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From: 5.1.2e @ec.europa.eu
Sent: Fri 3/20/2020 10:05:47 AM
Subject: RE: supply shortage of active substances
Received: Fri 3/20/2020 10:05:50 AM

Dear colleagues,

Following on from the earlier mails sent on Monday, the Commission, ECHA and CEFIC have discussed further options to increase the supply of active substances. The following solutions are feasible, depending on whether the active substance is already approved (and products are thus authorised in accordance with the BPR) or still under review (and products are thus placed on the market in accordance with national rules):

1. The active substance used in the biocidal products is approved (i.e. isopropanol and 1-propanol):

- a. The most effective way to address the needs to have more biocidal products on the market is that MSCAs use Article 55(1) of the BPR to permit the placing on the market of biocidal products under derogation from Article 19 and in particular derogation from the technical equivalence requirement in Art. 19(1)(c).

ECHA proposes to support industry and the MS by providing guidance on the minimal requirements for the active substance in order to ensure that it can be safely used in the biocidal products. ECHA intends to have such guidance available in the course of next week.

Moreover, ECHA proposes to centralise the industry requests for derogation under Article 55(1) and to dispatch them to the concerned Member State. In that context, ECHA proposes also to check within a few days that the active substance source complies with the safety requirements. The procedure for this will be outlined in the course of next week.

- b. For biocidal products under regular authorisations of the BPR (e.g. companies who want to have products authorised with new sources of active substances), the requirement for technical equivalence applies. Supplying companies would have to submit a request for technical equivalence of the new source to ECHA for the specific substances under consideration. ECHA proposes to provide within a few working days a preliminary conclusion on the basis of limited information that would be confirmed later (if necessary) in a second step using additional information.

In addition, ECHA proposes the following to facilitate the consideration of technical equivalence by Member States and prevent an unnecessary duplication of technical equivalence applications for the same source: provide to Member States a confidential and regularly updated list of all the technically equivalent sources for isopropanol and 1-propanol, provide a service to companies to check whether their source of isopropanol or 1-propanol is already recognised as technically equivalent.

2. The active substance used in the biocidal products is not yet approved (i.e. ethanol): the situation is fully in the hands of the Member States, who can take all measures considered necessary under national legislation. If considered useful by the Member States, ECHA could also centralise the industry requests that would concern several MS.

Please be also informed that we plan to send to you a more comprehensive question and answer document addressing a broader range of issues early next week.

Regards,

5.1.2e



European Commission

DG Health and Food Safety

Unit 5.1.2e - Pesticides and Biocides

Tel.: 5.1.2e

e-mail: 5.1.2e @ec.europa.eu

Web: [http://ec.europa.eu/dgs/health food-safety/](http://ec.europa.eu/dgs/health_food-safety/)

From: 5.1.2e

Sent: Monday, March 16, 2020 4:08 PM

To: 5.1.2e; SANTE BIOCIDES; 5.1.2e; 5.1.2e @health.fgov.be'; 5.1.2e @health.fgov.be'; 5.1.2e @environnement.belgique.be'; 5.1.2e @health.fgov.be'; 5.1.2e @mccaa.org.mt'; 5.1.2e @echa.europa.eu'; 5.1.2e @mh.government.bg'; 5.1.2e @ncpha.government.bg'; 5.1.2e @bag.admin.ch'; 5.1.2e @bafu.admin.ch'; 5.1.2e @bag.admin.ch'; 5.1.2e @bag.admin.ch'; 5.1.2e @da.moa.gov.cy'; 5.1.2e @da.moa.gov.cy'; 5.1.2e @da.moa.gov.cy'; 5.1.2e @mzp.cz'; 5.1.2e @mzcr.cz'; 5.1.2e @bmu.bund.de'; 5.1.2e @baua.bund.de'; 5.1.2e @bmu.bund.de'; 5.1.2e @bmu.bund.de'; 5.1.2e @mfvm.dk'; 5.1.2e @mst.dk'; 5.1.2e @mfvm.dk'; 5.1.2e @mst.dk'; 5.1.2e @terviseamet.ee'; 5.1.2e @sm.ee'; 5.1.2e @eof.gr'; 5.1.2e @minagric.gr'; 5.1.2e @minagric.gr'; 5.1.2e @minagric.gr'; 5.1.2e @msssi.es'; 5.1.2e @mapama.es'; 5.1.2e @mapama.es'; 5.1.2e @tukes.fi'; 5.1.2e @tukes.fi'; 5.1.2e @anses.fr'; 5.1.2e @anses.fr'; 5.1.2e @developpement-durable.gouv.fr'; 5.1.2e @developpement-durable.gouv.fr'; 5.1.2e @developpement-durable.gouv.fr'; 5.1.2e @anses.fr'; 5.1.2e @developpement-durable.gouv.fr'; 5.1.2e @miz.hr'; 5.1.2e @miz.hr'; 5.1.2e @miz.hr'; 5.1.2e @nnk.gov.hu';

