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Safety of the food chain
Pesticides and Biocides

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59th meeting of representatives of Members States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products

Management of in situ generated active substances in the context of the BPR

1. PURPOSE OF THE DOCUMENT

This document provides details of the management of in situ generated active substances under Regulation (EU) No 528/2012 as agreed at the 59th CA meeting.

2. BACKGROUND

At the 52nd CA meeting, the Commission presented a paper *CA-July13-Doc.5.1.l* proposing a *Way forward on the management of in situ generated active substances in the context of the BPR*.

During the discussions of that paper, it was pointed out that the proposed approach could lead to a substantial increase to the number of active substance /product-type combinations to be examined under the review programme. It was therefore agreed to gather more information with a view to have an informed discussion concerning the impact of the different policy options.

Against that background, the Commission initiated a wide consultation of stakeholders to identify the combination of precursors/active substances currently made available or used on the EU market. More than 300 contributions were received.

After several consultations and a workshop held on 15 October 2014 with participation of Member States and stakeholders, it was concluded that it would be better to consider as many precursors as possible at the substance approval stage, despite the potential workload implied, with a view however to make the product authorisation process more efficient afterwards.

The analysis however confirms the initial concern that such an approach would entail a significant number of re-submissions. On some substances, it seems nevertheless possible to perform an assessment that could cover various precursors at the same time. Therefore, a compromised approached was agreed for certain substances, such as chlorine dioxide.

From that analysis, it also appears that some of the precursors/active substances combinations currently placed on the market were not supported under the review programme (e.g. monochloramine), or are supported for different product-types than the ones for which they are used.

3. WAY FORWARD

Section 3.1 addresses the situation of in situ generated active substances, whilst section 3.2 brings clarification regarding active substance releasers, as these should be clearly distinguished from in situ generated active substances. Lastly, the case of specific substances such as ozone, nitrogen or hydroxylradicals remains to be addressed.

3.1. Substances generated in situ

In situ generated active substances can be defined as substances, which are generated at the place of use from one or more precursors.

Review programme

All applications under evaluation in the review programme include a dossier on the active substance and a dossier on a representative biocidal product, which for in situ generated active substances will be the precursor(s).

For all substances generated in situ, the active substance shall be defined by reference to the precursor(s) supported in the dossier under evaluation and to the substance generated.

This may in certain cases lead to a re-definition of the substance, as originally notified, and/or to the creation of additional entries, when data on several precursors were provided in a dossier, or when multiple dossiers have been submitted for a substance (e.g. *chlorine dioxide* to be redefined *as Chlorine dioxide generated from sodium chlorite by electrolysis* and as *chlorine dioxide generated from sodium chlorate and hydrogen peroxide in the presence of a strong acid*)[1].

For those substances to be redefined, Article 13, 14 and 17 of Regulation (EU) No 1062/2014[2] (hereafter referred as the Review Programme Regulation) shall apply and persons affected by the substance re-definition shall be given the possibility to take over the role of participant[3].

Upon receiving information from ECHA that notifications to take over the role of participant have been found compliant, the Commission will amend part 1 of Annex II of the Review Programme Regulation so that in situ generated active substances are described as indicated in Annex I of this document.

[1] Further details of the proposed re-definitions are provided in Annex I (in column 3 of the tables).

[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 (Text with EEA relevance) OJ L 294, 10.10.2014, p. 1–34

[3] Further details on the process are provided in Annex III.

Substance approval

At the time of the substance approval, the Commission implementing Regulation would then refer to the precursor(s) supported in the dossier and to the active substance that will be generated from this(ese) precursor(s), including when relevant the generation method.

Article 95

Likewise, the list published by ECHA shall be updated and in situ generated active substances supported under the review programme shall be described as indicated in Annex I of this document.

Current participants in the review programme will be listed as substance/product suppliers.

Other companies will be added to the list provided they submit their own dossier, or an LoA to such a dossier.

In the case of in situ generated active substances, the dossier or LoA will need to cover data on both the in situ generated active substance and the precursor(s), which form the representative product, supported in the dossier under evaluation.

