies when it comes to determine for example the endocrine-disrupting properties of chemical substances. Therefore, additional requests submitted during the feedback to further reduce tests on vertebrate animals for the testing of endocrine-disrupting properties have not been accepted.

(2) Regulation (EU) No 528/2012 requires a determination of the endocrine disrupting properties of active substances. Moreover, Commission Delegated Regulation (EU) No 2017/2100 sets out the scientific criteria for the determination of endocrine-disrupting properties and applies from 7 June 2018. Therefore, it is not possible to accommodate the request made by some industry associations and individual companies to postpone the entry into force of amendments to the information requirements for determining endocrine-disrupting properties until the finalisation of the work programme for the systematic examination of existing active substances.

(3) The wording of the information requirements for genotoxicity, neurotoxicity, and carcinogenicity have been clarified in the final version of the Delegated Regulation.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis for the Delegated Regulation is Article 85 of the BPR. The Delegated Regulation amends Annexes II and III to Regulation (EU) No 528/2012, and adapts them to scientific and technical progress.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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[6] and in particular Article 85 thereof,

Whereas:

(1) Annexes II and III to Regulation (EU) No 528/2012 set out the information requirements for respectively active substances and biocidal products, which an application for approval of an active substance and an application for authorisation of a biocidal product need to fulfil.

(2) It is necessary to modify the information requirements concerning active substances and biocidal products in order to take into account new methods for generating better information on toxicological properties (such as irritation, neurotoxicity, genotoxicity, etc.), new testing strategies favouring *in vitro* tests over *in vivo* tests in order to reduce testing on vertebrate animals and a testing strategy and methods for the determination of endocrine disrupting properties of substances in accordance with the criteria laid down in Commission Delegated Regulation (EU) No 2017/2100[7].

(3) A dossier should be considered as complete if it complies with the requirements of Article 6(1) and Article 20(1), and in particular with the information requirements of Annexes II and III to Regulation (EU) No 528/2012. Pre-submission consultations between the applicant for the approval of an active substance or for the authorisation of a biocidal product and the evaluating competent authority contribute to the quality of the dossier and the progress of the evaluation process. The text of paragraphs 5 and 7, respectively, of points 2 of the introductory parts of Annexes II and III should be modified to ensure that the applicants include the conclusions of such consultation in the application to ensure the smooth operation of the evaluation procedure.

(4) In accordance with Annexes II and III to Regulation (EU) No 528/2012, tests submitted for the purpose of the approval of an active substance or the authorisation of a biocidal product, respectively, are to be conducted in accordance with the methods

[6] OJ L 167, 27.6.2012, p. 1.

[7] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

described in Commission Regulation (EC) No 440/2008[8]. As there may be a period between the validation of an internationally recognised test method and its inclusion in Regulation (EC) No 440/2008, point 5 of the introductory parts of Annexes II and III to Regulation (EU) No 528/2012 should be amended to allow applicants to apply the most updated version of test methods.

(5) Specific rules for the adaptation of the information requirements listed in the first column of the tables in Titles 1 and 2 of Annexes II and III to Regulation (EU) No 528/2012 are limited to concerns related to the recourse to testing on vertebrates. As some requirements listed in that first column do not include testing on vertebrates, the scope of adaptations listed in the third column of the tables listed in Titles 1 and 2 of Annexes II and III should be extended to cover cases where no testing on vertebrates is involved.

(6) Point 2 of Title 1 of Annex II sets out the information requirements for the identification of the active substance. Those requirements need to be adapted in order to allow identification of active substances generated *in situ*.

(7) Point 6 of Title 1 of Annexes II and III set out the requirements for the assessment of the effectiveness of an active substance or a biocidal product, respectively, against target organisms. Such effectiveness should also be demonstrated for the activity of an active substance in the absence of other substances that may affect the effectiveness. For treated articles, the effectiveness of the biocidal properties conferred to the article should be demonstrated. Moreover, the current provisions on unintended side-effects in point 6 do not specify on which type of organisms or objects information should be provided. Therefore, it should be clarified that any observation on undesirable or unintended side effects is to be limited to non-target organisms or objects and material to be protected by the active substance or biocidal product.

(8) Article 62 of Regulation (EU) No 528/2012 requires that testing on vertebrate animals be undertaken only as a last resort. In setting data requirements for the approval of active substances and the authorisation of biocidal products, priority should be given to reliable *in vitro* methods as a substitute to *in vivo* methods requiring the use of vertebrate animals. The testing strategies included in Annexes II and III to Regulation (EU) No 528/2012 therefore need to be adapted to recently validated *in vitro* test guidelines of the Organisation for Economic Co-operation and Development (OECD) and other international standards.

(9) The first mandatory requirement for following up on a positive *in vitro* gene mutation test is currently the *in vivo* unscheduled DNA synthesis (UDS) test, which has inherent limitations and low sensitivity. The Scientific Committee of the European Food Safety Authority[9] concluded in an opinion published in November 2017 that negative UDS results are not a proof that a substance does not induce gene mutation. The reference to the UDS test should, therefore, be removed and replaced by a reference to an appropriate *in vivo* somatic cell genotoxicity study.

(10) The current data requirements in Annex II to Regulation (EU) No 528/2012 require a two-generation reproductive toxicity study (TGRTS) to be used to investigate the reproductive toxicity of a substance. That Annex furthermore stipulates that the

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[8] 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).

[9] Scientific Opinion on the clarification of some aspects related to genotoxicity assessment. EFSA Journal 2017;15(12):5113, 25 pp. https://doi. org/10.2903/j.efsa.2017.5113.

extended one-generation reproductive toxicity study (EOGRTS) can be considered as an alternative approach to the TGRTS. The EOGRTS offers a number of advantages in comparison to the TGRTS as it assesses in addition to effects on the male and female reproductive system more toxicological effects linked to endocrine-disrupting mode of actions. Therefore, if there is no TGRTS available, an EOGRTS should be performed instead.

(11) Exposure to neurotoxicants in utero or during childhood can contribute to a variety of neurodevelopmental and neurological disorders that manifest themselves only as a person ages, and may contribute to neurodegenerative diseases such as Parkinson's or Alzheimer's diseases. To address this concern, test guidelines to adequately screen and characterise active substances potentially toxic for the developing brain should be included in Annex II to Regulation (EU) No 528/2012.

(12) The current structure of the information requirements relating to health data and medical treatment in points 8.12.1 to 8.12.8 of Title 1 of Annex II to Regulation (EU) No 528/2012 may lead to submission of overlapping information under a number of those points. The data requirements should therefore be streamlined to reduce compliance costs and unnecessary delays in the evaluation of applications.

