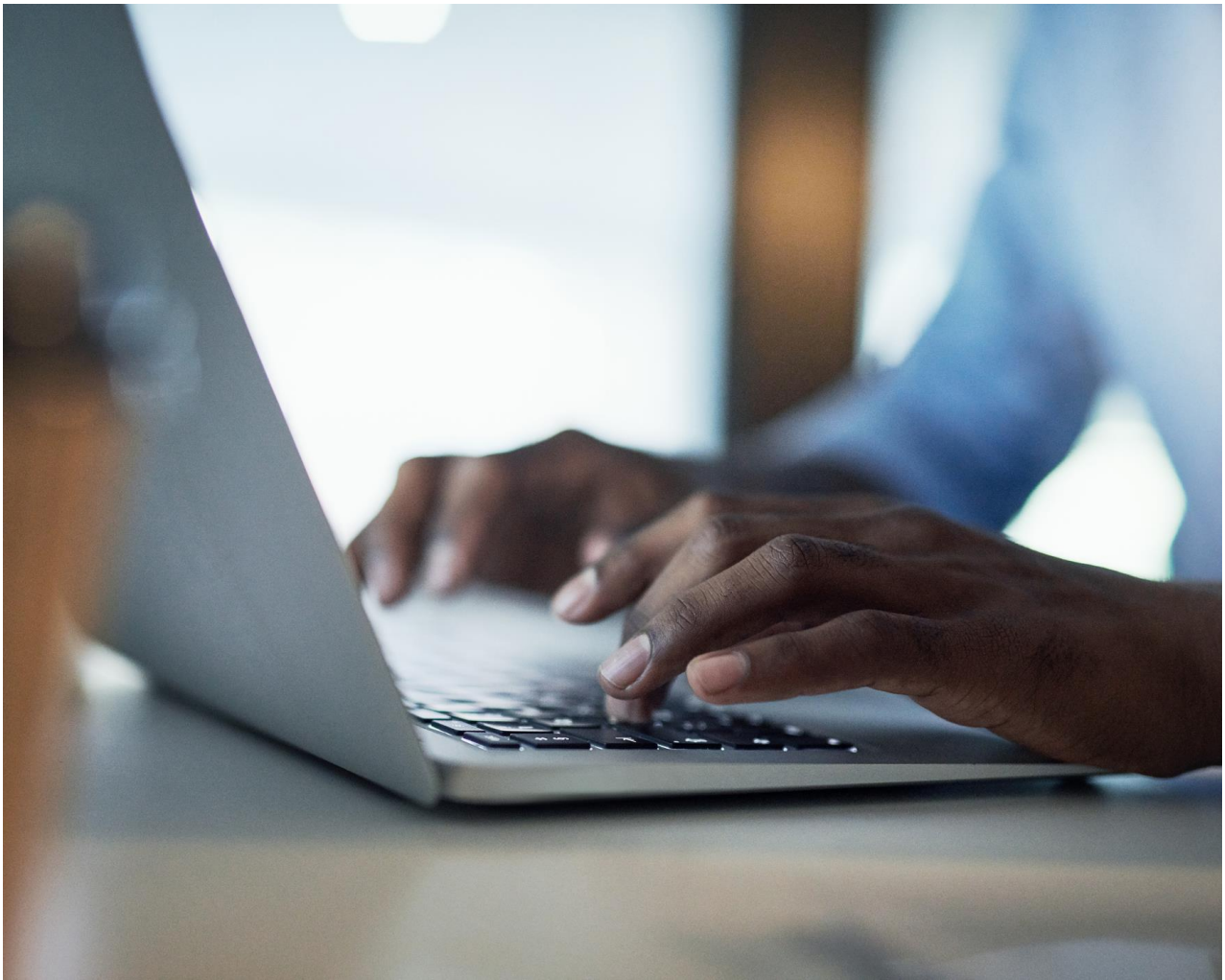
Health and Safety Executive – Changes to Biocidal Products Regulations Annexes II and III

Consultation Response

03/2024



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Contents

Introduction

1. This consultation relates to the Great Britain Biocidal Products Regulation[1] (GB BPR) (assimilated 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.

2. The Health and Safety Executive (HSE) consulted 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.
    - 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 authorised.