Suppliers of substances to be used as precursors for the in situ generation of active substances included in the review programme have to submit to ECHA their own dossier on the precursor(s) and the in situ generated active substance, or a letter of access to such a dossier, in so far as the precursor(s) placed on the market and the active substance generated from this(ese) precursor(s) are the same as the ones supported under the review programme[4]. These suppliers will have to be listed by 1 September 2015.

It is to be noted though that, as Article 95(2) refers to biocidal products, substances made available on the market without any indication (e.g. butane in the form of gas canisters) that they can be used as precursors for the in situ generation of an active substance would not be covered, although they might be used for that purpose. Such substances could therefore still be used during the transitional period provided for under Article 93 of the BPR. However, beyond this transitional period, such a use of a substance will be considered as use of a biocidal product and would not be allowed unless that biocidal product is authorised.

In addition, the additional precursor(s)/active substance combinations listed in the fourth column of Annex I would initially not be included in the Article 95 list (as no "complete substance dossier" according to Article 95(1) would have been submitted). Consequently, the deadline of 1 September 2015 does not apply to suppliers of these additional precursor(s)/active substance combinations. However, as soon as a "complete substance dossier" has been submitted under Article 13 of the Review Programme Regulation or Article 93 of the BPR and accepted, the substance would be included in the Article 95 list and consequently Article 95(2) would apply.

[4] These are listed in the third column of Annex I of this document.

Technical equivalence

It is acknowledged that a comparison of the chemical composition and hazard profile of the in situ generated active substances would be technically difficult, if not impossible, to achieve, as it may in particular be challenging to establish a reference source.

It might however be possible to establish technical specifications or to refer to existing standards, such as CEN standards. These technical specifications could be established either for the active substance itself or its precursors, as appropriate, at the time of the substance approval.

It will then have to be ensured and demonstrated at the time of product authorisation that the precursors or the active substances, as appropriate, meet the agreed specifications.

Finally, when an in situ generated active substance may also be placed on the market itself (e.g. peracetic acid), specifications would still have to be established in order to allow the establishment of technical equivalence in those cases where the active substance itself is placed on the market.

Article 93

Several in situ generated active substances are either not supported under the review programme or are supported for different product-types than the ones for which they are used.

Those in situ generated active substances will therefore not be able to benefit from the provisions of Article 13 of the Review Programme Regulation, which can only cover what was already within the scope of the BPD.

They could however benefit from the provisions of Article 93 as precursors for the in situ generation of active substances were not considered to be in the scope of the Directive in so far as no claim was made that these precursors could be used for a biocidal purpose.[5]

Article 13 of the Review Programme Regulation vs. Article 93 of the BPR

For some in situ generated active substances, submissions of applications could be done for some product-types on the basis of Article 13 of the Review Programme Regulation, for others on the basis of Article 93 of the BPR.

This would happen in cases where the re-defined precursor(s)/active substance combination is supported under the review programme for greater number of product-types than those in use for the precursor(s)/active substance, for which the role of participant is to be taken over (see for instance active chlorine).

In such cases, for the sake of simplification, the applicant may decide to group all product-types together and use only one application route (i.e. Article 13 of the Review Programme Regulation or Article 93 of the BPR).

[5] Those precursor/active substance combinations which could benefit from the provisions of Article 93 of the BPR are listed in the last column of the tables provided in Annex I.

Consortium

Specific precursor(s)/active substance combinations may be supported individually. This does however not rule out that a consortium could be set up to support different generation systems through the same application. This could be of interest for monochloramine, peracetic acid or active bromine.

Biocidal products

For in situ generated active substances, the biocidal product which is subject to authorisation before it can be supplied or used is either:

- the substance(s) or mixture(s) generating the active substance; or

- the active substance generated from substances or mixtures, which cannot themselves be authorised as biocidal products.[6]

3.2. Active substance releasers

Active substance releasers are substances which upon use release a substance, which has a biocidal activity. For such substances, no other precursor is required, the reaction is taking place under certain conditions and not necessarily at the place of use.

The substance released and the substance releaser shall be regarded as the active substance and be managed as such.

Furthermore, the name of the active substance will be the combination of the names of the substance released and of the substance releaser (e.g. *Formaldehyde released from N,N'-methylenebismorpholine*).

This name will be used for the substance approval as well as for the purpose of Article 95 listing.