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 5.1.2e @mhsr.sk'; 5.1.2e @mhsr.sk'; 5.1.2e @mh.government.bg'

Cc: 5.1.2e

Subject: supply shortage of active substances

Dear colleagues,

Following on from my message this morning, we had some further discussion with CEFIC, from which the following suggestion emerged:

CEFIC will contact the Biocidal Product companies to suggest that data owners (i.e. companies on the Article 95 list) who can purchase ethanol and/or isopropanol from other suppliers, submit the technical data sheet for the other source to ECHA for assessment of technical equivalence, and can then place on the market the needed disinfectants even if they have not produced themselves the actives. We have already alerted ECHA that this might come in the near future and require swift action.

In the meantime, and depending on the urgency in your country, you can also consider giving Article 55(1) derogations in a national context for products containing active substances with other specifications if companies approach you with such a solution and you are satisfied about the equivalence being sufficient.

Regards,

5.1.2e

5.1.2e



European Commission

DG Health and Food Safety

5.1.2e Pesticides and Biocides

Tel. 5.1.2e

e-mail: 5.1.2e @ec.europa.eu

Web: http://ec.europa.eu/dgs/health_food-safety/

From: 5.1.2e

Sent: Monday, March 16, 2020 11:51 AM

To: 5.1.2e <5.1.2e @bmk.gv.at>; 5.1.2e <5.1.2e @ec.europa.eu>; 5.1.2e
 <5.1.2e @bmk.gv.at>; 5.1.2e @health.fgov.be; 5.1.2e @health.fgov.be;
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 Cc: 5.1.2e <5.1.2e@ec.europa.eu>; 5.1.2e <5.1.2e@ec.europa.eu>;
 5.1.2e <5.1.2e@bmk.gv.at>; 5.1.2e <5.1.2e@bmk.gv.at>

Subject: RE: Art. 55 (1) Notification AT

Dea 5.1.2e

Thank you for our message. We have noted the authorisation under Article 55(1).

As regards Article 95: following verification with the Legal Service, it seems unfortunately not possible to use Article 55(1) for a derogation from Article 95.

This was clearly overlooked when Article 55(1) was drafted as there is no reference to Article 95.

We see two solutions:

- Member States temporarily tolerate supply by companies not listed on Article 95 – but this has some legal uncertainty in case companies listed on Article 95 later seek redress
- Member States authorities approach national associations or directly companies listed under Article 95 who are not able to increase production capacity and suggest to them to grant (temporary) letters of access to others who are not listed – and inform ECHA thereof so that they can be included in the list – or they make contractual arrangements for toll-manufacturing among themselves to be able to increase delivery volumes.

We have just suggested this to CEFIC and await a response.

Regards,

5.1.2e

5.1.2e



European Commission

DG Health and Food Safety

5.1.2e – Pesticides and Biocides

Tel.: 5.1.2e

e-mail: 5.1.2e @ec.europa.eu

Web: http://ec.europa.eu/dgs/health_food-safety/

From: 5.1.2e <5.1.2e@bmk.gv.at>

Sent: Monday, March 16, 2020 11:33 AM

To: SANTE BIOCIDES <5.1.2e@ec.europa.eu>; 5.1.2e <5.1.2e@bmk.gv.at>;

5.1.2e @health.fgov.be; 5.1.2e @health.fgov.be;

5.1.2e @environnement.belgique.be; 5.1.2e @health.fgov.be;

5.1.2e @mccaa.org.mt; 5.1.2e @echa.europa.eu; 5.1.2e @mh.government.bg;

