

**DECISION OF THE MANAGEMENT BOARD
ON THE SERVICE CHARGE FOR CHEMICAL SIMILARITY CHECK
PERFORMED FOR BIOCIDAL ACTIVE SUBSTANCES**

THE MANAGEMENT BOARD OF THE EUROPEAN CHEMICALS AGENCY,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, and in particular Article 80(1) thereof;

Having regard to Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, and in particular Article 15 thereof;

WHEREAS:

- (1) The European Chemicals Agency (hereinafter referred to as "the Agency") may collect charges for other services it provides beyond the established fees.
- (2) It is for the Management Board, subject to a favourable opinion from the Commission, to establish charges for administrative or technical services that the Agency provides upon request to facilitate implementation of Regulation (EU) No 528/2012.
- (3) A need has arisen to provide a chemical similarity check service to applicants and other parties submitting information pursuant to Regulation (EU) No 528/2012 to facilitate their dossier submission. The Agency may provide this service provided it has resources available.
- (4) The Agency should levy a charge for such services to cover its costs for these tasks not foreseen in Regulation (EU) No 528/2012.
- (5) The level of charges for services provided by the Agency should be fixed to cover the costs of the Agency.
- (6) The Executive Director should be able to review these charges by reference to the inflation rate as measured by the European Index of Consumer Prices as published by Eurostat pursuant to Regulation (EC) No 2494/95.

Following a favourable opinion from the Commission (C(2013)8349 final of 29 November 2013),

HAS DECIDED AS FOLLOWS:

**Article 1
Definitions**

1. "Service charge" shall mean charges pursuant to Article 15(1) of Regulation (EU) No 564/2013 which are established in this decision.
2. "Chemical similarity check" shall mean an assessment similar to technical equivalence assessment described in Article 54 of Regulation (EU) No 528/2012, but performed solely on the substance identity and chemical composition of a substance with the aim of establishing its similarity as regards the chemical composition of a second substance.

3. "Target processing time" shall mean the time within which the Agency would normally be able to undertake the service. It starts from the date when the Agency has all necessary information available, either from the applicant or from the competent authorities.
4. "Applicant" shall mean the entity applying for the chemical similarity service.
5. "Participant" shall mean an entity which has submitted a complete dossier for an active substance that has been accepted by a Member State for assessment under the Review Programme established under Article 16 of the Biocidal Products Directive 98/8/EC.

Article 2

Scope of Application

1. The service for a chemical similarity check is only available for the purposes of facilitating the implementation of Regulation (EU) No 528/2012, in particular submissions under Article 95 of that Regulation.
2. The service for a chemical similarity check is designed for the following situations:
 - a. The comparison of one substance to a biocidal active substance which has been submitted for assessment under the Biocidal Products Directive 98/8/EC or Regulation (EU) No 528/2012 but for which no final decision on the approval has yet been adopted.
 - b. The comparison of two or more substances (which are generally not under evaluation, under the Biocidal Products Directive 98/8/EC or Regulation (EU) No 528/2012), in view of a prospective joint application for active substance approval under Regulation (EU) No 528/2012.
3. The service is of a voluntary nature. The Agency may reserve the right to perform it only when its resources allow.

Article 3

Service request

1. Where a service for a chemical similarity check is requested, the Agency shall inform the applicant of the possibility to process the request, of the target processing time and of the charges payable.
2. The charges must be paid within 30 calendar days to the Agency.
3. The Agency shall undertake the requested service upon receipt of the charge and make every effort to process it within the target processing time, calculated from the date of receipt of all necessary information.

Article 4

Scale of charges

1. The charge referred to in Article 3 shall be based on the daily rate of the Agency and in such a way that it covers the costs of the services delivered by the Agency.
2. The tables of the annex to this Decision set out the scale of the service charges. This scale is based on ECHA's staff and overhead costs in 2011 and may be updated by a decision of the Executive Director of the Agency, using as reference rate the inflation

rate as measured by the European Index of Consumer Prices as published by Eurostat pursuant to Regulation (EC) No 2494/95.

**Article 5
Review**

After having finalised 50 services for a chemical similarity check the Agency will inform the Management Board without delay on the experience gained and, where appropriate, prepare a proposal amending this Decision.

**Article 6
Application date**

This Decision shall apply from the day of its adoption.

**Article 7
Publication**

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

Annex

Scale of charges

Table 1
 Service charges referred to in Article 3

Comparison of one source with an active substance (existing or new) under evaluation under BPD or BPR	Service charge (EUR)
Temporary reference source exists	4.200 EUR
Temporary reference source does not exist and only one participant has submitted a dossier under the Review Programme for existing active substances or under new active substance approval (Article 7 of the BPR ¹ or Article 11 of BPD ²)	9.400 EUR
Temporary reference source does not exist and more than one participant has submitted a dossier under the Review Programme for existing active substances or under new active substance approval (Article 7 of the BPR or under Article 11 of BPD)	Basic charge 11.200 EUR for two dossiers used for establishing the temporary reference source, topped by an additional charge of 1.500 EUR per additional dossier

Table 2
 Service charges referred to in Article 3

Comparison of two or more sources of an active substance which is not yet under evaluation under BPD or BPR	Service charge (EUR)
Two datasets submitted for comparison	9.400 EUR
Three or more datasets submitted for comparison	Basic charge 11.500 EUR for three datasets, topped by an additional charge of 1.900 EUR per additional dataset

¹ Biocidal Products Regulation (EU) No 528/2012

² Biocidal Products Directive 98/8/EC