

# Revision of GB Biocidal Products Regulation Annexes II and III

## Overview

### Purpose of this consultation

This consultation relates to the Great Britain Biocidal Products Regulation (GB BPR) (Regulation EU No 528/2012). GB BPR applies to the supply and use of biocidal products. Biocidal products are products that control harmful organisms, and include insecticides, rodenticides, wood preservatives, anti-fouling coatings on ships, disinfectants, and hand sanitisers. Biocides are essential to society to protect human health and infrastructure but can also cause risks to human and animal health and the environment if used incorrectly. GB BPR therefore aims to ensure a high level of protection for both human and animal health and the environment.

We are consulting on proposed revisions to Annexes II and III of GB BPR, which deal with the following:

**Annex II** – information requirements for biocidal active substances. The Annex details the information that must be submitted by applicants who wish to apply for a biocidal active substance to be approved. It must be read in conjunction with article 6(1) of GB BPR, which provides the general requirements for active substance applications

**Annex III** – information requirements for biocidal products. This Annex details the information that must be submitted by applicants who wish to apply for biocidal products to be approved. It must be read in conjunction with BPR article 6(1) and 20(1) which provide the general requirements for biocidal product applications.

On 26 March 2021, after the EU Exit Transition period had ended, the EU published Regulation 2021/525 which amended Annexes II and III of the EU BPR. HSE specialists had been involved in development of the EU Regulation while the UK was still a member of the EU. This EU Regulation came into force in 27 EU countries and Northern Ireland with effect from 15 April 2022. As this date came after the end of the Brexit Transition Period the changes did not apply in Great Britain.

### Proposed changes to GB BPR

Where HSE is considering recommending adoption of legislation similar to legislation that has been enacted in the EU, it is appropriate that it reviews the EU legislation before making similar changes in Great Britain. Therefore, HSE specialists have considered the EU amendments from a GB perspective and considered whether these are appropriate to adopt in GB. This consultation document sets out changes that we are proposing to GB BPR.

The existing wording in GB BPR and the proposed new wording are set out in Appendix 1.

HSE believes the changes to data requirements to Annexes II and III that are outlined in the Appendix are important to make to GB BPR, to ensure that GB is keeping up with scientific and technical progress, to reduce the need for animal testing in line with wider government goals, to provide legal certainty and to do so while minimising additional compliance costs for businesses. The changes we are proposing to make will:

1. Introduce and place emphasis on in vitro studies rather than in vivo studies.
2. Make new tests for endocrine disruptors part of the legal data requirements in GB BPR, rather than only being done on an ad hoc basis.
3. Change mutagenicity requirements to reflect new information.
4. Change requirements in relation to reproductive toxicity and generational studies.
5. Change the requirements to include developmental neurotoxicity studies if certain triggers are met.
6. Change the requirements to include efficacy data to support the innate activity of the active substance for the intended use.

These changes would enable:

- A reduction in animal testing
- Alignment with current guidance, and Organisation for Economic Co-operation and Development (OECD) validated tests
- Keeping up with new developments and scientific progress

The proposed reduction in animal testing will not reduce the quality of testing or safety of products, as reliable non-animal-based tests are now available to provide information which was previously only available through testing using live animals.

The changes would be made using legal powers within BPR to make changes to annexes using a negative-resolution statutory instrument under powers delegated to the Secretary of State in Article 85 of BPR (adaptation to scientific and technical progress). The changes will also require the consent of ministers in Scotland and Wales.

Subject to views elicited by this consultation, we propose the Regulation making the changes would take legal effect in Autumn 2023, with a 12-month transitional period after which the new requirements would become mandatory from that point for any new evaluations starting from that point onwards (even if the application had been received prior to that point). However, data that had been generated under the current requirements would still be accepted where it is considered scientifically adequate for the purposes of evaluation.

## Comparison with EU BPR

Most of the changes are similar to those made to EU BPR. However, there are some differences. The differences are:

1. 2.11.1 – the EU change makes no reference to impurities that are referred to in section 2.10, where the proposed GB BPR changes will.
2. 6.6 – the EU change states efficacy data would be required to support claims made about treated articles, where GB BPR will only require efficacy data for the innate activity of the active substance.
3. 8.10.3 – the EU change makes additional developmental neurotoxicity testing on rats part of the core data set, where the changes we propose to GB BPR would only request these changes when triggered.