Technical equivalence

The requirement to proof technical equivalence at product authorisation applies to biocidal products containing active substance releasers.

Technical equivalence shall confirm the similarity, as regards the chemical composition and hazard profile, of the active substance releasers being compared.

Article 95

The list will refer to the name of the active substance releaser and the substance released.

Current participants in the review programme will thus be listed under the combination of the active substance releaser and the substance released.

Other companies will be added to the list provided they have their own dossier on the active substance, or a letter of access to such a dossier.

[6] This would apply to ozone generated from ambient air, active chlorine generated from sea water.

4. CONCLUSION

The principles of this note were endorsed at the 58th CA meeting and the annexes finalised at the 59th CA meeting after a final consultation between the Commission services, the evaluating competent authorities and the participants concerned.

In accordance with Article 14 of Regulation (EU) No 1062/2014, the European Chemicals Agency will now publish an open invitation to take over the role of participant for those substance/precursor/product-type combinations, which have been the subject of a redefinition, as described in Article 13 of that Regulation.

Furthermore, it shall be noted that the list of substances described in the fourth column of the tables in Annex I and II is not exhaustive and that there might be other active substance/precursor/product-type combinations placed on the market, which might be eligible for a taking over pursuant to Article 14 of Regulation (EU) No 1062/2014 or for which applications can be submitted pursuant to Article 93 of the BPR.

However, for new systems (i.e. active substance/precursor/product-type combinations which were not made available on the market on 1 September 2013), the active substance will need to be approved and the biocidal product authorised before such new systems can be made available on the market.

Finally, for the purpose of product authorisation, it shall be recalled again that any company can be authorisation holder. It may thus be either the company supplying the precursors, the company manufacturing the devices in which these precursors will be used, or the company using the device with a view to generate the active substance.

Annex I

In situ generated active substances

	Current name	Current precursor(s)/active substance combinations[7]	Additional precursor(s)/active substance combinations[8]	RMS	Legal basis for taking over[9]
1. Active chlorine[10]					
939	Active Chlorine	Active chlorine generated from sodium chloride by electrolysis[11]		SK 1[12], 2, 3, 4, 5	n/a
			Active chlorine generated from sodium chloride[13] by electrolysis	11, 12	Art. 13 (432)
			Active chlorine generated from potassium chloride by electrolysis	11	Art. 13 (457)

[7] For greater clarity, it is proposed to rename active substances as indicated in the column, referring to the combinations supported in the dossier under evaluation in the review programme. When no second precursor is given, only the reaction with water is covered by the entry.

[8] These combinations are not supported in the dossier under evaluation in the review programme.

[9] Art. 13 refers to Article 13 of the Review Programme Regulation; Art. 93 to Article 93 of the BPR; the number in brackets (e.g. (457) to the substance re-defined and on the basis of which a taking over could take place; Art. 13 / Art. 93 to cases where not enough information is available to indicate the legal basis for a taking over.

[10] Under this section, what is generated in water and will be regarded as the active substance consists of chlorine, hypochlorous acid and hypochlorite anion in equilibrium. The predominant species will depend on pH value (chlorine is available only at pH < 4, hypochlorous acid is predominant in the range 4 to 5.5, whereas only hypochlorite anion is present at pH >10). As a result, what is generated is indicated more generically as "active chlorine", which is defined as the sum of chlorine, hypochlorous acid and hypochlorite anion.

[11] This entry refers to the in situ generation of active chlorine from sodium chloride by electrolysis as well as to the case where active chlorine is produced by electrolysis and subsequently placed on the market as a biocidal product.

[12] PT 1 is being evaluated as a new active substance.

[13] It is useful to note that there exist already different standards for sodium chloride:

- For treating swimming pool water : EN 16401 - Sodium chloride used with electrochlorination systems;
- For treating water intended for human consumption: EN 973 - Sodium chloride for regeneration of ion exchange resins, EN 14805 - Sodium chloride for the electrochemical generation of chlorine using non-membrane technology, EN 16370 - Sodium chloride for the electrochemical generation of chlorine using membrane electrolyser.

