

Practical guide on appeals under the biocidal products regulation

December 2021



Disclaimer

This document <u>aims to assist users in complying with their obligations under the Biocidal Products Regulation (BPR)</u>. However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. <u>Usage of the information remains under the sole responsibility of the user.</u> The European Chemicals Agency does not accept any liability with regard to <u>the use that may be made of the information contained in this document.</u>

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V2	Editorial improvements	December 2021

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WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS



The Biocidal Products Regulation ((EU) No 528/2012 (BPR)) foresees the possibility to appeal certain decisions taken by the European Chemicals Agency (ECHA) before the ECHA Board of Appeal (BoA).¹ Appeals are possible against the following types of decisions:

Decisions to reject the application due to non-payment of the ECHA fee

- approval of active substance;
- amending Annex I to the BPR;
- renewal of approval of active substance;
- Union authorisation of biocidal product;
- · renewal of Union authorisation of biocidal products;
- technical equivalence.

Decisions on substance

- Technical equivalence:
 - Rejection of application because additional information has not been provided;
 - Decision on technical equivalence.
- permission to refer to tests or studies;
- permission to refer to data for which the data protection period is deemed to have expired.

It is also possible to appeal against some of ECHA's decisions taken under certain related Commission regulations. These Agency decisions concern:

- Applications for recognition of SME status (see Commission Implementing Regulation (EU) No 354/2013);
- Notifications or applications for changes of authorised products (see Commission Implementing Regulation (EU) No 564/2013):
 - rejection of notification of administrative, or application for minor or major change because of non-payment of ECHA fee;

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¹ Ref: Article 77 of the BPR.

- rejection of application for minor change because of failure to provide additional information.
- Notifications of additional active substance/product-type combination to be examined in the Review Programme (see Commission Regulation (EU) No 613/2013²):
 - rejection of notification because of non-payment of ECHA fee;
 - rejection of notification because of failure to provide additional information.

The BoA set up within ECHA is responsible for processing appeals against the relevant decisions adopted by the Agency under the BPR and related Commission regulations.

The main rules for bringing an appeal against an Agency decision are the same as for appeals under the REACH Regulation³. They are further detailed in the Rules of organisation and procedure of the BoA⁴.

WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?



Any natural or legal person may appeal against any of the above decisions addressed to that person. Any natural or legal person may also appeal against a decision that is of direct and individual concern to them, even though the decision is addressed to another person.

WHEN

TIMELINES AND DEADLINES RELATED TO THE OBLIGATION/PROCESS



If the appeal is brought by the addressee of the decision, an appeal has to be lodged within three months of the notification of the decision to the person concerned. If the appellant (i.e. the person making the appeal) is not the addressee of the decision, the appeal must be lodged within three months of the day on which the decision became known to the appellant.

For the types of ECHA decisions set out above which are appealable to ECHA's BoA, an appeal must be brought to the BoA before an action can be brought to the Court of Justice of the European Union.

² Note that new Review Programme regulation is likely to be adopted in Autumn 2014.

³ Ref: Article 77 of the BPR as well as Article 92(1) and (2) and Articles 93 and 94 of the REACH Regulation.

⁴ Ref: Commission Regulation (EC) No 771/2008.

WHAT

INFORMATION REQUIREMENTS AND SOURCES



Information requirements

Forms, a supporting check list as well as *Practice Directions* are available on BoA's section of *ECHA's website. Practice Directions* give further advice on the information to be submitted by the appellants.

HOW

PROCEDURE TO FOLLOW



All procedural documents, as well as any other correspondence must be sent by post, telefax or email to and lodged at the Registry of the Board. Documents may also be lodged directly at ECHA's reception.

An appeal will be considered to be received only once the applicable fee has been received.

If, after consultation with the Chairman of the BoA, the Executive Director of ECHA considers the appeal to be admissible and well founded, he may rectify the decision within 30 days of the appeal being filed.

ECHA has the opportunity to lodge the defence within two months after being notified of the notice of appeal.

Each appeal lodged before the BoA is announced on ECHA's website. Within two weeks of the publication of the announcement, any persons who consider that they have sufficient interest may apply to intervene in the proceedings by submitting an application for leave to intervene.

Parties to appeal proceedings may request an oral hearing no later than two weeks from the date of notification of the closure of the written part of the proceedings. Alternatively, a hearing may also be organised at the request of the BoA ⁵ are normally held in public. Following the oral procedure, the BoA takes a decision on appeals.⁶

Appellants will find the relevant rules and further information on appeal proceedings in *Rules of Procedure*⁷ and in the *Practice directions*, available on ECHA's website.

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⁵ http://www.echa.europa.eu/about-us/who-we-are/board-of-appeal/hearings

⁶ Ref: Article 77 of the BPR, Article 92(1) and (2) and Articles 93 and 94 of the Regulation (EC) No 1907/2006 (REACH Regulation), Commission Regulation (EC) No 771/2008.

⁷ Ref: Commission Regulation (EC) No 771/2008.

RESULT

OUTCOME OF THE OBLIGATION/PROCESS



The BoA may exercise any power which lies within the competence of ECHA or remit the case to the competent body of the Agency for further action.

An appeal has suspensive effect on the contested decision until the decision of the BoA is taken.

An action, contesting a decision taken by the BoA, may be brought before the Court of Justice of the European Union⁸.

TO NOTE

EXCEPTIONS AND PARTICULAR CASES



An action concerning an ECHA decision where no right of appeal lies before its BoA may be brought before the Court of Justice of the European Union, in accordance with Article 263 of the Treaty on the Functioning of the European Union.

COST

RELATED FEES



ECHA fee is applicable for this process. It is given in Annex III to Commission Implementing Regulation (EU) No 564/2013.

HELP

TO CONTACT FOR FURTHER INFORMATION



Board of Appeal:

http://www.echa.europa.eu/about-us/who-we-are/board-of-appeal/contact/enquiry-form

MORE

INFORMATION



Legislation relevant to biocides

http://echa.europa.eu/regulations/biocidal-products-regulation/legislation

ECHA's Board of Appeal

http://www.echa.europa.eu/regulations/appeals

⁸ Ref: Article 263 of the Treaty on the Functioning of the European Union and Article 94 of the REACH Regulation.