(13) An evaluation of the potential for unintended effects of substances on the immune system should be conducted. However, as no specific developmental immunotoxicity study is available in an OECD test guideline, relevant data should be required to be provided as additional data set.

(14) Point 8.18 of Title 1 of Annex II to Regulation (EU) No 528/2012 duplicates the content of point 13 of that Title and should therefore be deleted.

(15) Point 9.1.1 of Title 1 of Annex II to Regulation (EU) No 528/2012 should be amended in order to clarify when long-term toxicity testing on fish is to be carried out. The list of OECD test methods in point 9.1.6.1 should be replaced in order to take into account on-going developments as regards the information requirements on long-term toxicity studies on fish.

(16) Several information requirements for microorganisms included in Title 2 of Annexes II and III to Regulation (EU) No 528/2012 are either overlapping with other provisions in the Annexes or are irrelevant for microorganisms. Title 2 of Annexes II and III to Regulation (EU) No 528/2012 should therefore be amended in order to eliminate such overlaps and irrelevant information requirements.

(17) The fourth paragraph of point 2 of the introductory part of Annex III to Regulation (EU) No 528/2012 provides that for non-active substances, the applicants are to use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006[10]. That paragraph should be amended in order to clarify that applicants may need to provide additional information on substances of concern included in biocidal products in particular in order to submit a data set that enables the identification of their endocrine disrupting properties.

[10] Regulation (EC) No 1907/2006 of 18 December 2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), stablishing 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).

(18) In order to avoid imposing a disproportionate burden on economic operators, certain tests required by Annex II or Annex III to Regulation (EU) No 528/2012 that were already initiated or carried out before the date of application of this Regulation should be considered appropriate to address the information requirements.

(19) A reasonable period should be allowed to elapse before the data requirements, as modified by this Delegated Regulation become applicable so that the applicants can make the necessary arrangements to meet those requirements. However, in the interests of the protection of human and animal health and of the environment, the applicants should be allowed to apply the changes introduced by this Regulation before its date of application on a voluntary basis.

(20) Regulation (EU) No 528/2012 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) No 528/2012 is amended in accordance with Annex I to this Regulation.

Annex III to Regulation (EU) No 528/2012 is amended in accordance with Annex II to this Regulation.

Article 2

Notwithstanding the date of application of this Regulation laid down in Article 3, applications for approval of an active substance and applications for authorisation of a biocidal product submitted before … [*OJ: please insert a date - 12 months after entry into force of this amending Regulation*] shall be evaluated based on information requirements applicable on the day of submission of such applications.

Article 3

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

It shall apply from … [*OJ: please insert a date - 12 months after entry into force of this amending Regulatio*n].

By way of derogation, applicants may choose to apply the data requirements as set out in the Annexes I and II to this Regulation from … [*OJ: please insert the date of entry into force of this amending Regulation*].

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

Done at Brussels, 19.10.2020

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

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ANNEXES 1 to 2

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) .../....

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ANNEX I

Annex II to Regulation (EU) No 528/2012 is amended as follows:

(1) the introductory part is amended as follows:

(a) the fifth paragraph of point 2 is replaced by the following:

'The applicant shall initiate a pre-submission consultation with the prospective evaluating body. In addition to the obligation set out in Article 62(2), applicant may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out. The applicant shall document such pre-submission consultations and their outcomes and shall include the relevant documents in the application.'

(b) point 5 is replaced by the following:

'5. Tests submitted for the purpose of the approval of an active substance shall be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008[*], or any revised version of these methods not yet included in that Regulation.

However, if a method is inappropriate or not described in Commission Regulation (EC) No 440/2008, other methods shall be used which are scientifically appropriate and their appropriateness shall be justified in the application.

When test methods are applied to nano-materials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of these materials.

[*] 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).'

(2) the table in Title 1 is amended as follows:

(a) the heading of the third column is replaced by the following:

		'Column 3 Specific rules for adaptation from column 1'

(b) row 2 is replaced by the following:

'2	IDENTITY OF THE ACTIVE SUBSTANCE (AND ITS PRECURSOR(S) IF THE ACTIVE SUBSTANCE IS GENERATED *IN SITU*) For the active substance and, if applicable, its precursors, the		

	information given in this Section shall be sufficient to enable the active substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items listed in this Section, the reasons shall be clearly stated'		

(c) row 2.5 is replaced by the following:

'2.5	Molecular and structural formula (including SMILES notation, if available and appropriate). For precursor(s) and for active substances generated *in situ*, information about all generated chemical substances (intended and unintended)		In case it is not possible to exactly define the molecular structure of the precursor(s) and/or active substance, the molecular and structural formulas do not need to be provided'

(d) row 2.8 is replaced by the following:

'2.8	Method of manufacture (syntheses pathways) of active substance including information on starting materials and solvents including suppliers, specifications and commercial availability. For active substances generated *in situ*, a description of the reaction schemes including all intermediate reactions and their associated chemical substances (intended and unintended) shall be provided'		

(e) the following row 2.11.1 is inserted:

'2.11.1	Analytical profile of at least five representative samples taken from the *in situ* generated substance(s), providing information on the content of the active substance(s) and any other constituent above 0,1% w/w, including residues of precursor(s)'		

(f) row 6.6 is replaced by the following:

'6.6	Efficacy data to support: – the innate activity of the		

	active substance for the intended use(s) and – any claims made on treated articles regarding the biocidal properties conferred to the article Efficacy data shall include any available standard protocols, laboratory tests or field trials and performance standards where appropriate, or data similar to those available for suitable reference products'		

(g) row 6.7.2 is replaced by the following:

'6.7.2	Observations on undesirable or unintended side effects on non-target organisms or on objects and material to be protected'		

(h) rows 8.1, 8.2 and 8.3 are replaced by the following:

'8.1	Skin corrosion or irritation The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data (b) skin corrosion, *in vitro* testing (c) skin irritation, *in vitro* testing (d) skin corrosion or irritation, *in vivo* testing		The study/ies in column 1 do(es) not need to be conducted if: – the available information indicates that the substance meets the criteria for classification for skin corrosion or irritation, – the substance is a strong acid (pH≤2,0) or base (pH≥11,5), – the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, – the substance meets the classification criteria for acute toxicity (Category 1) by the dermal route or,

