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Questions and answers

This advice is aimed at companies seeking to make available on the EU market disinfectants for the purpose of managing the Covid-19 pandemic. It particularly aims to target biocidal products that are meant to be used in the following product types (PTs):

- human hygiene (PT 1);
- surface disinfection (PT 2); and
- disinfection of surfaces in contact with food and feed (PT 4)

For a more thorough description of these PTs see:
https://echa.europa.eu/regulations/biocidal-products-regulation/product-types

Applicable rules will depend on the type of active substance (AS) included in your product:

- 'Existing' AS being evaluated for approval – see Q&A 1
  - E.g. ethanol in PT 1, 2, 4
- 'Not included in the Review Programme' AS being evaluated for approval – see Q&A 3
- Approved AS – see Q&A 2
  - E.g. propan-1-ol, propan-2-ol in PT 1, 2, 4
  - Hydrogen peroxide in PT 1, 2, 4
  - Active chlorine generated from sodium chloride by electrolysis in PT1, 2, 4
  - Active chlorine released from hypochlorous acid in PT1, 2, 4

To start, you need to:

- Identify the AS/PT combinations relevant for your product; subsequently
- Contact the relevant National Helpdesk(s) to learn how to proceed further. Each country (EU/EEA/Switzerland) is responsible for deciding how products can be on their market in this emergency situation.
- See our Covid-19 webpage: https://echa.europa.eu/covid-19

Question 1:

I represent a (non-)EU company that wishes to place on the EU/EEA/Swiss market **ethanol** based products (e.g hand sanitisers). What do I need to do to quickly place on the market my products?

Answer 1:

If you are a non-EU based company – start reading from here:

Firstly, note that companies established outside of the EU are not bound by the obligations of the BPR, even if they export their products into the European Union. The responsibility for fulfilling the requirements of the BPR, such as the approval of active

substances or the authorisation of biocidal products lies in principle with the **importers** established in the **European Union**. It is the EU based importer which needs to comply with the BPR obligations illustrated below.

If you are an EU based company – start reading from here:

Products containing ethanol used for disinfection purposes are covered by the scope of the Biocidal Products Regulation (EU) No 528/2012 (BPR). At the moment, ethanol is being evaluated for approval under the BPR in the following disinfectant product types PT 1, 2 and 4. Accordingly, it is the national rules of each country that apply both for regular authorisation of the products and also to any derogation from those rules due to the current situation (Covid-19 pandemic).

Since the substance ethanol is still under evaluation, it is not possible to get a Union wide authorisation for products containing it.

Suppliers of ethanol based biocidal products (e.g. hand sanitisers) need to:

- Contact the **national helpdesk of the country where the product will be marketed**: https://echa.europa.eu/support/helpdesks/
  The national helpdesks will indicate what you need to do to place the biocidal product on their market.

Question 2:

I represent a (non-)EU company that wishes to place on the EU/EEA/Swiss market **isopropanol (propan-2-ol)** based hand sanitisers. What do I need to do to quickly place on the market my products?

Answer 2:

If you are a non-EU based company – start reading from here:

Firstly, note that companies established outside of the EU are not bound by the obligations of the BPR, even if they export their products into the European Union. The responsibility for fulfilling the requirements of the BPR, such as the approval of active substances or the authorisation of biocidal products lies in principle with the **importers** established in the **European Union**.

It is the EU based importer which needs to comply with the BPR obligations illustrated below.

If you are an EU based company – start reading from here:

The substance is already approved under the BPR for use in PT 1, 2 and 4, therefore suppliers of propan-2-ol based products need to consider that:

Normally, biocidal products must be authorised **prior** to being made available on the market and used, in accordance with Article 17 and 19 of the BPR. Technical Equivalence must be proved **prior** to submitting an application for biocidal product authorisation (Article 54 BPR).

However, in **exceptional situations** (e.g. in case of danger to public health), a Member State may permit products on its market that do not comply with the BPR, under **Article 55(1)** of the BPR.

This is valid for:

- Biocidal products containing approved AS (such as propan-1-ol or propan-2-ol); or
- Biocidal products containing AS/PT combinations that are not covered by the Review Programme

Note that the decision to apply Article 55(1) falls entirely **under the remit of the Member States and can be granted only within a given national territory**. For such matters, it is necessary to contact and liaise with the relevant national helpdesks: https://echa.europa.eu/support/helpdesks/

Question 3:

I represent a (non-)EU company that wishes to place on the EU/EEA/Swiss market products based on an active substance that is **'not included in the Review Programme'**. How can I quickly access the market?