				2, 3, 4, 5	Art. 13 (939)
				1, 12	Art. 93
			Active chlorine generated from magnesium chloride hexahydrate and potassium chloride by electrolysis	2	Art. 13 (939)
			Active chlorine generated from hydrochloric acid by electrolysis	2, 4, 5	Art. 13 (432)
			Active chlorine generated from sodium chloride and pentapotassium bis(peroxymonosulphate) bis(sulphate)[14]	2, 5, 11	Art. 13 (457)
				2, 3, 4, 5	Art. 13 (693)
				1, 12	Art. 93
			Active chlorine generated from sodium dichloroisocyanurate and pentapotassium bis(peroxymonosulphate) bis(sulphate)~~14~~~~16~~	2, 3, 4, 5,	Art. 13 (693)
				11, 12	Art. 13 (345)
			Active chlorine generated from sodium dichloroisocyanurate dihydrate and pentapotassium bis(peroxymonosulphate) bis(sulphate)~~14~~~~16~~	2, 3, 4, 5,	Art. 13 (693)
				11, 12	Art. 13 (346)
			Active chlorine generated from trichloroisocyanuric acid and pentapotassium bis(peroxymonosulphate) bis(sulphate)~~14~~~~16~~	2, 3, 4, 5,	Art. 13 (693)
				11, 12	Art. 13 (85)

[14] As KMPS is currently supported under the review programme, this system could be taken over upon clarification that KPMS only covers the active substance (see entry 693) for the product-types currently supported (i.e. 2, 3, 4 and 5).

2. Active bromine[15]					
424	Sodium bromide	Active bromine generated from sodium bromide and sodium hypochlorite Active bromine generated from sodium bromide and calcium hypochlorite Active bromine generated from sodium bromide and chlorine		NL 2, 11, 12	n/a
424	Sodium bromide	Active bromine generated from sodium bromide by electrolysis		NL 2	n/a
		Active bromine generated from sodium bromide and a second precursor[17][18]	Active bromine generated from sodium bromide and hydrogen peroxide	2	Art. 13 (424)
			Active bromine generated from sodium bromide and hypochlorous acid	2	Art. 13 (424)
			Active bromine generated from sodium bromide and pentapotassium bis(peroxymonosulfate) bis(sulfate) [14][16]	2, 11, 12	Art. 13 (424)
				3, 4, 5	Art. 13 (693)
			Active bromine generated from sodium bromide and ozone	2, 11	Art. 13 (424)
			Active bromine generated from sodium bromide by direct oxidation	4	Art. 93
			Active bromine generated from potassium bromide by direct oxidation	4, 11	Art. 93
529	Bromine chloride	Active bromine generated from bromine chloride		NL 11	n/a

[15] Under this section, what is generated in water and will be regarded as the active substance consists of bromine, hyprobromous acid and the hypobromite anion in equilibrium. The predominant species will depend on pH value. As a result, what is generated is indicated more generically as “active bromine”, which is defined as the sum of bromine, hyprobromous acid and the hypobromite anion.

3. Stabilised halogenated compounds[16]

3.1 Stabilised chlorine

458	Ammonium sulphate	Monochloramine generated from ammonium sulphate and a chlorine source		UK 11, 12	n/a
		Monochloramine generated from a chlorine source and a chlorine stabiliser[17]	Monochloramine generated from ammonium sulphate and a chlorine source	2, 4, 5	Art. 93
			Monochloramine generated from a mixture of ammonium sulphate and diammonium hydrogenorthophosphate and a chlorine source	2, 4, 5, 11, 12	Art. 93
			Monochloramine generated from ammonia and a chlorine source	2,5, 11	Art. 93
			Monochloramine generated from ammonium chloride and a chlorine source	n/a	Art. 93
			Monochloramine generated from diammonium hydrogenorthophosphate and a chlorine source	2, 4, 5, 11, 12	Art. 93
			Monochloramine generated from ammonium carbamate and a chlorine source	6, 11, 12	Art. 93

[16] The group contains stabilised chlorine/bromine molecules which are produced on site, and release the chlorine in-situ. This is very different from other groups of active releasers, which are delivered to the point of use and not produced at the point of use.
The group of stabilised compounds includes different stabilisers (e.g. DMH, ammonium bromide, ammonium chloride, ammonium sulphate, urea, ammonium carbamate).