The reasons for these differences are:

1. HSE proposes a minor addition to the EU wording, to make clear that analytical information required for in situ generated active substances (i.e. active substances generated or released at the point of use from other chemicals) includes information on any additional impurities that may be present. This information is required for other active substances (i.e. not in situ generated) in the existing annex point 2.11 and therefore is included in the new point 2.11.1 for consistency.
2. HSE considers that the EU's requirement for efficacy data for treated articles at the active substance evaluation stage is unnecessary because innate activity is the focus of the efficacy assessment at this stage. Because efficacy can be very dependent on overall formulation, HSE considers that it is more appropriate to consider efficacy in detail at the full product stage as is already the case.
3. HSE considers this requirement should not be CDS (core data set) but only ADS (additional data set). Our proposal is that developmental neurotoxicity studies would be required only if triggered by the occurrence of neurotoxicity or thyroid toxicity (including changes in thyroid hormones) in adult experimental animals, or a biocidal mode of action targeting molecules in the nervous system of the target organism. Given that a developmental neurotoxicity is normally only encountered in situations where at least one of these trigger conditions has been met, and that these studies involve live animals, HSE considers that this more targeted approach is appropriate as opposed to triggering this test in every case.

## Impact on businesses

HSE is aware that many biocides businesses trade in both GB and the countries to which EU BPR applies (the EU-27 countries, European Economic Area countries, Switzerland and Northern Ireland). Although we are proposing some minor differences to EU BPR data requirements, it would remain the case that a data package generated for the purposes of EU BPR compliance would also suffice for compliance with GB BPR. Taking this into account, we anticipate the changes will have low costs for businesses.

In relation to point 1, this is a minor addition to EU requirements. However, it is mainly a point of clarification and we anticipate that the information will be available to applicants alongside other information they will generate on analytical profile. It may also not be relevant to a number of in situ generated substances and could simply be addressed with a waiver. Therefore, we do not believe it would lead to extra costs for applicants compared to EU BPR compliance.

Points 2 and 3 have the effect of ensuring that HSE has appropriate data in line with improved scientific understanding, but at a lower additional cost than EU BPR requirements

A full analysis of the anticipated costs to businesses is in the draft Impact Assessment at Appendix 2.

## Invitation to comment

HSE is seeking the views of interested parties on its proposed revisions to BPR Annexes II and III. HSE believes that effective consultation is one element in its open and transparent approach to decision-making. The responses to this consultation exercise will be considered by HSE before the proposals are finalised.

The consultation is available online. Please use the link below titled 'give us your views'. If possible, we would prefer to receive responses via the online survey, but if you would prefer to respond in writing please contact us using the details below to arrange.

HSE – BPR Annex II/III consultation, Biocides Policy Team, Health and Safety Executive, Redgrave Court, Merton Road, Bootle, L20 7HS.

Email: [BiocidesPolicy@hse.gov.uk](mailto:BiocidesPolicy@hse.gov.uk)

We will fully acknowledge and consider all responses. We may contact you again if, for example, we have a query in respect of your response.

## The Consultation Document

This consultative document is issued by the Health and Safety Executive (HSE). HSE is undertaking this consultation in compliance with its duty to consult under section 50(3) of the Health and Safety at Work Act 1974.

HSE tries to make its consultation procedures as thorough and open as possible. A summary of responses to this consultation document will be made available on the consultation webpage after the close of the consultation period where they can be viewed by members of the public.

Information provided in response to this consultation may be subject to publication or disclosure in accordance with the following access to information regimes: the Freedom of Information Act 2000 (FOIA); the Data Protection Act 2018; General Data Protection Regulations (GDPR); and the Environmental Information Regulations 2004 (EIR). Statutory Codes of Practice under the FOIA and EIR also deal with confidentiality obligations, among other things.

If you would like us to treat any of the information you provide as confidential, please explain your reasons for this in your response. If we receive a request under FOIA or EIR for the information you have provided, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will be disregarded for these purposes. Requests for confidentiality should be made explicit within the body of the response.

HSE will process all personal data collected as part of this consultation in accordance with the General Data Protection Regulations. HSE's Privacy Policy Statement is available on the [HSE website](#).

## Code of Practice on Consultation

HSE is committed to best practice in consultation and to the Government's Consultation Principles. The Government is improving the way it consults by adopting a more proportionate and targeted approach, so that the type and scale of engagement is proportional to the potential impacts of the proposal. The emphasis is on understanding the effects of a proposal and focussing on real engagement with key groups rather than following a set process.

Additional guidance can be found at [GOV.uk](#).

If you require a more accessible format of this document, please send details to [HSE.Online@hse.gov.uk](mailto:HSE.Online@hse.gov.uk) and your request will be considered.

## Quality assurance and complaints

If you have any complaints about the consultation process (as opposed to comments about the issues, which are the subject of the consultation) please address them to:

Susan Robinson, HSE Consultation Coordinator, 2.2 Redgrave Court, Merton Road, Bootle L20 7HS

Email: [susan.robinson@hse.gov.uk](mailto:susan.robinson@hse.gov.uk)

We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome, you can raise the matter with the Information Commissioner's Office at

Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF or HSE Chief Executive, Sarah Albon at Health and Safety Executive, Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS. You can also write and ask your MP to take up your case with us or with Ministers. Your MP may also ask the independent Parliamentary Commissioner for Administration (the Ombudsman) to review your complaint.

**Appendices:**

Appendix 1 – List of proposed changes to Annex II and III of GB BPR

Appendix 2 – Consultation Stage Impact Assessment