		– an acute toxicity study by the dermal route provides conclusive evidence on skin corrosion or irritation adequate for classification If results from one of the two studies listed in point (b) or point (c) in column 1 of this row already allow conclusive decision on the classification of a substance or on the absence of skin irritation potential, the second study does not need to be conducted An *in vivo* study for skin corrosion or irritation shall be considered only if the *in vitro* studies listed in points (b) and (c) in column 1 of this row are not applicable, or the results of these studies are not adequate for classification and risk assessment *In vivo* studies for skin corrosion or irritation that were carried out or initiated before … (*OJ please insert the date of application of this amending Regulation*) shall be considered appropriate to address this information requirement

8.2	Serious eye damage or eye irritation The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data (b) serious eye damage or eye irritation, *in vitro* testing (c) serious eye damage or eye irritation, *in vivo* testing		The study/ies in column 1 do(es) not need to be conducted if: – the available information indicates that the substance meets the criteria for classification for eye irritation or causing serious damage to eyes,

		– the substance is a strong acid (pH≤2,0) or base (pH≥11,5), – the substance is spontaneously flammable in air or in contact with water or moisture at room temperature or, – the substance meets the classification criteria for skin corrosion leading to classification of the substance as 'serious eye damage' (category 1) If results from a first *in vitro* study do not allow a conclusive decision on the classification of the substance or on the absence of eye irritation potential (an)other(s) *in vitro* study(ies) for this endpoint shall be considered. An *in vivo* study for serious eye damage or eye irritation shall be considered only if the *in vitro* study(ies) listed in point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment *In vivo* studies for serious eye damage or eye irritation that were carried out or initiated before … (*OJ please insert the date of application of this amending Regulation*) shall be considered appropriate to address this information requirement
'8.3 Skin sensitisation		The study/ies in column 1

The information shall allow to conclude whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Category 1A). The information should be sufficient to perform a risk assessment where required The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data (b) skin sensitisation, *in vitro* testing. Information from *in vitro or in chemico* test method(s) referred to in point 5 of the introductory part of this Annex and addressing each of the following key events of skin sensitisation: (i)molecular interaction with skin proteins; (ii)inflammatory response in keratinocytes; (iii)activation of dendritic cells (c) skin sensitisation *in vivo* testing. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for *in vivo* testing. Another skin sensitisation test may only be used in exceptional cases. If another skin sensitisation test is used, justification shall be provided		do(es) not need to be conducted if: – the available information indicates that the substance meets the criteria for classification for skin sensitisation or skin corrosion, – the substance is a strong acid (pH≤2,0) or base (pH≥11,5) or – the substance is spontaneously flammable in air or in contact with water or moisture at room temperature *In vitro* tests do not need to be conducted if: – an *in vivo* study referred to in point (c) of column 1 of this row is available or, – the available *in vitro or in chemico* test methods are not applicable for the substance or the results obtained from those studies are not adequate for classification and risk assessment If information from test method(s) addressing one or two of the key events described under point (b) in column 1 of this row allows for classification of the substance and risk assessment, studies addressing the other key event(s) do not need to be conducted An *in vivo* study for skin

		sensitisation shall be conducted only if *in vitro or in chemico* test methods described under point (b) in column 1 of this row are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment *In vivo* skin sensitisation studies that were carried out or initiated before … (*OJ please insert the date of application of this amending Regulation*) shall be considered appropriate to address this information requirement'

(i) row 8.6 is replaced by the following:

'8.6 *In vivo* genotoxicity study The assessment shall comprise the following tiers: (a) If there is a positive result in any of the *in vitro* genotoxicity studies as listed in 8.5 and there are no reliable results available from an appropriate *in vivo* somatic cell genotoxicity study, an appropriate *in vivo* somatic cell genotoxicity study shall be conducted (b) A second *in vivo* somatic cell genotoxicity study may be necessary depending on the *in vitro* and *in vivo* results, type of effects, quality and relevance of all available data (c) If there is a positive result from an *in vivo* somatic cell genotoxicity study available, the potential for germ cell mutagenicity should be considered based on all available data, including	ADS	The study/ies in column 1 do(es) not need to be conducted if: – the results are negative for the three *in vitro* tests listed in 8.5 and no other concern has been identified (e.g. metabolites of concern formed in mammals) or, – the substance meets the criteria to be classified as a germ cell mutagen category 1A or 1B The germ cell genotoxicity test does not need to be conducted if the substance meets the criteria to be classified as a carcinogen, category 1A or 1B and a germ cell mutagen category 2'

	toxicokinetic evidence to demonstrate whether the substance has the capacity to reach germ cells. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered		

(j) rows 8.10 to 8.10.3 are replaced by the following:

‘8.10	Reproductive toxicity For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		The studies do not need to be conducted if: – the substance meets the criteria to be classified as a genotoxic carcinogen (classified both as germ cell mutagen category 2, 1A or 1B and carcinogenic category 1A or 1B), and appropriate risk management measures are implemented including measures related to reproductive toxicity, – the substance meets the criteria to be classified as a germ cell mutagen category 1A or 1B and appropriate risk management measures are implemented including measures related to reproductive toxicity, – the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently

		comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma or blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates that there is no or negligible human or animal exposure, – the substance meets the criteria to be classified as reproductive toxicity category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for sexual function and fertility will be necessary. A full justification must be provided and documented if investigations for developmental toxicity are not conducted or, – the substance is known to cause developmental toxicity, meeting the criteria for classification as

			reproductive toxicity category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. A full justification must be provided and documented if investigations for sexual function and fertility is not conducted Notwithstanding the provisions of this column of this row, studies on reproductive toxicity may need to be conducted to obtain information on endocrine disrupting properties as laid down in 8.13.3.1.
8.10.1	Pre-natal development toxicity study (OECD TG 414) on two species, preferred first species is rabbit (non-rodent) and preferred second species is rat (rodent); oral route of administration is the preferred route		The study on the second species shall not be conducted if the study performed on the first species or other available data indicate that the substance causes developmental toxicity meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment
8.10.2	Extended One-Generation Reproductive Toxicity Study (OECD		A two-generation reproductive toxicity study conducted in

	TG 443), with cohorts 1A and 1B and extension of cohort 1B to include the F2 generation with the aim to produce 20 litters per dose group, F2 pups must be followed to weaning and investigated similarly as F1 pups. Rat is the preferred species and oral route of administration is the preferred route The highest dose level should be based on toxicity and selected with the aim to induce reproductive and/or other systemic toxicity		accordance with OECD TG 416 (adopted 2001 or later) or equivalent information shall be considered appropriate to address this information requirement, if the study is available and was initiated before … (*OJ please insert the date of application of this amending Regulation*)