5.1.2e @ncpha.government.bg; 5.1.2e @bag.admin.ch; 5.1.2e @bafu.admin.ch;
 5.1.2e @bag.admin.ch; 5.1.2e @bag.admin.ch; 5.1.2e @da.moa.gov.cy;
 5.1.2e @da.moa.gov.cy; 5.1.2e @da.moa.gov.cy; 5.1.2e @mzp.cz;
 5.1.2e @mzcr.cz; 5.1.2e @bmu.bund.de; 5.1.2e @baua.bund.de; 5.1.2e @bmu.bund.de;
 5.1.2e @bmu.bund.de; 5.1.2e @mfvm.dk; 5.1.2e @mst.dk; 5.1.2e @mfvm.dk; 5.1.2e @mst.dk;
 5.1.2e @terviseamet.ee; 5.1.2e @sm.ee; 5.1.2e @eof.gr; 5.1.2e @minagric.gr;
 5.1.2e @minagric.gr; 5.1.2e @minagric.gr; 5.1.2e @msssi.es; 5.1.2e @mapama.es;
 5.1.2e @mapama.es; 5.1.2e @tukes.fi; 5.1.2e @tukes.fi; 5.1.2e @anses.fr;
 5.1.2e @anses.fr; 5.1.2e @developpement-durable.gouv.fr; 5.1.2e @developpement-durable.gouv.fr;
 5.1.2e @anses.fr; 5.1.2e @developpement-durable.gouv.fr; 5.1.2e @miz.hr;
 5.1.2e @miz.hr; 5.1.2e @miz.hr; 5.1.2e @nnk.gov.hu;
 5.1.2e @nnk.gov.hu; 5.1.2e @nnk.gov.hu; 5.1.2e @agriculture.gov.ie;
 5.1.2e @agriculture.gov.ie; 5.1.2e @agriculture.gov.ie; 5.1.2e @agriculture.gov.ie;
 5.1.2e @agriculture.gov.ie; 5.1.2e @ust.is; 5.1.2e @ust.is;
 5.1.2e @umh.stjr.is; 5.1.2e @sanita.it; 5.1.2e @sanita.it; 5.1.2e @iss.it; 5.1.2e
 5.1.2e < 5.1.2e @bmk.gv.at>; 5.1.2e
 < 5.1.2e @echa.europa.eu>; info@nvsc.lt; 5.1.2e @nvsc.lt; 5.1.2e @aev.etat.lu;
 5.1.2e @lvgmc.lv; 5.1.2e @lvgma.gov.lv; 5.1.2e @mccaa.org.mt; 5.1.2e @gov.mt;
 5.1.2e @gov.mt; 5.1.2e @mccaa.org.mt; 5.1.2e @mccaa.org.mt; 5.1.2e
 5.1.2e @mccaa.org.mt; 5.1.2e @rivm.nl; 5.1.2e @minienm.nl; 5.1.2e @ctgb.nl;
 5.1.2e @ctgb.nl; 5.1.2e @ctgb.nl; 5.1.2e @ctgb.nl; 5.1.2e @miljodir.no;
 5.1.2e @miljodir.no; 5.1.2e @urpl.gov.pl; 5.1.2e @urpl.gov.pl;
 5.1.2e @urpl.gov.pl; 5.1.2e @urpl.gov.pl; 5.1.2e @urpl.gov.pl; 5.1.2e @dgav.pt;
 5.1.2e @dgs.min-saude.pt; 5.1.2e @dgav.pt; 5.1.2e @dgav.pt; 5.1.2e @dgav.pt;
 5.1.2e @dgav.pt; 5.1.2e @dgs.min-saude.pt; 5.1.2e @insp.gov.ro; 5.1.2e @anpm.ro;
 5.1.2e @rpro.eu; 5.1.2e @anpm.ro; 5.1.2e @ms.ro;
 5.1.2e @mmediu.ro; 5.1.2e @mmediu.ro; 5.1.2e @insp.gov.ro;
 5.1.2e @kemi.se; 5.1.2e @kemi.se; 5.1.2e @kemi.se; 5.1.2e @kemi.se;
 5.1.2e @kemi.se; 5.1.2e @kemi.se; 5.1.2e @gov.sj; 5.1.2e @gov.sj;
 5.1.2e @mhsr.sk; 5.1.2e @mhsr.sk; 5.1.2e @mhsr.sk; 5.1.2e @mh.government.bg
 Cc: 5.1.2e < 5.1.2e @ec.europa.eu>; 5.1.2e < 5.1.2e @ec.europa.eu> 5.1.2e
 A 5.1.2e < 5.1.2e @ec.europa.eu>; 5.1.2e < 5.1.2e @bmk.gv.at>;
 5.1.2e < 5.1.2e @bmk.gv.at>

Subject: Art. 55 (1) Notification AT

Dear 5.1.2e

Dear 5.1.2e

Please find attached to this message the notification of an Art. 55 (1) granted by the AT-CA.

In addition to this notification, we would need further clarification on the scope of Art. 95 BPR. In particular, does the exemption from the requirements of Art. 17 and 19 contained in Art. 55 (1) also imply a derogation from Art. 95? And, as a second question, can Art. 55 (1) be used to grant a derogation from Art. 95?

Best regards,

5.1.2e

Bundesministerium für Klimaschutz, Umwelt, Energie, Mobilität, Innovation und Technologie

Chemiepolitik und Biozide

5.1.2e

5.1.2e

5.1.2e

Mobil: 5.1.2e

Stubenbastei 5, 1010 Wien, Österreich

5.1.2e @bmk.gv.at

www.bmk.gv.at