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Dear Visitor,

On the use of the ozone gas as a biocide active substance:

Decree No. 316 of 2013 (VIII.28.) of the Government on certain rules concerning the authorization and the placing on the market of biocidal products

…
§ 24/B. * (1) The biocidal product not subject to authorisation according to this decree is to be registered for the purpose of poison control register and the register of biocidal products by the manufacturer or the entity importing into Hungary to the national chief medical officer within 90 days from the manufacturing or the beginning of the import. If the biocidal product can only be marketed if authorised pursuant to this decree, the notification of the product can only be made until the time of the approval of the active substance or last substance contained with having a valid and effective authorisation. To the biocide product register, the provisions for confidential data processing according to Article 66. of the Regulation (EU) No. 528/2012 of the European Parliament and of the Council are to be applied.
(2) The notification according to Paragraph (1) shall be made within 90 days from the day of the granting of the authorisation electronically with the content according to Appendix 1 in a way provided by the Specialized Information System. Any change in the data of the notification shall also be reported with the appropriate application of the Paragraph (1). The national chief medical officer will send a confirmation on the receipt of the notification within 15 days.

Ozone gas

In-situ generated active substances

The biocidal active substances are called in-situ generated substances if they are produced of one or more precursors at the location of use. For the approval of such substance regarding every product type, it is necessary to assess the active substance generated and those precursor(s) it is made up of. Some examples of such combinations:

- Active chlorine produced from sodium-chloride via electrolysis;
- Active chlorine produced from potassium-chloride via electrolysis;

- Active bromine produced from sodium-bromide and sodium-hypochlorite;
- Hydrogen-peroxide produced from sodium-percarbonate via solubilisation in water.

Though several in-situ generated active substances are present in the audit program, the submittal of the data regarding the precursors was not consequent (for example, data regarding several precursors were provided in one documentation), and due to this, the consequent assessment of the precursors was not done.

The European Committee prepared a proposal, the objective of which is the determination of in-situ generated active substances referring to the precursor(s) supported in the documentation under assessment and to the substance generated. As a result of this, further combinations were registered to ensure that all combinations being placed on the market be assessed appropriately. The proposal was discussed and supported by the member states at the session 58., on 12-14th November, 2014.

Therefore the proposal of the Committee includes the listing of the precursor(s)/active substance/product type combination known to be used or marketed in the Union. A part of the combinations are already supported by the Review Programme, however, others are not. For the companies to be able to keep their biocidal products on the market, shall take steps according to the details below.

What happens to the in-situ generated substances after?

- The final list of the Committee will be published on the website of ECHA. The list will include the combinations **presently not supported** under the Review Programme. If the companies wish to undertake the role of the participant of the Review Programme, they will have to submit a notification, then an application.
- Some combinations cannot be involved in the Review Programme (because the active substance was not registered originally or because the combination is supported only for other product types), however, the companies will have the option to use the transitional measure according to BPR Article 93. and to submit an application for the approval of the active substance produced in-situ. If this submittal is done before 1st September of 2016, the product, that is the precursor(s) creating the active substance may remain on the market.
  - Provisional measure under Article 93.
- If a precursor/active substance combination is relevant to more than one product type, and to some of them the first mode of application (that is the undertaking of the role of participant of the Review Programme) applies, while to others the second one (Article 93), the applicants may decide, choosing one of the two application modes, to apply for the approval of all the combinations under one motion.

Combinations presently not listed in the Review Programme: The list published by the Agency in accordance with BPR Article 95 is the list of the "concerned substances". A substance is "concerned" only of the complete substance dossier had been submitted and it had been approved or validated by any of the member states in accordance with the BPR or BPD (Directive 98/8/EC).

Thus, as soon as the application for approval of the active substance, which shall include the information prescribed in Appendix II., or in case of documentation submitted in accordance with the BPD, those prescribed in Appendix IIA or IVA, or in certain cases the IIIA, is approved or validated by the member state, the applicant is added to the list according to Article 95 related to the given precursor(s)/active substance/product type combination.

3234	Ozone generated from oxygen	Not allocated	Not allocated	2	EurO3zon	Belgium	Not applicable	Article 93
3235	Ozone generated from oxygen	Not allocated	Not allocated	2	The European Ozone Trade Association Limited	United Kingdom	Not applicable	Article 93
3236	Ozone generated from oxygen	Not allocated	Not allocated	4	EurO3zon	Belgium	Not applicable	Article 93
3237	Ozone generated from oxygen	Not allocated	Not allocated	4	The European Ozone Trade Association Limited	United Kingdom	Not applicable	Article 93
3238	Ozone generated from oxygen	Not allocated	Not allocated	5	EurO3zon	Belgium	Not applicable	Article 93
3239	Ozone generated from oxygen	Not allocated	Not allocated	5	The European Ozone Trade Association Limited	United Kingdom	Not applicable	Article 93
3240	Ozone generated from oxygen	Not allocated	Not allocated	11	EurO3zon	Belgium	Not applicable	Article 93
3241	Ozone generated from oxygen	Not allocated	Not allocated	11	The European Ozone Trade Association Limited	United Kingdom	Not applicable	Article 93

However, if the application is not yet validated, the substance is not "concerned", and the requirement related to the compliance to Article 95. Paragraph (2), that is the obligation under which the supplier shall be included on the list for the products to be able to be marketed after 1st September, 2015, will not be met. In practice, this means that in the case of additional precursor(s)/active substance/product type combination registered as a consequence of the amendment of the definition of the in-situ generated active substances presently included in the Review Programme, the deadline of 1st September, 2015 will not be normative, and the obligations in accordance with the Article 95 will enter into force at a later time, namely at the time of the validation of the application for approval.

