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Chur, 26.02.2014

The new Biocide Regulation

Dear Lorena

On September 1st 2013 the current Biocidal Products Directive 98/8/EC was superseded by the new Biocides Regulation (EU) No 528/2012. The new regulation regarding the marketing and use of biocidal products was adopted in May 2012 and entered into force on July 17th 2012. Since September 1st 2013 the regulation must be implemented throughout Europe and, since it is a directly applicable EU law, does not need to be transferred to the national legislations.

The new regulation includes changes in the authorization of biocidal products but also contains the following new features:

- The scope of the new regulation was expanded and will include in situ generated as well as locally produced biocidal products (Article 3 and Article 17).
- The use of biocidal products is now explicitly regulated (Article 17).
- Also nanomaterials and treated articles (Article 1 and Article 58) will be included by the Regulation in future. If a product contains nanomaterials, the risks to the environment need to be considered separately (Article 19 Paragraph 1f) and the products need to be marked and labelled accordingly.
- Biocidal products which were used for treatment of goods before they are placed on the market may only contain active substances which are approved by the EU law for the corresponding purpose. The labels of these treated articles must be marked accordingly (Article 58)
- ...

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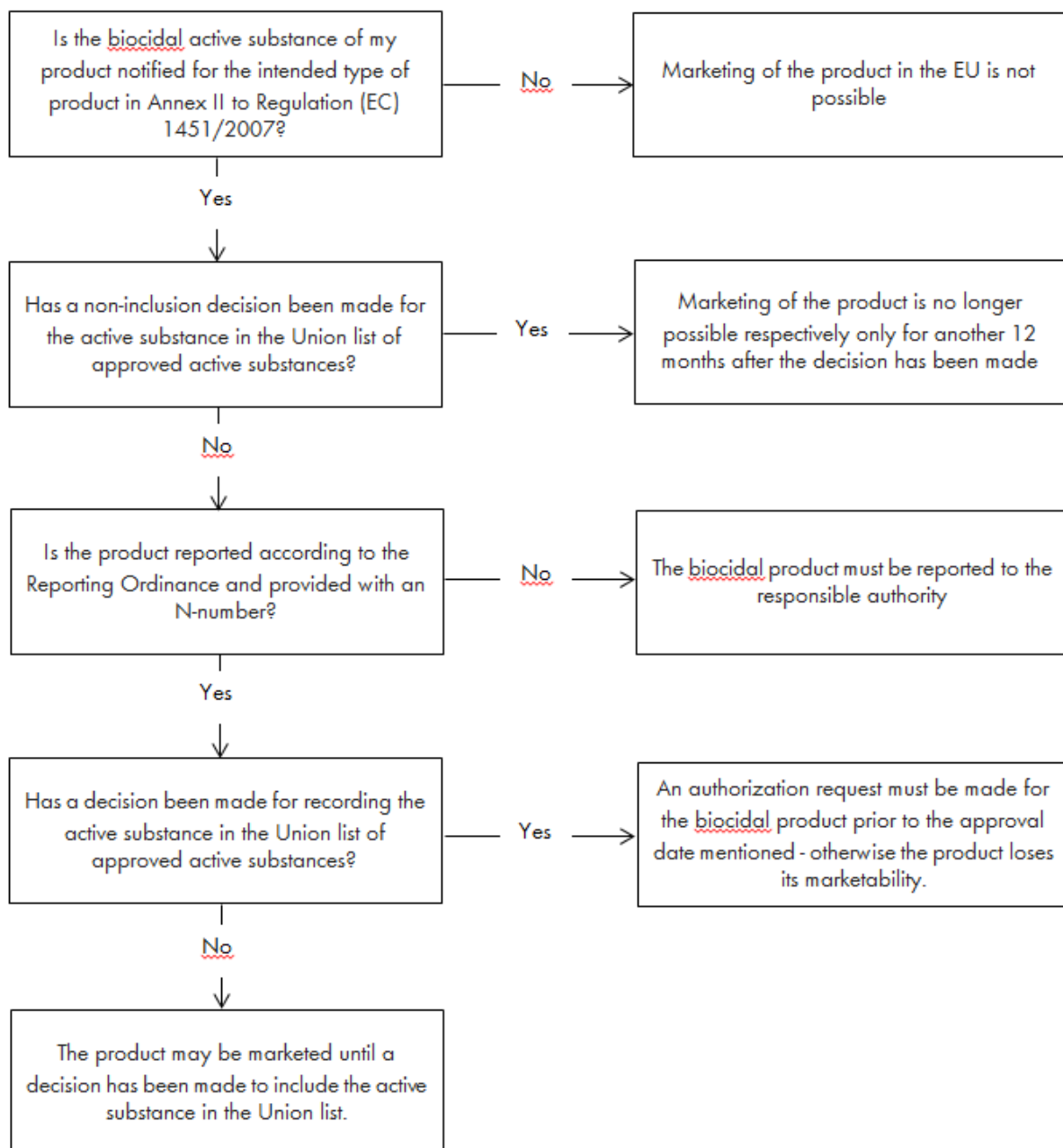
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It is basically positive that a collaborative product approval (so-called „union authorization“) is introduced, since this will bring a relief in the approval process for manufacturers and importers.

What does this mean for Würth?

The current Würth range of chemical technical items includes various biocidal products (see Appendix). In case you have these products in active sales, it must be ensured that the products are registered according to the previous Directive 98/8/EC.

For products which are reported according to the old Directive, the following flow chart shows when an authorization is required according to the new Biocides Regulation:



How to deal with the scheme above is described below using the product „moss and mould remover“, 0890 966, as an example:

The biocidal active substance is didecyldimethylammoniumchloride (CAS 7173-51-5). This active substance is notified according to the Regulation (EC) 1451/2007 for the product types 1,2,3,4,6,7,8,9,10,11,12,13.

In ESIS (European chemical Substances Information System) the latest decision about decision about inclusion or non-inclusion can be found under the headline BPD (<http://esis.jrc.ec.europa.eu/index.php?PGM=bpd>):



The outcome for the „moss and mould remover“ is as follows:

Non-inclusion of the active substance for the product types 7/9/13/16/18, i.e. the product must be removed from the market within 12 months from the date the decision was made.

Inclusion of the active substance for product type 8, i.e. in accordance with Directive 2013/4/EU an application for approval must be submitted until 01.02.2015.

If no application for the authorization or mutual recognition in accordance with subparagraph 2 has been made,

- a) the biocidal product shall not be placed on the market 180 days after the date of approval of the active substance / substances and
- b) the stocks of biocidal products can be removed and used up for 365 days after the date of approval of the active substance.

The product types 1, 2, 3, 4, 6, 10, 11, 12 are still in the Review Program of ECHA and can thus be marketed without admission until a decision on inclusion or non-inclusion of the active substance for the product types 2 and 10 which are relevant for the “moss and mould remover” has been made.

The suppliers of biocidal products which you purchase from AWKG or WIAG have been requested to follow the enclosure or non-enclosure of the active substances for the different product types and to inform Würth on time in order for us to define the correct measures.

Please note that, in case you purchase biocidal products locally, you ought to contact your suppliers and inform them about their duties as described above.

Please feel free to contact us in case you have any further questions.

Best regards,

Würth International AG



Pia Ahlgren

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