Answer 3:

If you are a non-EU based company – start reading from here:

Firstly, note that companies established outside of the EU are not bound by the obligations of the BPR, even if they export their products into the European Union. The responsibility for fulfilling the requirements of the BPR, such as the approval of active substances or the authorisation of biocidal products lies in principle with the **importers** established in the **European Union**.

It is the EU based importer which needs to comply with the BPR obligations illustrated below.

If you are an EU based company – start reading from here:

Biocidal products containing active substances (AS/PT combinations) that are not in the Review Programme can only be placed on the market following approval of the substances and authorisation of the products.

However, in **exceptional situations** (e.g. in case of danger to public health), a Member State may permit products on its market that do not comply with the BPR, under **Article 55(1)** of the BPR.

This is valid for:

- Biocidal products containing approved AS (such as propan-1-ol or propan-2-ol); or
- Biocidal products containing AS/PT combinations that are not covered by the Review Programme

Note that the decision to apply Article 55(1) falls entirely **under the remit of the Member States and can be granted only within a given national territory**. For

such matters, it is necessary to contact and liaise with the relevant national helpdesks: https://echa.europa.eu/support/helpdesks/

Question 4:

Do companies supplying disinfectants to be used for managing the Covid-19 pandemic need to comply with the Article 95 obligation?

Answer 4:

In principle, Article 95 of the BPR applies to all biocidal products put on the EU market. To comply with the Article 95 obligation:

- the supplier of the active substance used in a biocidal product, or
- the supplier of the biocidal product

has to be included in the Article 95 list.

Not all the companies need to be on the Article 95 list. Within the same supply chain, it is sufficient that one company of that supply chain is listed.

To be included in the Article 95 list, companies that are not the original applicant for the active substance approval have to submit an application to ECHA.

In practice, the national enforcement authorities are the ones checking whether the products comply with this requirement and some Member States have communicated that, **in the current Covid-19 circumstances, disinfectant products do not have to comply with this legal requirement**.

Note that ECHA does not have a list of Member States that are currently not enforcing the Article 95 obligation for disinfectants (in PT 1, 2 or 4). You need to contact the relevant National Helpdesk(s) to find out.

Question 5:

How can I quickly place on the market the hand rub formulations recommended by WHO?

Answer 5:

Formulation 1 contains ethanol and hydrogen peroxide – see Q&A 1 and Q&A 2 for clarification.

Formulation 2 contains propan-2-ol and hydrogen peroxide – see Q&A 2 for clarification.

Question 6:

How can I quickly place on the market alcohol based hand sanitisers? What about other types of sanitisers?

Answer 6:

For alcohol based sanitisers, the applicable rules depend on which alcohol substance you intend to use. You first need to identify which alcohol is included in your product and then proceed as indicated in Q&A 1 or 2 or 3, whichever is applicable to your case.

In general, regardless of the type of sanitisers (which could be alcohol or non-alcohol based), you will always need to identify which active substances are included in the sanitisers. Particularly, the AS/PT combinations that are relevant for your product. You can check the status of your active substance of interest at: https://echa.europa.eu/information-on-chemicals/biocidal-active-substances

Nevertheless, all possible scenarios of AS/PT combinations are covered by Q&A 1, 2 and 3. In all these cases, you will need to contact the National Helpdesk(s) to learn how to proceed further.

Question 7:

Do I need to register the substances contained in the biocidal product under REACH?

Answer 7:

Approved active substances as well as existing active substances still being evaluated for approval are regarded as registered under REACH, therefore they are exempted from REACH registration. However, other substances used for producing the biocidal product are subject to REACH registration (if the manufactured or imported quantity is higher than a 1 tonne/year per company).

For further information, you can refer to Q&A 0906, as well as section 2.2.4.1- 'Substance for use in biocidal products' of the Guidance on registration

Question 8:

To manage the Covid-19 outbreak, is it possible to obtain a temporary permit, similar to a provisional union authorisation that allows the placing on the market of disinfectants EU wide?

Answer 8:

No. The applicability of the Art 55(1) derogation as well national rules are decided at national level. To allow the temporary placing on the market of disinfectants EU wide, you need to contact each of the individual EU countries to find out what steps to take.