[17] Specific precursor(s)/active substance combinations may be supported individually. This does however not rule out that a consortium could be set up to support different generation routes through the same application route.

3.2 Bromide activated chloramine					
515	Ammonium bromide	Bromide activated chloramine (BAC) generated from ~~precursors~~ ammonium bromide and sodium hypochlorite		SE 11, 12	n/a

4. Chlorine dioxide					
491	Chlorine dioxide	Chlorine dioxide generated from sodium chlorite[18] by electrolysis		PT 2, 3, 4, 5, 11, 12	n/a
		Chlorine dioxide generated from sodium chlorite[18~~19~~] by acidification[19]			n/a
		Chlorine dioxide generated from sodium chlorite[18~~19~~] by oxidation[20]			n/a
			Chlorine dioxide generated from sodium chlorite and sodium chloride / sodium chloride brine	2, 3, 4, 5, 11	Art. 13 (491)
			Chlorine dioxide generated from sodium chlorite and sodium dichloro isocyanurate dihydrate	2, 3, 4, 5, 11, 12	Art. 13 (491)
			Chlorine dioxide generated from sodium chlorite sodium dichloroisocyanurate, and citric acid	2, 3, 4, 5	Art. 13 (491)
			Chlorine dioxide generated from sodium chlorite, sodium bisulfate and sodium dichloro isocyanurate dihydrate	2, 3, 4, 5, 11, 12	Art. 13 (491)
			Chlorine dioxide generated from sodium chlorite and sodium bisulfate	2, 3, 4, 5, 11, 12	Art. 13 (491)

[18] The second precursor will be considered in further details at the time of product authorisation and shall, where relevant, be considered as substance of concern. In that respect, it remains to be agreed how to consider precursors which would meet the exclusion criteria (e.g. boric acid).

[19] This entry would cover chlorine dioxide generated from sodium chlorite and acids such as:

- hydrochloric acid (included in the dossier under evaluation in the review programme)
- acetic acid
- boric acid
- citric acid
- glycolic acid
- lactic acid
- L(+)-Lactic acid
- phosphoric acid
- sorbic acid

[20] This entry would cover chlorine dioxide generated from sodium chlorite and oxidizing agents such as:

- chlorine (included in the dossier under evaluation in the review programme)
- sodium hypochlorite (included in the dossier under evaluation in the review programme in combination with hydrochloric acid)
- disodium peroxodisulfate
- sodium peroxodisulfate, also known as sodium persulfate
- pentapotassium bis(peroxymonosulfate) bis(sulfate)
- potassium peroxymonosulphate

			Chlorine dioxide generated from sodium chlorite and sodium bisulfate and calcium hypochlorite	2, 3, 4, 5, 11, 12	Art. 13 (491)
491	Chlorine dioxide	Chlorine dioxide generated from sodium chlorate and hydrogen peroxide in the presence of a strong acid[21]		PT 2, 5, 11, 12	n/a
			Chlorine dioxide generated from sodium chlorate by electrolysis	2, 3, 4	Art. 13 (491)
792	Tetrachlorodecaoxide complex (TCDO)	Chlorine dioxide generated from Tetrachlorodecaoxide complex (TCDO) by acidification[22]		DE 1, 2, 4	n/a

5. Hydrogen peroxide					
439	Hydrogen peroxide[23]	n/a		FI 1, 2, 3, 4, 5, 6, 11, 12	n/a
			Hydrogen peroxide generated from beta-d-glucose pentaacetate (Information on second precursor is missing)	2[24]	Art. 13 (439)
			Hydrogen peroxide generated from sodium percarbonate by dissolution in water	2, 3, 5	Art. 13 (439)
				21	Art. 93
			Hydrogen peroxide generated from sodium hydroxide by electrolysis	2, 3, 4, 5, 11	Art. 13 (439)
			Hydrogen peroxide generated from sodium sulphate by electrolysis	2, 3, 4, 5, 11	Art. 13 (439)
			Hydrogen peroxide generated from sulphuric acid by electrolysis	2, 3, 4, 5, 11	Art. 13 (439)

[21] The strong acid included in the dossier under evaluation in the review programme is sulphuric acid.
[22] This entry would cover chlorine dioxide generated from TCDO and precursors such as:

- hydrochloric acid
- sulphuric acid

[23] Hydrogen peroxide is either made available in solution or is generated in situ. Only the water solution is however supported under the review programme.
[24] Used for surgical instruments disinfection.