8.10.3	Developmental neurotoxicity Developmental Neurotoxicity Study in accordance with OECD TG 426, or any relevant study (set) providing equivalent information, or cohorts 2A and 2B of an Extended One-Generation Reproductive Toxicity study (OECD TG 443) with additional investigation for cognitive functions		The study shall not be conducted if the available data: – indicate that the substance causes developmental toxicity and meets the criteria to be classified as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and – are adequate to support a robust risk assessment’

(k) the following row 8.10.4 is inserted:

‘8.10.4	Further studies A decision on the need to perform additional studies including those informing on the mechanisms should be based on the outcomes of the studies listed in 8.10.1, 8.10.2 and 8.10.3 and all other relevant available data	ADS’	

(l) row 8.11.2 is replaced by the following:

‘8.11.2	Carcinogenicity testing in a second species (a) A second carcinogenicity study should be conducted		The second carcinogenicity study does not need to be conducted if the applicant can justify on the basis of scientific

	using the mouse as test species (b) For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		grounds that it is not necessary'

(m) rows 8.12.1 to 8.12.8 are replaced by the following:

'8.12.1	Information on signs of poisoning, clinical tests, first aid measures, antidotes, medical treatment and prognosis following poisoning		
8.12.2	Epidemiological studies		
8.12.3	Medical surveillance data, health records and case reports'		

(n) rows 8.13.2 and 8.13.3 are replaced by the following:

'8.13.2	Neurotoxicity If the active substance is an organophosphorus compound or if there is an indication, knowledge of the mechanism of action or knowledge from acute or repeated dose studies that the active substance may have neurotoxic properties, additional information or specific studies (such as OECD TG 424 or OECD TG 418 or 419 or equivalent) will be required If anticholinesterase activity is detected a test for response to reactivating agents should be considered For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route	ADS	

8.13.3	Endocrine disruption The assessment of endocrine		Where sufficient weight of evidence to conclude on the

	disruption shall comprise the following tiers: (a) An assessment of the available information from the following studies and any other relevant information, including *in vitro* and *in silico* methods: (i)8.9.1 A 28-day oral toxicity study in rodents (OECD TG 407) (ii)8.9.2 A 90-day oral toxicity study in rodents (OECD TG 408) (iii)8.9.4 A repeated dose oral toxicity study in non-rodents (OECD TG 409) (iv)8.10.1 A prenatal developmental toxicity study (OECD TG 414) (v)8.10.2 An extended one-generation reproductive toxicity study (OECD TG 443) or two-generation reproductive toxicity study (OECD TG 416) (vi)8.10.3 A developmental neurotoxicity study (OECD TG 426) (vii)8.11.1 A combined carcinogenicity study and long-term repeated dose toxicity study (OECD TG 451-3) (viii)A systematic review of the literature including studies on mammals and non-mammalian organisms (b) If there is any information		presence or absence of a particular endocrine disrupting mode of action is available: – further testing on vertebrate animals for that effect shall be omitted for that mode of action; – further testing not involving vertebrate animals may be omitted for that mode of action. In all cases, adequate and reliable documentation shall be provided’

	suggesting that the active substance may have endocrine disrupting properties, or if there is incomplete information on key parameters relevant for concluding on endocrine disruption, then additional information or specific studies shall be required to elucidate: (1) the mode or the mechanism of action and/or; (2) potentially relevant adverse effects in humans or animals For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to consider the oral route and conduct animal studies by the oral route		

(o) the following row 8.13.3.1 is inserted:

‘8.13.3.1	Specific additional studies to investigate potential endocrine disrupting properties may include, but are not limited to the following: (a) the mammalian toxicity studies listed in 8.13.3 (a) (b) the *in vitro* assays: (i) Estrogen receptor transactivation assay (OECD TG 455), (ii)Androgen receptor transactivation assay, (OECD TG 458), (iii)H295R steroidogenesis assay (OECD TG 456) (iv)the Aromatase assay (human recombinant)OPPTS 890.1200 (c) Uterotrophic bioassay in	ADS’	

	rodents (OECD TG 440) and Hershberger bioassay in rats (OECD TG 441) (d) Pubertal development and Thyroid Function in Intact Juvenile or Peripubertal Male Rats (OPPTS 890.1500) The decision to carry out studies in mammals shall be taken based on all available information, including a systematic review of the literature (including information on endocrine disrupting effects in non-target organisms) and the availability of suitable *in silico or in vitro* methods		

(p) rows 8.13.4 and 8.13.5 are replaced by the following:

‘8.13.4	Immunotoxicity and developmental immunotoxicity If there is any evidence from repeat dose or reproductive toxicity studies that the active substance may have immunotoxic properties, then additional information or specific studies shall be required to elucidate: (1) the mode or the mechanism of action and/or; (2) potentially relevant adverse effects in humans or animals. For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to consider the oral route and conduct animal studies by the oral route	ADS	

8.13.5	Further mechanistic studies A decision on the need to perform additional studies should be based on all relevant data	ADS’	

(q) row 8.18 is deleted.

(r) row 9.1.1 is replaced by the following:

‘9.1.1	Short-term toxicity testing on fish When short-term fish toxicity data is required, the threshold approach (tiered strategy) should be applied A long-term toxicity testing on fish in accordance with point 9.1.6.1 shall be considered if the substance is poorly water soluble, i.e. below 1 mg/L		The study does not need to be conducted if: – a valid long-term aquatic toxicity study on fish is available – sufficient weight of evidence including the use of other data such as the Fish Embryo Acute Toxicity (FET, OECD TG 236) and/or results obtained from non-animal methods is available for this data requirement’

(s) row 9.1.6.1 is replaced by the following:

‘9.1.6.1	Long term toxicity testing on fish The information shall be provided from long-term toxicity testing on fish in which early life-stages (eggs, larvae or juveniles) are exposed	ADS’	

(t) row 9.10 is replaced by the following:

‘9.10	Endocrine disruption The assessment of endocrine disruption properties shall comprise the following tiers: (a) An assessment of the mammalian data set in accordance with 8.13.3 to assess whether the substance has endocrine disrupting properties based on data in relation to mammals (b) If it cannot be concluded based on the mammalian data in accordance with 8.13.3 or 9.1.6.1 that the substance has endocrine disrupting properties, then studies set out in 9.10.1 or 9.10.2 shall be considered taking account		

	of any other available relevant information, including a systematic review of the literature'		