Combinations already listed in the Review Programme: In case of the combinations presently included in the Review Programme, the deadline of 1st September, 2015 is normative. The present entries on the list according to Article 95 will be renamed for the clear indication of both the active substance and its precursor(s).

If a combination is listed there, the alternate supplier of this combination will have to apply for registration to the list and is to be added until 1st September, 2015.

Article 93. Transitional measure

Several *in situ* generated active substance-product type-combinations are 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 product type combinations may benefit from the provisions of Article 93, as the precursors for the in situ generation of active substances were not considered to be in the scope of the Biocidal Product Directive if no claim was made that these precursors could be used for a biocidal purpose. **These provisions apply to the free radicals, the ozone and some non-in situ active substances.**

The Article 93 transitional measures only apply to biocidal products consisting of, containing or generating only active substances that were available on the market, or used in biocidal products, on 1 September 2013.

Where an application relevant for Article 93 was submitted by 1 September 2016, the combination benefits from the extended deadlines to be made available on the market and used set out in Article 89(2),(3) and (4) of the BPR. Where an application is not made by 1 September 2016, the derogation lasts only until 1 September 2017.

A list of applications submitted by 1 September 2016 is provided in the document "**Article 93 list**".

A list of examples of *in situ* systems that may fall under these exemptions is provided in the Commission CA paper "substance generated in situ".

Active Substances	CAS	PT	eCA	Type of application	Applicant	Status
Ozone generated from oxygen	10028-15-6	11	DE	New active BPR	EurO3zon	In progress
Ozone generated from oxygen	10028-15-6	2	NL	New active BPR	The European Ozone Trade Association Limited	In progress
Ozone generated from oxygen	10028-15-6	4	NL	New active BPR	The European Ozone Trade Association Limited	In progress
Ozone generated from oxygen	10028-15-6	5	NL	New active BPR	The European Ozone Trade Association Limited	In progress
Ozone generated from oxygen	10028-15-6	11	NL	New active BPR	The European Ozone Trade Association Limited	In progress
Reaction mass of titanium dioxide and silver chloride		4	SE	New active BPR	Clariant Produkte (Deutschland) GmbH	In progress
Silver phosphate glass	308069-39-8	4	SE	New active BPR	ISHIZUKA GLASS (UK)LTD.	In progress

Interpretation of the Decree on biocidal products

Regulation (EU) No 528/2012 on the biocidal product is applicable to the making available on the market and use of biocidal products. These products are used for the protection of humans, animals, materials and articles against harmful

microorganisms (e.g. parasites or bacteria) which is made possible by the active substance in the biocidal product. The objective of this regulation to improve the operation of the biocidal products in the EU, and to provide the high-level protection of people and the environment.

The text of the regulation was approved on 22nd May, 2012, and is effective from 1st September, 2013. Some of its provisions become effective following a transitional period. Simultaneously, the directive on biocidal products (Directive 98/8/EC) will be repealed.

Before being distributed, all biocidal products shall be authorises and the active substance included in the given biocidal product has to be approved in advance. However, there are some exceptions to this principle. For example, the active substances included in the Review Programme, and the biocidal products containing them may already be distributed while the final decision on the approval is made. The conditional product permits related to the new substances currently under assessment may also be distributed.

The objective of the BPR is to harmonize the market at Union level, make the approval of the active substances and the authorisation of the biocidal products more easy and to set due dates for the assessment, evaluation and decision making to be done by the member states. In addition to this, it promotes the mitigation of the testings made on animals by prescribing obligatory disclosure of information and encourages the application of alternate testing methods.

Similarly to the former directive, the approval of the active substances are done at union level, and the subsequent authorisation of the biocidal products is done at the level of the member states. This authorisation is extensible to other member states by mutual recognition procedure. The new decree, however, also allows for a new type, union-level authorisation (union authorisation procedure) for the applicants.

The submission of the applications, the data and information exchange between the applicant, the ECHA, the competent authority of the member state and the European Commission will take place on an IT platform (the register for biocidal products [R4BP 3]) made for this purpose. For the preparation of the applications, an other IT tool, the IUCLID5 is provided.

The Ozone White Technology is a NON-PURCHASABLE APPLIANCE!
The Ozone White Technology can only be operated by our specifically trained Partners! All pilot customers of the Ozone White Technology will be registered in the www.rlod.org database!

The authorisation of the Ozone White Technology as biocidal disinfection procedure and system is in progress. Until the conclusion of the authorisation, the pilot program of the Ozone White air conditioning and deodorizing process in the scientific confirmation stage is for the collection of data and their later use for scientific purposes.

The manufacturer of the Ozone White Technology is the

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