			Hydrogen peroxide generated from sea water by electrolysis	2, 3, 4, 5, 11	Art. 13 (439)
			Hydrogen peroxide generated from barley straw in water	2	Art. 13 (439)

6. Peracetic acid					
70	Peracetic acid[25]	n/a		FI 1, 2, 3, 4, 5, 6, 11, 12	n/a
70	Peracetic acid	Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate[26]		FI 2, 3, 4	n/a
		Peracetic acid generated from an acetate donor (including acetic acid) and a peroxide (including hydrogen peroxide)[17~~18~~]	Peracetic acid generated from acetic acid and hydrogen peroxide	2, 3, 4, 5, 11	Art. 13 (70)
			Peracetic acid generated from 1,3-diacetyloxypropan-2-yl acetate[27] and hydrogen peroxide	2, 4	Art. 13 (70)
			Peracetic acid generated by perhydrolysis of acetyltriethylcitrate by hydrogen peroxide in alkaline conditions.	2, 4	Art. 13 (70)
			Peracetic acid generated by perhydrolysis of D-Sorbitol hexaacetate by hydrogen peroxide in alkaline conditions	2, 4	Art. 13 (70)
			Peracetic acid generated by perhydrolysis of N-acetylcaprolactam by hydrogen peroxide in alkaline conditions	2, 4	Art. 13 (70)
			Peracetic acid generated by perhydrolysis of pentaacetylglucose by hydrogen peroxide in alkaline conditions	2, 4	Art. 13 (70)
			Peracetic acid generated by perhydrolysis of methylacetate by hydrogen peroxide in alkaline conditions	2, 4	Art. 13 (70)

[25] Peracetic acid is either made available in solution in equilibrium with hydrogen peroxide and acetic acid or is generated in situ. Only ~~the~~ equilibrium PAA and in-situ PAA generated from TAED/SPC are currently ~~is however~~ supported under the review programme.

[26] The active substance peracetic acid is formed in-situ when the precursors sodium percarbonate and tetraacetylethylenediamine (TAED) are diluted in water. Upon contact with water, sodium percarbonate dissociates to sodium, carbonate and hydrogen peroxide. In the presence of the formed hydrogen peroxide, TAED rapidly undergoes perhydrolysis to form DAED (diacetylethylenediamine) and the active substance peracetic acid.

[27] Also known as triacetin and glycerin triacetate. It is the triester of glycerol and acetic acid.

			Peracetic acid generated from acetic acid and disodium carbonate compound with hydrogen peroxide		Art. 13 (70)
			Peracetic acid generated of Tetra-acetylethylenediamine (TAED) and sodium perborate/ sodium perborate monohydrate		Art. 13 (70)
			Peracetic acid generated from tetra-acetylendediamine (TAED) and hydrogen peroxide	2	Art. 13 (70)

7. Other substances supported in the review programme					
37	Formic acid	Formic acid Performic acid generated from formic acid and hydrogen peroxide		BE 2, 3, 4, 5, 6, 11, 12	n/a
136	Glutaral (Glutaraldehyde)[28]	n/a		FI 1, 2, 3, 4, 6, 11, 12	n/a
179	Carbon dioxide[29]	n/a		FR 19	n/a
179	Carbon dioxide	Carbon dioxide generated from propane, butane or a mixture of both by combustion		FR 19	n/a
			Carbon dioxide generated from oxalic acid by electrolysis	19	Art.13 (179)
405	Sulphur dioxide	Sulphur dioxide generated from sulphur by combustion		DE 4	n/a

[28] Glutaral (Glutaraldehyde) is supported as an active substance itself.
[29] Carbon dioxide is supported as an active substance itself.