(u) the following rows 9.10.1, 9.10.2 and 9.10.3 are inserted:

'9.10.1	Endocrine disruption in fish Specific studies to investigate potential endocrine disrupting properties may include, but are not limited to the following data requirements: (a) Medaka extended one-generation test (MEOGRT, OECD TG 240), (b) Fish life cycle toxicity test (FLCTT, OPPTS 850.1500) covering all the 'estrogen-, androgen- and steroidogenic-mediated' (EAS) parameters foreseen to be measured in the MEOGRT study		The study does not need to be carried out if : – there is no indication for endocrine activity or endocrine related effects from a sufficient mammalian data set in accordance with 8.13.3 or from any other relevant information (e.g. literature) and – valid *in vivo* data is available, with no information suggesting that the active substance may elicit endocrine activity or effects potentially related to endocrine activity in either the Fish short term reproduction assay (FSTRA; OECD TG 229), or the 21-days fish assay (OECD TG 230) or Fish sexual developmental test (FSDT, OECD TG 234) If other data are available covering the estrogenic, androgenic and steroidogenic, (EAS) related modalities or parameters investigated in OECD TG 229 or OECD TG 230 or OECD TG 234, then those data can be used instead

9.10.2	Endocrine disruption in amphibians Specific additional studies to investigate potential endocrine disrupting properties may include, but are not limited to Larval amphibian growth and development assay (LAGDA; OECD TG 241)		The study does not need to be carried out if: – there is no indication for endocrine activity or endocrine related effects from a sufficient mammalian data set in accordance with 8.13.3 or from any other relevant information (e.g. literature) and – valid *in vivo* data is available, with no information suggesting that the active substance may have endocrine disrupting properties in an Amphibian metamorphosis assay (AMA; OECD 231)

9.10.3	If there is information suggesting that the active substance may have endocrine disrupting properties, or if there is incomplete information on key parameters relevant for concluding on endocrine disruption, additional information or specific studies, as necessary, shall be required to elucidate: (a)the mode or the mechanism of action and/or; (b)potentially relevant adverse effects in humans or animals.	ADS’	

(3) the table in Title 2 is amended as follows:

(a) the heading of the third column is replaced by the following:

		‘Column 3 Specific rules for adaptation from column 1’

(b) row 2.4 is replaced by the following:

‘2.4	Specification of the technical grade active ingredient’		

(c) the following rows 2.4.1, 2.4.2 and 2.4.3 are inserted:

‘2.4.1	Content of the active micro-organism and identity and content of relevant metabolites or toxins		

2.4.2	Identity and content of impurities, additives, contaminating micro-organisms		

2.4.3	Analytical profile of batches’		

(d) row 2.5 is replaced by the following:

‘2.5	Method of production and quality control’		

(e) rows 2.6 to 2.9 are deleted

(f) row 3.5 is replaced by the following:

‘3.5	Information on the production of relevant metabolites and toxins’		

(g) rows 4.1 and 4.2 are replaced by the following:

‘4.1	Methods, procedures and criteria used to establish the presence and identity of the micro-organism		
4.2	Analytical methods for the analysis of the micro-organism as manufactured’		

(h) the following row 4.3 is inserted:

‘4.3	Methods used for monitoring purposes to determine and quantify residues (viable or non-viable)’		

ANNEX II

Annex III to Regulation (EU) No 528/2012 is amended as follows:

(1) the introductory part is amended as follows:

(a) the fourth paragraph of point 2 is replaced by the following:

'For some of the information requirements set out in this Annex, it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by the Agency in accordance with point (e) of Article 77(2) of that Regulation. However, the information may be not sufficient or adequate to determine whether a non-active substance contained in a biocidal product has hazardous properties and the evaluating body may conclude that further data are required.'

(b) The seventh paragraph of point 2 is replaced by the following:

'The applicant shall initiate a pre-submission consultation with the prospective evaluating body. In addition to the obligation set out in Article 62(2), the applicant may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out. The applicant shall document such pre-submission consultations and their outcomes and shall include the relevant documents in the application.'

(c) point 5 is replaced by the following:

'5. Tests submitted for the purpose of authorisation shall be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008 or any revised version of these methods not yet included in that Regulation.

However, if a method is inappropriate or not described in Commission Regulation (EC) No 440/2008*, other methods shall be used which are scientifically appropriate and their appropriateness shall be justified in the application.

When test methods are applied to nano-materials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of these materials.

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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).'

(2) The table in Title 1 is amended as follows:

(a) the heading of the third column is replaced by the following:

		'Column 3 Specific rules for adaptation

		from column 1’

(b) row 6.6 is replaced by the following:

‘6.6 The proposed claims for the product and, where claims are made, for treated articles regarding the biocidal properties conferred to the article’		

(c) row 6.8.2 is replaced by the following:

‘6.8.2 Observations on undesirable or unintended side-effects on non-target organisms or on objects and material to be protected’		

(d) Rows 8.1, 8.2 and 8.3 are replaced by the following:

‘8.1 Skin corrosion or irritation The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data (b) skin corrosion, *in vitro* testing (c) skin irritation, *in vitro* testing (d) skin corrosion or irritation, *in vivo* testing		Testing of the product or mixture does not need to be conducted if: – there are sufficient valid data on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected, – the product or mixture is a strong acid (pH≤2,0) or base (pH≥11,5), – the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature, – the product or mixture meets the classification criteria for acute toxicity

			category 1 by the dermal route or, – an acute toxicity study by the dermal route provides conclusive evidence on skin corrosion or irritation adequate for classification. If results from one of the two studies listed in points (b) or (c) in column 1 of this row already allow conclusive decision on the classification of product or mixture or on the absence of skin irritation potential, the second study does not need to be conducted An *in vivo* study for skin corrosion or irritation shall be considered only if the *in vitro* studies listed in points (b) and (c) in column 1 of this row are not applicable, or the results of these studies are not adequate for classification and risk assessment and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable *In vivo* studies for skin corrosion or irritation that were carried out or initiated before … [*OJ please insert the date of application of this amending Regulation]* shall be considered appropriate to address this information requirement

