

Submission via Green Alliance from a consortium of online NGOs on the Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc.) Regulations 2024

Background

Great Britain Biocidal Products Regulation (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 can also cause risks to human and animal health and the environment.

Wider context

The GB Biocidal Products Regulation in 2022 extended the deadline for the Health and Safety Executive (HSE) to re-evaluate product application to Dec 2027 (having already pushed this deadline back to 2023), which means the biocidal active substances which were due to expire in 2021-22 will now not expire until 2027. This means that substances which get restricted in the EU from now until 2027 will still circulate freely on the UK market without undergoing new checks – which poses risk to consumer safety, especially if those goods are increasingly dumped on the GB market. Further details in [this ENDS article](#).

Questions for the Department for Work and Pensions

Need for greater transparency in formulating these new requirements

The explanatory memorandum refers to the consultation and summarises its response to concerns raised, but those submissions have not been published. The [EM says](#): “Comments received raised concerns about issues such as additional costs, divergence from the EU position, or expressed a desire to move further away from animal testing. However, many of these concerns were based on a misunderstanding of the impact of the changes, which will be very small (i.e. they will only apply to new applications) or raised broader questions of government policy beyond the scope of this technical update”. The HSE [document](#) summarising the consultation responses says: “The summary reflects the views offered, but it is not possible to describe all responses in detail to ensure anonymity is preserved”.

Could the Department for Work and Pensions publish the responses to the consultation referenced in the impact assessment or explain why they are being kept anonymous?

Comparison with EU BPR

We are concerned how significant this divergence is from the EU BPR data requirements which could affect scrutiny on new biocidal substances entering the UK market. For example, it has removed some studies from the core toxicology data set for biocides, including developmental neurotoxicity testing on rats, and some efficacy testing at the active substance assessment stage. HSE summarises the difference in updates to EU information requirements (last document hyperlinked from this [page](#)), cut and pasted in the appendix below which suggests a watering down of information requirements.

This could make it more difficult to assess the safety of new biocidal substances entering the UK market. For example, the document summarising the consultation responses reports some concerns including “sufficiency of specific endocrine activity tests to draw conclusive results, related implications and uncertainty”. **How do these changes align with the UK government’s vision/commitment to design a bespoke regulatory system that responds to GB risk?**

The reasons given suggest that the UK has opted for a less precautionary approach than the EU where the science is uncertain. **In making the decision to alter requirements for accession to the UK-only/non-EU market, did the Secretary of State for Work and Pensions have due regard for the precautionary principle, following the [approach](#) set out in the Environmental Principles Policy Statement?**

Animal testing

Currently, industrial chemicals are deemed safe until regulators have provided overwhelming, often animal-based, evidence of unacceptable risks, e.g. identifying a substance as a carcinogen Categories 1A and B under the Globally Harmonised System of Classification and Labelling always requires animal testing. The introduction of non-animal tests therefore needs to be done in a way where progress on chemical safety can continue to be made. If New Approach Methodologies are to be integrated while continuing to make progress on chemical safety, they must be accepted for removing a substance from, as well as placing it on, the market (i.e. in registration data), despite uncertainties. **Can HSE confirm this data will provide sufficient information for determining if a product can be used safely and for removing it from the market if it isn’t?**

Divergence from EU requirements

HSE notes that: “comments were received about the possibility of these changes leading to regulatory divergence from the EU.... HSE believes that the changes are right for GB as they reduce animal testing requirements for defined endpoints, align the requirements with internationally validated guidance and test methods update data requirements in line with scientific and technical developments. Where requirements will differ from those in the EU, this is to remove the submission of data where HSE does not consider it to be necessary in all cases (such as a requirement being triggered rather than obligatory in every case), which HSE believes will make the requirements more proportionate for GB businesses”.