693	Pentapotassium bis(peroxymonosulphate) bis(sulphate) (KMPS)[30]	n/a		SI 2, 3, 4, 5	n/a
813	Peroxyoctanoic acid[31]	~~Peroxyoctanoic acid generated from octanoic acid and hydrogen peroxide~~n/a		FR 2, 3, 4	n/a
453	Disodium peroxodisulphate / Sodium persulphate[32]			PT 4	n/a
			Disodium peroxodisulphate generated from sodium sulphate by electrolysis[33]	n/a	Art. 13 / Art. 93
			Dipotassium peroxodisulfate generated from potassium sulphate[33~~34~~]	n/a	Art. 13 / Art. 93
			Diammonium peroxodisulfate generated from ammonium sulphate[34]	n/a	Art. 13 / Art. 93

8. Other substances not supported in the review programme

			Disodium/dipotassium/diammonium peroxodisulphate generated by electrolysis of sodium/ potassium/ammonium sulphate in water	n/a [35]	Art. 93

[30] KMPS is supported as an active substance itself. KMPS can however – in its function as an oxidizer - be used or react with other substances for the in situ generation of several active substances. For example:

- Sodium chloride and KMPS generating active chlorine
- Sodium or potassium bromide and KMPS generating active bromine
- Sodium chlorite and KMPS generating chlorine dioxide

[31] Peroxyoctanoic acid is only made available on the market in solution in equilibrium with octanoic acid and hydrogen peroxide only.

[32] Only supported as an active substance.

[33] Upon confirmation that disodium peroxodisulphate is only supported as an active substance,

[34] As ammonium sulphate is currently supported under the review programme, this system could be taken over upon re-redefinition of ammonium sulphate as monochloramine generated from ammonium sulphate and a chlorine source (see entry 458) for the product-types currently supported (i.e. 11 and 12).

[35] Industrial use.

			Sodium/potassium/ calcium percarbonate generated by electrolysis of sodium/ potassium/calcium carbonate in water	2, 3, 4	Art. 93
			Sodium perborate generated by electrolysis of sodium borate decahydrate in water	2, 3, 4	Art. 93
			Ozone generated from oxygen	-	Art. 93

Annex II - Releasers

1. Substances releasing halogen

1.1 Substances releasing active chlorine[36]

85	Symclosene	Active chlorine released from trichloroisocyanuric acid		UK 2, 3, 4, 5, 11, 12	n/a
345	Troclosene sodium	Active chlorine released from sodium dichloroisocyanurate		UK 2, 3, 4, 5, 11, 12	n/a
346	Sodium dichloroisocyanurate dihydrate	Active chlorine released from sodium dichloroisocyanurate dihydrate		UK 2, 3, 4, 5, 11, 12	n/a
432	Sodium hypochlorite	Active chlorine released from sodium hypochlorite		IT 1, 2, 3, 4, 5, 11, 12	n/a
455	Calcium hypochlorite	Active chlorine released from calcium hypochlorite		IT 2, 3, 4, 5, 11	n/a
457	Chlorine	Active chlorine released from chlorine		IT 2, 5, 11	n/a
777	Reaction products of 5,5-dimethylhydantoin, 5-ethyl-5-methylhydantoin with chlorine (DCEMH)	Active chlorine released from a mixture of N,N'-dichloro-5,5-dimethylhydantoin (DCDMH) and N,N'-dichloro-5-ethyl-5-methylhydantoin (DCEMH)		NL 11	n/a
185	Tosylchloramide sodium	Active chlorine released from tosylchloramide sodium		ES 2, 3, 4, 5	n/a

[36] The substances listed below when added to water release chlorine (in the form of active chlorine).

1.2 Substances releasing active chlorine and active bromine					
588	Bromochloro-5,5-dimethylimidazolidine-2,4-dione (BCDMH / Bromochlorodimethylhydantoin)	Active chlorine and active bromine released from N,N'-bromochloro-5,5-dimethylhydantoin (BCDMH)		NL 2, 11, 12	n/a
152	Reaction products of 5,5-dimethylhydantoin, 5-ethyl-5-methylhydantoin with bromine and chlorine (DCDMH)	Active chlorine and active bromine released from a mixture of N,N'-bromochloro-5,5-dimethylhydantoin (BCDMH) and N,N'-dichloro-5,5-dimethylhydantoin (DCDMH) and N,N'-dichloro-5-ethyl-5-methylhydantoin (DCEMH)		NL 11	n/a