8.2	Serious eye damage or eye irritation The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal		Testing on the product or mixture does not need to be conducted if: – there are sufficient valid data available

	data (b) serious eye damage or eye irritation, *in vitro* testing (c) serious eye damage or eye irritation, *in vivo* testing		on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected, – the product or mixture is a strong acid (pH≤2,0) or base (pH≥11,5), – the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature or, – the product or mixture meets the classification criteria for skin corrosion leading to its classification as 'serious eye damage' category 1 If results from a first *in vitro* study do not allow a conclusive decision on the classification of the product or mixture or on the absence of eye irritation potential (an)other(s) *in vitro* study(ies) for this endpoint shall be considered An *in vivo* study for serious eye damage or eye irritation shall be considered only if the *in vitro* study(ies) under point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk

		assessment and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable *In vivo* studies for serious eye damage or eye irritation that were carried out or initiated before … (*OJ please insert the date of application of this amending Regulation*) shall be considered appropriate to address this information requirement

8.3	Skin sensitisation The information shall allow to conclude whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Category 1A). The information should be sufficient to perform a risk assessment where required The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data (b) skin sensitisation, *in vitro* testing. Information from *in vitro or in chemico* test method(s) conducted in accordance with point 5 of the introductory part of this Annex and addressing each of the following key events of skin sensitisation: (i)molecular interaction with skin proteins; (ii)inflammatory response in keratinocytes; (iii)activation of dendritic cells.		Testing on the product or mixture does not need to be conducted if: – there are sufficient valid data available on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008 , and synergistic effects between any of the components are not expected, – the available information indicates that the product or mixture should be classified for skin sensitisation or skin corrosion, – the product or mixture is a strong acid (pH≤2,0) or base (pH≥11,5) or, – the product or mixture is spontaneously flammable in air or

(c)	skin sensitisation *in vivo* testing. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for *in vivo* testing. Another skin sensitisation test may only be used in exceptional circumstances. If another skin sensitisation test is used, scientific justification shall be provided.		in contact with water or moisture at room temperature *In vitro* tests do not need to be conducted if: – an *in vivo* study referred to in point (c) in column 1 of this row is available or, – the available *in vitro or in chemico* test methods are not applicable for the product or mixture or the results obtained from these studies are not adequate for classification and risk assessment If information from test method(s) addressing one or two of the key events described in point (b) in column 1 of this row already allows for classification of the substance and risk assessment, studies addressing the other key event(s) do not need to be conducted An *in vivo* study for skin sensitisation shall be considered only if *in vitro or in chemico* studies referred to in point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicabl *In vivo* studies for skin sensitisation that were carried out or initiated before … (*OJ*

		please insert the date of application of this amending Regulation) shall be considered appropriate to address this information requirement'

(e) row 8.7 is replaced by the following:

'8.7 Available toxicological data relating to: (a) non-active substance(s) (i.e. substance(s) of concern) and, (b) a mixture that a substance(s) of concern is a component of Tests listed in Section 8 of the table in Title 1 of Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of if insufficient data are available and cannot be inferred through read-across, *in silico* or other accepted non-testing approaches		Testing on the product or mixture does not need to be conducted if all of the following conditions are met: – there are valid data available on each of the components in the mixture to allow classification of the mixture in accordance with the rules laid down in Regulation (EC) No 1272/2008, – a conclusion can be made whether the biocidal product can be considered as having endocrine disrupting properties, – synergistic effects between any of the components are not expected'

(f) row 9.1 is replaced by the following:

'9.1 Available ecotoxicological data relating to: (a) non-active substance(s) (i.e. substance(s) of concern), (b) a mixture that a substance(s) of concern is a component of Tests listed in Section 9 of Title 1 of Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of if insufficient data are available and cannot be inferred		Testing on the product or mixture does not need to be conducted if all the following conditions are met: – there are valid data available on each of the components in the mixture to allow classification of the mixture in accordance with the rules laid down in Regulation (EC) No

through read-across, *in silico* or other accepted non-testing approaches		1272/2008, – a conclusion can be made whether the biocidal product can be considered as having endocrine disrupting properties, – synergistic effects between any of the components are not expected.’

(3) the table in Title 2 is amended as follows:

(a) the heading of the third column is replaced by the following:

		‘Column 3 Specific rules for adaptation from column 1’

(b) row 2.3 is replaced by the following:

‘2.3	Detailed quantitative (g/kg, g/l, % w/w (v/v), cfu/g, cfu/l or IU/mg or any other appropriate unit) and qualitative information on the constitution, composition and function of the biocidal product, e.g. micro-organism, active substance(s) and non-active substances and any other relevant components All relevant information on individual ingredients and the final composition of the biocidal product shall be given’		

(c) rows 3.6.8 to 3.6.12 are deleted

(d) the following rows 3.6.8 and 3.6.9 are inserted:

‘3.6.8	Spraying patterns - aerosols		
3.6.9	Other technical characteristics’		

(e) rows 4 to 4.12.3 are replaced by the following

4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISITICS		

‘4.1. Explosives		
4.2. Flammable aerosols		
4.3. Flammable liquids		
4.4. Flammable solids		
4.5. Oxidising liquids		
4.6. Oxidising solids		
4.7. Corrosive to metals		
4.8. Other physical indications of hazard		
4.8.1. Auto-ignition temperatures of products (liquids and gases)		
4.8.2. Relative self-ignition temperature for solids		
4.8.3. Dust explosion hazard’		

(f) row 10.3 is replaced by the following:

‘10.3 Leaching behaviour and/or mobility	ADS’	

EUROPEAN
COMMISSION

Brussels, 3.11.2020
C(2020) 7402 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 3.11.2020

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include citric acid as an active substance in Annex I thereto

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 28(1) of Regulation (EU) No 528/2012 (the BPR) empowers the Commission to adopt delegated acts in order to include an active substance into Annex I to the BPR after receiving the opinion of the European Chemicals Agency (ECHA), provided that there is evidence that the active substance do not give rise to concern according to the conditions set out in Article 28(2) of that Regulation. A simplified authorisation procedure is provided in Chapter V of the BPR for biocidal products containing active substances listed in Annex I to the BPR and fulfilling other conditions set out in Article 25 of that Regulation.

Citric acid has been assessed as an existing active substance within the review programme set out in Article 89(1) of the BPR established by Commission Delegated Regulation (EU) No 1062/2014 (the Review Regulation) for use in biocidal products of product-type n°2 "disinfectants and algaecides not intended for direct application to humans or animals".

In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Product Committee of ECHA adopted its opinion on 16 February 2016 (ECHA/BPC/088/2016), concluding that biocidal products of product-type n°2 containing citric acid may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC which were the requirements applicable to the examination of the application for approval of citric acid in accordance with Article 90(2) of Regulation (EU) No 528/2012. Citric acid was therefore approved as an active substance for use in biocidal products of product-type n°2 by Commission Implementing Regulation (EU) 2016/1938 of 4 November 2016.