There is little acknowledgement of the impact of divergence from the EU (which aligning with OECD guidance does not mitigate) for lowered standards in GB, trade between GB and Northern Ireland, and between GB and the EU, or on regulatory costs and complexity on businesses. A more strategic approach to divergence is needed to minimise these risks in highly regulated sectors, but pursue it in areas of strategic interest, rather than the current position where divergence is happening automatically, e.g. on the basis of differing scientific opinion. As highlighted by UK in a Changing Europe: “The [emerging consensus](#) (including within government) appears to be that the regulatory costs of major divergence from the EU outweigh the benefits, and thus the opportunities for comparative advantage lie in a few niche areas, perhaps novel medicines, foods, or early-stage AI. The problem is that the UK does not appear to have a strategy for identifying those areas, nor ensuring they are

pursued coherently across Whitehall, with – crucially – adequate resources”. **How does HSE track divergence stemming from changes in UK regulation to assess and manage the impact of any changes on Northern Ireland’s place in the UK internal market?**

Can the department clarify whether this regulation is consistent with the repeated commitments ministers have given to maintain environmental protections while revising or updating assimilated law?

Appendix: HSE summary of the difference in updates to EU information requirements

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.

20 March 2024.

Q&A with Health and Safety England (HSE)

Comparison with EU BPR

Q1: “We are concerned how significant this divergence is from the EU BPR data requirements which could affect scrutiny on new biocidal substances entering the UK market. For example, it has removed some studies from the core toxicology data set for biocides, including developmental neurotoxicity testing on rats, and some efficacy testing at the active substance assessment stage. HSE summarises the difference in updates to EU information requirements (last document hyperlinked [from this page](#)) This could make it more difficult to assess the safety of new biocidal substances entering the UK market. For example, the document summarising the consultation responses reports some concerns including “sufficiency of specific endocrine activity tests to draw conclusive results, related implications and uncertainty”. **How do these changes align with the UK government’s vision/commitment to design a bespoke regulatory system that responds to GB risk?”**

A1: With regard to developmental neurotoxicity (DNT) testing, HSE does not believe that this change will lead to divergent regulatory outcomes compared to the EU position. A more pragmatic, but still scientifically sound, approach is being adopted.

Rather than being removed, this test has been reclassified as an Additional Data Set requirement, i.e. one which must be submitted when required by the intrinsic properties of an active substance. Instead of being required for every application, testing is required when any of the trigger conditions are met. These are:

- where neurotoxicity occurs in adult animals
- where the active substance interacts with molecules in the nervous system of the target organism or
- where thyroid toxicity, including changes in thyroid hormones, occurs

This will ensure that animal tests are performed only when it is scientifically justified, and will reduce the unnecessary animal testing of substances which do not possess the potential to cause DNT.

With regard to the efficacy testing requirements, HSE is correcting an error in the current version of the Biocidal Products Regulation (BPR) which was inherited from EU BPR when the Regulation was assimilated into GB law. In both GB and the EU, only data on the innate activity of the active substance against target organisms is considered for the active substance assessment, whereas a full evaluation of data to support the activity and claims made on a product label takes place when biocidal products are evaluated.

The requirement in Annex II is being corrected in GB BPR to require only data on the innate activity of the active substance. This change will not lead to any lowering of standards or levels of scrutiny, as product claims have in practice never been assessed as part of the active substance evaluation.

HSE is adopting a bespoke regulatory system for GB by reducing the burdens on industry, through removing unnecessary animal testing and dossier preparation requirements where reasonable and proportionate. Because both GB and EU systems reflect international scientific developments and validated test methods, the systems in practice remain closely aligned. As the scientific rigour of the GB requirements is very high, the safety of the biocidal substances entering the UK market is maintained.

Q2: “The reasons given suggest that the UK has opted for a less precautionary approach than the EU where the science is uncertain. **In making the decision to alter requirements for accession to the UK-only/non-EU market, did the Secretary of State for Work and Pensions have due regard for the precautionary principle, following [the approach](#) set out in the Environmental Principles Policy Statement?**”

A2: GB BPR as a whole is based on the precautionary principle (Article 1(1) states “The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment.”)