2. Substances releasing formaldehyde				
359	(ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm))	Formaldehyde released from ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm))		PL
368	Methenamine 3-chloroallylochloride (CTAC)	Formaldehyde released from Methenamine 3-chloroallylochloride (CTAC)		PL
377	2,2',2"-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (HHT)	Formaldehyde released from 2,2',2"-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (HHT)		PL
387	N,N'-methylenebismorpholine (MBM)	Formaldehyde released from N,N'-methylenebismorpholine (MBM)		AT
393	1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH)	Formaldehyde released from 1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH)		PL
797	cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis CTAC)	Formaldehyde released from cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis CTAC)		PL
444	7a-ethyldihydro-1H,3H,5H-oxazolo[3,4-c]oxazole (EDHO)	Formaldehyde released from 7a-ethyldihydro-1H,3H,5H-oxazolo[3,4-c]oxazole (EDHO)		PL
531	(benzyloxy)methanol	Formaldehyde released from (benzyloxy)methanol		UK
566	.alpha.,.alpha.',.alpha."-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol (HPT)	Formaldehyde released from .alpha.,.alpha.',.alpha."-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol (HPT)		AT
656	3,3'-methylenebis[5-methyloxazolidine] (Oxazolidin / MBO)	Formaldehyde released from 3,3'-methylenebis[5-methyloxazolidine] (Oxazolidin / MBO)		AT

382	Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione (TMAD)	Formaldehyde released from tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione (TMAD)		ES
691	Sodium N-(hydroxymethyl)glycinate	Formaldehyde released from sodium N-(hydroxymethyl)glycinate		AT

Annex III

Procedural steps for the taking over of the role of participant

1. Active substances generated in situ will now be identified precisely in the review programme by the name of the active substance generated in situ and by the name of its precursor(s), as supported by the participant(s).

   When only a precursor was notified and supported under the review programme (e.g. ammonium sulphate), it will thus be replaced by the name of the active substance generated in situ and that precursor (e.g. ammonium sulphate generating monochloramine). In parallel to this modification, opportunity shall also be given to persons wishing to support this precursor for being used as an active substance on its own or to support other active substances generated from this precursor to take over the role of participant and to submit an application under the review programme of existing active substances.

2. This opportunity shall **only be open to existing active substance (precursor) / product-type combinations still under assessment under the current review programme**.

   The opportunity has already been given to persons interested to support existing active substance (precursor) / product-type combinations withdrawn from the review programme to take them over, as it covered any possible precursors of the substance, and no additional opportunity should thus be given to support them again under the review programme.

   Likewise, it is considered that for substances already included in Annex I, matters have already been clarified.

3. **Persons wishing to support the same existing active substance** / product type combination **shall submit a joint application**.

4. **Regarding the timing for the taking over of the role of participants, this will be done in accordance with the provisions of Article 13 of Regulation 1062/2014[37]**

   - Upon clarification of the substance identity, ECHA shall update the R4BP and publish an open invitation to take over the role of participant. This invitation will contain the names of precursor/product-type combinations no longer supported (e.g. ammonium sulphate for PT 11 and 12) and those of the active substances/product-type combinations supported instead (e.g. ammonium sulphate generating monochloramine for PT 11 and 12).

   - Within 12 months from the date of that publication, any person wishing to take over the role of participant for a precursor/product-type combination to be used as an active substance or for any other active substance to be generated

[37] 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 (Text with EEA relevance) OJ L 294, 10.10.2014, p. 1–34

from that precursor shall submit a notification to ECHA through the R4BP.

- Within 30 days of receipt of payment of the fee, ECHA shall verify that the notification complies with the requirements of Article 17 (2) of Regulation 1062/2014.

- Within two years of the notification having been found compliant by ECHA, applications for approval or inclusion in Annex I shall be submitted by the participant whose notification was accepted.

- Precursors/active substances for which an application will have been received and accepted will be allowed to remain on the market until a decision is taken on their approval.

2. If no application is submitted at the expected submission date, if the notification is rejected by ECHA, if the application is rejected by ECHA or by the evaluating Competent Authority, or if it is withdrawn by the participant **no additional possibility will be given** to support the active substance.

   If another person wishes to support that active substance, it would have to be done under the normal procedure of Article 7(1) of the BPR. Until that active substance is approved, it will not be possible to make it available on the market or use a biocidal product containing or generating it.