The opinion of ECHA also concluded that citric acid does not give rise to concern and is eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

During the 81st meeting of Member States' Competent Authorities on biocidal products in November 2018, Member States' Competent Authorities agreed that this active substance could be included into Annex I to the BPR, with the view to replace in the long term its previous approval made by Commission Implementing Regulation (EU) No 2016/1938 of 4 November 2016. Such inclusion would in particular reduce the administrative burden, facilitate the placing on the EU market of biocidal products presenting lower concerns for human health, animal health and the environment, and promote innovation for such biocidal products.

The opinion of ECHA of 16 February 2016 is considered as an opinion of the Agency pursuant to Article 28(1) of Regulation (EU) No 528/2012.

This Delegated Regulation therefore proposes to include citric acid in Annex I to Regulation (EU) No 528/2012.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission has consulted an expert group (the 'Biocides CA meeting') consisting of representatives of Member States' competent authorities for biocidal products, of the European Chemicals Agency, of the biocides industry and of the civil society during the meeting of 25 September 2020. During this consultation, no concerns were raised.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated Regulation amends Annex I to Regulation (EU) No 528/2012. The legal basis is Article 28(1) of that Regulation.

COMMISSION DELEGATED REGULATION (EU) …/...

of 3.11.2020

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include citric acid as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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[1], and in particular Article 28(1) thereof,

Whereas:

(1) Citric acid has been assessed as an existing active substance within the review programme set out in Article 89(1) of Regulation (EU) No 528/2012 established by Commission Delegated Regulation (EU) No 1062/2014[2].

(2) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency ("the Agency") was adopted on 16 February 2016 by the Biocidal Products Committee[3], having regard to the conclusions of the evaluating competent authority. That opinion concluded that biocidal products of product-type 2 containing citric acid may be expected to fulfill the requirements of Article 5 of Directive 98/8/EC of the European Parliament and of the Council[4] which were the requirements applicable to the examination of the application for approval of citric acid in accordance with Article 90(2) of Regulation (EU) No 528/2012.

(3) Citric acid was therefore approved as an active substance for use in biocidal products of product-type 2 by Commission Implementing Regulation (EU) 2016/1938[5].

(4) The opinion of the Agency also concluded that citric acid does not give rise to concern and is eligible for inclusion in Annex I to Regulation (EU) No 528/2012.

(5) Taking into account the opinion of the Agency, it is therefore appropriate to include citric acid in Annex I to Regulation (EU) No 528/2012. As citric acid has been assessed based on an active substance dossier satisfying the requirements laid down in

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1 OJ L 167, 27.6.2012, p. 1.

2 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).

3 Biocidal Products Committee Opinion on the application for approval of the active substance: Citric acid, Product type: 2, ECHA/BPC/088/2016, adopted on 16 February 2016.

4 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

5 Commission Implementing Regulation (EU) 2016/1938 of 4 November 2016 approving citric acid as an existing active substance for use in biocidal products of product-type 2 (OJ L 299, 5.11.2016, p. 54).

Article 11(1) of Directive 98/8/EC, citric acid should be included in category 6 of Annex I to that Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 528/2012 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 3.11.2020

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, 3.11.2020
C(2020) 7402 final

ANNEX

ANNEX

to the

COMMISSION DELEGATED REGULATION (EU) .../...

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include citric acid as an active substance in Annex I thereto

ANNEX

In Annex I to Regulation (EU) No 528/2012, in Category 6 of the List of active substances referred to in Article 25(a), the following entry is added:

EC number	Name/group	Restriction	Comment
‘201-069-1	Citric acid	Minimum degree of purity of the active substance(*): 995 g/kg	CAS No 77-92-9

(*) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.’.

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1763

of 25 November 2020

approving formaldehyde as an existing active substance for use in biocidal products of product-types 2 and 3

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ([1]), and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That lists includes formaldehyde.

(2) Formaldehyde has been evaluated for use in biocidal products of product-type 2, private area and public health area disinfectants and other biocidal products, and product-type 3, veterinary hygiene biocidal products, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond respectively to product-types 2 and 3 as described in Annex V to Regulation (EU) No 528/2012.

(3) The evaluating competent authority of Germany submitted the assessment reports together with its conclusions to the Commission on 29 July 2013.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency ([4]) (the 'Agency') were adopted on 10 December 2019 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) It can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC.

(6) According to the opinions of the Agency, biocidal products of product-types 2 and 3 containing formaldehyde may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(7) It is therefore appropriate to approve formaldehyde for use in biocidal products of product-types 2 and 3, subject to compliance with certain specifications and conditions.

(8) The opinions of the Agency conclude that formaldehyde meets the criteria for classification as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([5]).

(9) Since formaldehyde should be approved under the terms of Directive 98/8/EC, taking into account that property, the period of approval should be considerably shorter than 10 years, in accordance with the latest practice established under that Directive. In addition, since formaldehyde has benefitted from the transitional period provided for in Article 89 of Regulation (EU) No 528/2012 since 14 May 2000 and has been under peer review since 29 July 2013,

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) 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).

([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

([4]) Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Formaldehyde, Product type: 2, ECHA/BPC/232/2019, adopted on 10 December 2019; Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Formaldehyde, Product type: 3, ECHA/BPC/233/2019, adopted on 10 December 2019.

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

and with the view to examine at Union level as soon as possible in the context of a potential renewal of approval whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied for formaldehyde, the period of approval should be three years.

(10) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities of the Member States should evaluate whether the conditions of Article 5(2) of that Regulation can be satisfied in their territories in order to decide whether a biocidal product containing formaldehyde can be authorised.

(11) For the purposes of Article 23 of Regulation (EU) No 528/2012, formaldehyde meets the conditions laid down in point (a) of Article 10(1) of that Regulation and should therefore be considered a candidate for substitution. The competent authorities of the Member States should therefore perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing formaldehyde.

(12) Since, as concluded by the Agency, formaldehyde meets the criteria for classification as carcinogen category 1B and as skin sensitiser category 1 in accordance with Annex I to Regulation (EC) No 1272/2008, treated articles treated with or incorporating formaldehyde should be appropriately labelled when placed on the market.

(13) This Regulation does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC ([6]) and 98/24/EC ([7]), and Directive 2004/37/EC of the European Parliament and of the Council ([8]).

