



Request for an ECHA opinion - Mandate

"Status of copper sulphate in Manica Spa and Stormoellen' products"

1. Background

- (1) Pursuant to Article 15(a) of Regulation (EU) No 1062/2014, and following the repeal of the former Manual of Decision, persons placing biocidal products on the market which relied on that guidance could submit a declaration of interest to notify to the Commission in case that guidance gave objectively justified reasons to believe that their products were excluded from the scope of Directive 98/8/EC or of Regulation (EU) No 528/2012, although they were in the scope. The deadline for such submission was 3 October 2016¹.
- (2) On 22 February 2016 and 30 September 2016, Manica Spa and Stormoellen submitted declarations of interest to notify the active substance *Copper sulphate pentahydrate* (EC 231-847-6, CAS 7758-99-8) for use in biocidal products of product-type 3 (PT3).
- (3) Manica Spa and Stormoellen argue that the product Stalosan contain copper sulphate pentahydrate with the view to act as an inhibitor of the microbial enzyme urease and to control the production of ammonia resulting from the action of urease on urea. They argue that it has an indirect effect on bacteria, and that indirect effects were considered out of the scope of the Biocidal Product Directive 98/8/EC until the European Court's ruling in case C-420/10 Söll v Tetra GbH².
- (4) Although it was not notified in the review programme for product-type 3, it has to be noted that copper sulphate pentahydrate was notified in 2003 and included the review programme as an active substance for product-type 2. The application for approval was submitted by Manica Spa in 2007. The evaluation has been finalised, and copper sulphate has been approved as active substance for use in biocidal product of product-type 2 by Regulation (EU) No 1033/2013 of 24 October 2013.
- (5) Discussions took place during the 65th and 66th CA meetings of representatives of Members States Competent Authorities for the

¹ https://echa.europa.eu/view-article/-/journal_content/title/manual-of-decisions-repealed-check-the-status-of-products-formerly-excluded-from-biocides-legislation-with-the-national-helpdesk

² <http://curia.europa.eu/juris/liste.jsf?num=C-420/10&language=EN>

implementation of Regulation (EU) No 528/2012 of September and November 2016 concerning the acceptance of these declarations of interest to notify³.

- (6) During these discussions, it appeared that further technical input from ECHA was needed in order to be able to conclude on this case, in particular to know if, in the product Stalosan referred by Manica and Stormoellen, copper sulphate was acting as active substance or not. It was agreed that the Commission will request a formal opinion to ECHA on the matter, in order to help the decision making process on the acceptance or rejection of the declarations of interest to notify.
- (7) Pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012, ECHA is requested to formulate an opinion addressing the following questions.

2. The questions referred to ECHA

- (8) Taking into consideration this background information, as well as the enclosed documents, ECHA is requested to formulate an opinion on the following questions:
 - (a) Does copper sulphate pentahydrate act as an active substance in the product Stalosan F referred by Manica Spa and Stormoellen for product-type 3?
 - (b) If it acts as an active substance :
 1. What is the mode of action of copper sulphate in the product Stalosan?
 2. Is this the same mode of action as for copper sulphate used in PT2 biocidal products, which was notified in 2003 and already approved by Regulation (EU) No 1033/2013?
 3. Is this the same mode of action as other active substances notified and included in the review programme in 2003 for PT3, and currently under review or already approved?

3. Deadline for the ECHA opinion

31 October 2017

4. Supporting documents

- Declarations of interest to notify from Manica of 22 February 2016 and 30 September 2016, and from Stormoellen of 30 September 2016
- Safety data sheet of the product "Stalosan"

³ [CA-Nov16-Doc.5.7 - Restricted - DoI - Draft conclusions.docx](#)