

Helsinki, 23 April 2008 **Doc: MB/17/2008 final**¹

DECISION ESTABLISHING REMEDIES FOR REVIEWING A PARTIAL OR FULL REJECTION OF A CONFIDENTIALITY REQUEST PURSUANT TO ARTICLE 118(3) OF REGULATION (EC) N° 1907/2006

(Document adopted by the Management Board)

¹ Last amended on 1 April 2012 (Update of the Annex with Doc: ED/25/2012)

THE MANAGEMENT BOARD OF THE EUROPEAN CHEMICALS AGENCY

Having regard to Article 118(3) of Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directive 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (hereinafter the "REACH Regulation"),

Whereas:

- (1) Articles 118(2) and 119(2) of the REACH Regulation provide protection to commercial interests of persons submitting information to the Agency.
- (2) Article 118(3) of the REACH Regulation provides for the adoption of remedies necessary for reviewing a partial or full rejection of a confidentiality request.
- (3) It is necessary to establish rules for implementing Article 118(3) of the REACH Regulation which should be made publicly available,

HAS ADOPTED THIS DECISION:

Article 1 Scope

This Decision prescribes the arrangements under which the registrants within the meaning of the REACH Regulation may seek redress in a situation where the European Chemicals Agency (hereinafter 'the Agency') has rejected wholly or partly a request for confidentiality made in their registration dossier.

Article 2 Rejection of a confidentiality request

A decision by the Agency to reject a confidentiality request shall be notified to the registrant in writing, where appropriate by electronic means, and shall inform him of his right to request a review from the Agency within two months from receipt of the decision.

The information concerned shall not be published before the timeline for requesting a review has lapsed or the Agency has taken a decision on the request for review.

Article 3 Request for review

Any decision to reject a confidentiality request partially or fully may be contested within two months from receipt of the decision, by submitting a request for review to the Agency.

Requests for review of a decision rejecting a confidentiality request shall be sent in writing, stating the grounds on which a review of the decision is requested and including any supporting information necessary to substantiate those grounds. The addresses to which requests for review are to be sent are listed in the Annex to this Decision. The Executive Director may decide to update the Annex as necessary.

As soon as the request for review is registered, an acknowledgement of receipt shall be sent to the registrant in writing, where appropriate, by electronic means.

Article 4 Treatment of requests for review

The Agency shall take a decision on the request for review within two months from the date of registration of the request.

The decision shall be notified to the applicant in writing, where appropriate by electronic means, and shall inform him of his right to bring an action before the Court of First Instance or, if appropriate, to lodge a complaint with the European Ombudsman.

Article 5
Entry into force

This Decision shall enter into force on 1 June 2008.

Article 6
Publication

This Decision shall be published on the Agency's website.

ANNEX

ADDRESSES FOR SUBMISSION OF REQUESTS FOR REVIEW OF DECISIONS REJECTING A CONFIDENTIALITY REQUEST

If the request for review concerns decision rejecting wholly or partly a request for confidentiality under Article 119 (2) of Regulation (EC) No 1907/2006

By web-form available here:

https://comments.echa.europa.eu/comments_cms/RequestForReview.aspx

By fax: + 358 9 6861 8933

If the request for review concerns either a decision rejecting the use of an alternative chemical name under Article 24 (4) of Regulation (EC) No 1272/2008 or a decision by the Agency to withdraw or amend its decision on the use of an alternative chemical name on the basis of new information under Article 24 (6) of Regulation (EC) No 1272/2008

By web-form available here:

https://comments.echa.europa.eu/comments_cms/RequestForReviewACN.aspx

By fax: + 358 9 6861 8934

For both cases:

By mail: European Chemicals Agency (ECHA)

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