(14) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Formaldehyde is approved as an active substance for use in biocidal products of product-types 2 and 3, subject to the specifications and conditions set out in the Annex.

Article 2

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

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

Done at Brussels, 25 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

([6]) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

([7]) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

([8]) Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Formaldehyde	IUPAC Name: Methanal EC No: 200-001-8 CAS No: 50-00-0	25–55,5 % formaldehyde in aqueous solution (minimum purity 87,5 % w/w with regard to formaldehyde)	1 February 2022	31 January 2025	2	Formaldehyde is considered a candidate for substitution in accordance with point (a) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met. 3. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: (i) professional users for products used for disinfection by mopping and wiping of surfaces; (ii) secondary exposure of the general public and children; (iii) the aquatic environment for products used for room disinfection by fumigation in epidemic cases. The placing on the market of treated articles is subject to the following condition that the person responsible for the placing on the market of a treated article treated with or incorporating formaldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					3	Formaldehyde is considered a candidate for substitution in accordance with point (a) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10

						of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met. 3. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: (i) professional users for products used for disinfection by spraying of animal housing and of vehicles in epidemic cases; (ii) secondary exposure of the general public; (iii) surface water, sediment, soil and groundwater following use of products for disinfection of vehicles and disinfection of animal's feet by bathing or dipping. 4. For products that may lead to residues in food or feed, it shall be verified whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ([2]) or Regulation (EC) No 396/2005 of the European Parliament and of the Council ([3]), and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. The placing on the market of treated articles is subject to the condition that the person responsible for the placing on the market of a treated article treated with or incorporating formaldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

([2]) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

([3]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/1765

of 25 November 2020

not approving chlorophene as an existing active substance for use in biocidal products of product-type 2

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ([1]), and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That lists includes chlorophene (EC No: 204-385-8; CAS No 120-32-1).

(2) Chlorophene has been evaluated for use in biocidal products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, as described in Annex V to Regulation (EU) No 528/2012.

(3) Norway was designated as a rapporteur State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('Agency') on 22 December 2016.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency on 4 March 2020 ([3]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products of product-type 2 containing chlorophene may not be expected to meet the criteria laid down in Article 19(1)(b) of Regulation (EU) No 528/2012 as the human health risk assessment identified unacceptable risks.

(6) Taking into account the opinion of the Agency, it is not appropriate to approve chlorophene for use in biocidal products of product-type 2.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal products,

HAS ADOPTED THIS DECISION:

Article 1

Chlorophene (EC No: 204-385-8, CAS No: 120-32-1) is not approved as an active substance for use in biocidal products of product-type 2.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) 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).

([3]) Biocidal Products Committee Opinion on the application for approval of the active substance: Chlorophene, Product type: 2, ECHA/BPC/238/2020, adopted on 4 March 2020.

Article 2

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

Done at Brussels, 25 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1771

of 26 November 2020

approving reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) as an existing active substance for use in biocidal products of product-types 2, 3 and 4

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ([1]), and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes peroxyoctanoic acid, to be renamed reaction mass of peracetic acid and peroxyoctanoic acid, as the result of its evaluation.

(2) Reaction mass of peracetic acid and peroxyoctanoic acid has been evaluated for use in biocidal products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, product-type 3, veterinary hygiene, and product-type 4, food and feed area, as described in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 2 January 2019.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the Agency ([3]) on 4 March 2020, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 2, 3 and 4 containing reaction mass of peracetic acid and peroxyoctanoic acid may be expected to meet the criteria laid down in point (b) of Article 19(1) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.

(6) Taking into account the opinions of the Agency, it is appropriate to approve reaction mass of peracetic acid and peroxyoctanoic acid for use in biocidal products of product-types 2, 3 and 4, subject to compliance with certain specifications and conditions.

(7) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

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([1]) OJ L 167, 27.6.2012, p. 1.

([2]) 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).

([3]) Biocidal Products Committee Opinions on the application for approval of the active substance reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA); Product type: 2, 3 and 4; ECHA/BPC/242, 243 and 244, adopted on 4 March 2020.

HAS ADOPTED THIS REGULATION:

Article 1

Reaction mass of peracetic acid and peroxyoctanoic acid is approved as an active substance for use in biocidal products of product-types 2, 3 and 4 subject to the specifications and conditions set out in the Annex.

Article 2

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

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

Done at Brussels, 26 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

<table>
<tr><th>Common Name</th><th>IUPAC Name
Identification Numbers</th><th colspan="3">Minimum degree of purity of the active substance (1)</th><th>Date of approval</th><th>Expiry date of approval</th><th>Product type</th><th>Specific conditions</th></tr>
<tr><td rowspan="8">Reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)</td><td rowspan="8">IUPAC name:
Reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)

EC No: 201-186-8 and 450-280-7

CAS No: 79-21-0 and 33734-57-5</td><td colspan="3">The minimum purity of the active substance is not relevant as the active substance is a double equilibrium using hydrogen peroxide, acetic acid and octanoic acid as starting materials. The specifications correspond to a range of concentration.</td><td rowspan="8">1 April 2022</td><td rowspan="8">31 March 2032</td><td>2</td><td>The authorisations of biocidal products are subject to the following conditions:

(a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level assessment of the active substance.

(b) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.</td></tr>
<tr><td colspan="2">Components</td><td>Specifications range content (%w/w)</td><td rowspan="7"></td><td rowspan="7"></td></tr>
<tr><td>Active substance</td><td>Peracetic acid</td><td>1,8–13,9</td></tr>
<tr><td>Active substance</td><td>Peroxyoctanoic acid</td><td>0,15–2,42</td></tr>
<tr><td>Relevant impurity</td><td>Hydrogn peroxyde</td><td>1,1–25,45</td></tr>
<tr><td>Relevant impurity</td><td>Acetic acid</td><td>5,74–51</td><td>3</td><td>The authorisations of biocidal products are subject to the following conditions:

(a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level assessment of the active substance.

(b) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.</td></tr>
<tr><td>Relevant impurity</td><td>Octanoic acid</td><td>1,63–9,03</td><td>4</td><td>The authorisations of biocidal products are subject to the following conditions:

(a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an</td></tr>
</table>

						application for authorisation, but not addressed in the Union level assessment of the active substance. (b) Products containing reaction mass of peracetic acid and peroxyoctanoic acid shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council [2], unless the Commission has established specific limits on the migration of reaction mass of peracetic acid and peroxyoctanoic acid into food or it has established] in accordance with that Regulation that such limits are not necessary. (c) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.

[1] The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

[2] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).