The updated data requirements support the precautionary principle by ensuring that the most up to date information is available to regulators to undertake the necessary risk assessments while minimising unnecessary animal testing. GB has not adopted a position that is less precautionary than the EU, as the GB data requirements continue to allow HSE to take appropriate regulatory action where there is plausible evidence of a potential for serious and irreversible damage from the use of biocidal active substances or products.

Animal testing

Q3: “Currently, industrial chemicals are deemed safe until regulators have provided overwhelming, often animal-based, evidence of unacceptable risks, e.g. identifying a substance as a carcinogen Categories 1A and B under the Globally Harmonised System of Classification and Labelling always requires animal testing. The introduction of non-animal tests therefore needs to be done in a way where progress on chemical safety can continue to be made. If New Approach Methodologies are to be integrated while continuing to make progress on chemical safety, they must be accepted for removing a substance from, as well as placing it on, the market (i.e. in registration data), despite uncertainties. **Can HSE confirm this data will provide sufficient information for determining if a product can be used safely and for removing it from the market if it isn’t?**”

A3: New Approach Methodologies will only be implemented when scientifically valid, when they can predict real-world hazards and when they can ensure a similar, if not higher level of protection. Where any data demonstrates that a biocidal product does not meet the strict standards of safety and efficacy in GB BPR it will not be authorised and will need to be removed from the GB market.

Divergence from EU requirements

Q4: “HSE notes that: “comments were received about the possibility of these changes leading to regulatory divergence from the EU.... HSE believes that the changes are right for GB as they reduce animal testing requirements for defined endpoints, align the requirements with internationally validated guidance and test methods update data requirements in line with scientific and technical developments. Where requirements will differ from those in the EU, this is to remove the submission of data where HSE does not consider it to be necessary in all cases (such as a requirement being triggered rather than obligatory in every case), which HSE believes will make the requirements more proportionate for GB businesses”. There is little acknowledgement of the impact of divergence from the EU (which aligning with OECD guidance does not mitigate) for lowered standards in GB, trade between GB and Northern Ireland, and between GB and the EU, or on regulatory costs and complexity on businesses. A more strategic approach to divergence is needed to minimise these risks in highly

regulated sectors, but pursue it in areas of strategic interest, rather than the current position where divergence is happening automatically, e.g. on the basis of differing scientific opinion. As highlighted by UK in a Changing Europe: ‘The [emerging consensus](#) (including within government) appears to be that the regulatory costs of major divergence from the EU outweigh the benefits, and thus the opportunities for comparative advantage lie in a few niche areas, perhaps novel medicines, foods, or early-stage AI. The problem is that the UK does not appear to have a strategy for identifying those areas, nor ensuring they are pursued coherently across Whitehall, with – crucially – adequate resources’.

How does HSE track divergence stemming from changes in UK regulation to assess and manage the impact of any changes on Northern Ireland’s place in the UK internal market?”

A4: Potential impacts on Northern Ireland were considered in developing these regulatory changes. However, the changes are not anticipated to have any impact on the UK internal market. As explained above, the changes are closely aligned with those made in the EU (which apply in Northern Ireland under the Windsor Framework). Where there are differences, they are to avoid unnecessary generation of data where it is not proportionate or scientifically necessary. Therefore, the differences are not expected to lead to divergent regulatory outcomes between GB and NI.

In the broader context of regulation beyond these changes to biocides data requirements, HSE tracks divergence stemming from changes in UK regulation to assess and manage the impact of any changes on Northern Ireland’s place in the UK internal market in line with the UK-EU and Intra-UK Divergence Analytical Framework. . HSE also meets regularly with its counterparts in NI to discuss issues of mutual concern, including the possible impacts of divergence.

Q5: “Can the department clarify whether this regulation is consistent with the repeated commitments ministers have given to maintain environmental protections while revising or updating assimilated law?”

A5: These Regulations are consistent with this commitment. None of the changes are considered to weaken any of the provisions protecting humans, animals or the environment. The changes will improve environmental risk assessment by ensuring that the most up-to-date information is available to HSE to support its regulatory decision making.

28 March 2024.