3. Having considered all responses to the consultation, HSE will make technical updates to these Annexes which will:

    - Introduce and place emphasis on in vitro studies rather than in vivo studies for skin and eye irritation and skin sensitisation.
    - Specify new tests for endocrine disruptors to be performed as required by the available guidance and evidence.
    - Change mutagenicity requirements to reflect new technical and scientific progress.
    - Change requirements in relation to reproductive toxicity and generational studies to reflect technical and scientific progress.
    - Change the requirements to include developmental neurotoxicity studies if certain triggers are met.
    - Change the requirements to include efficacy data to support the innate activity of the active substance for the intended use.
    - Update ecotoxicology requirements to align with current technical guidance

[1] The Great Britain Biocidal Products Regulation: https://www.legislation.gov.uk/eur/2012/528/contents

4. These changes will enable:

    - A reduction in animal testing for defined endpoints
    - Alignment with current guidance, and Organisation for Economic Co-operation and Development[2] (OECD) validated tests
    - Keeping up with new developments and scientific progress

5. The 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.

6. The proposed changes are similar to updates made recently to data requirements in the European Union's Biocidal Products Regulation (EU) No 528/2012. However, there are some minor differences which HSE believes will make the requirements more proportionate for GB needs.

[2] Organisation for Economic Co-operation and Development: https://www.oecd.org/

Public consultation

7. A public consultation ran from 17 January to 14 March 2023. In consulting, HSE sought views and information on:

    - The proposed changes to the GB Biocidal Products Regulation data requirements
    - Potential impacts of changes on specific areas of industry
    - Current biocidal active substance and product test costs
    - Cost implications of the proposed test requirements for biocidal active substance and products
    - Other potential impacts of the proposed test requirements for biocidal active substance and products

8. Respondents were encouraged to reply using the online questionnaire, but responses received separately were also included in the analysis. There were no postal responses.

9. This report includes a quantitative analysis of responses to several dichotomous and multiple-choice questions, as well as a thematic analysis of free text fields to identify key themes and sentiments.

10. The summary reflects the views offered, but it is not possible to describe all responses in detail to ensure anonymity is preserved. Every response has been read and considered as we assessed the impact of the proposed changes to the Biocidal Product Regulation data requirements.

Analytical approach

11. The consultation was hosted on the HSE Consultation Hub[3] which produces a raw data set and basic charted responses. HSE Social Researchers and Economists collaborated with the biocides Policy Team and Subject Matter Experts from HSE's Chemicals Regulations Division to systematically analyse this data and consider qualitative consultation responses. Qualitative responses were each considered in detail on their own and have been subsequently summarised thematically in this report.

12. The collaborative approach described combined deep knowledge of the policy intent, scientific developments and scientific rigor during analysis of qualitative responses and interpretation of impacts on industry. Furthermore, it enabled triangulation of scientific,

[3] Revision of GB Biocidal Products Regulation Annexes II and III - https://consultations.hse.gov.uk/crd-biocides/rev-gb-bpr-annexes-ii-and-iii/

operational and consultative evidence to maximise impacts of the evidence and to assist policy decision making, while reducing analytical bias.

Section 1 - Consultation Responses

13. 21 consultation responses were received which break down as follows:
    - 19 online survey responses (quantitative and qualitative evidence):
        - One online response was started and continued in an email response.
    - 2 email responses
        - Qualitative evidence including technical detail and suggestions.
    - Of the 21 responses,17 were on behalf of an organisation and 3 were from individuals. One emailed response was from an individual but it was not clear if they were responding as an individual or on behalf of an organisation.

14. Not all questions have been reported against in this report either to protect identifiable information; due to its technical nature, or due to its limited value to readers of this brief narrative in the absence of the total dataset. For example, requests for respondent information and regional spread of respondents; or scientific detail analysed by technical experts.

Respondent overview

15. Just over half (10) of the 19 online survey responses were from the chemical business and trade association sectors; the rest of responses covered the following sectors though their responses are not generalisable to the wider sector: Non-governmental organisation, Testing house / chemical testing facility, Consultancy (some detail contained in an additional email response), Trade union, ‘Other’ or unspecified.

16. Six respondents provided an indication of the size of their organisation. Five responses were from large companies with 250+ employees while one worked for an organisation which employed 100-250 employees.

17. The following business types/activities were carried out by respondents:
    - Active substance manufacturer
    - Biocidal product formulator
    - Biocidal product importer
    - Biocidal product distributor
    - Biocidal product retailer

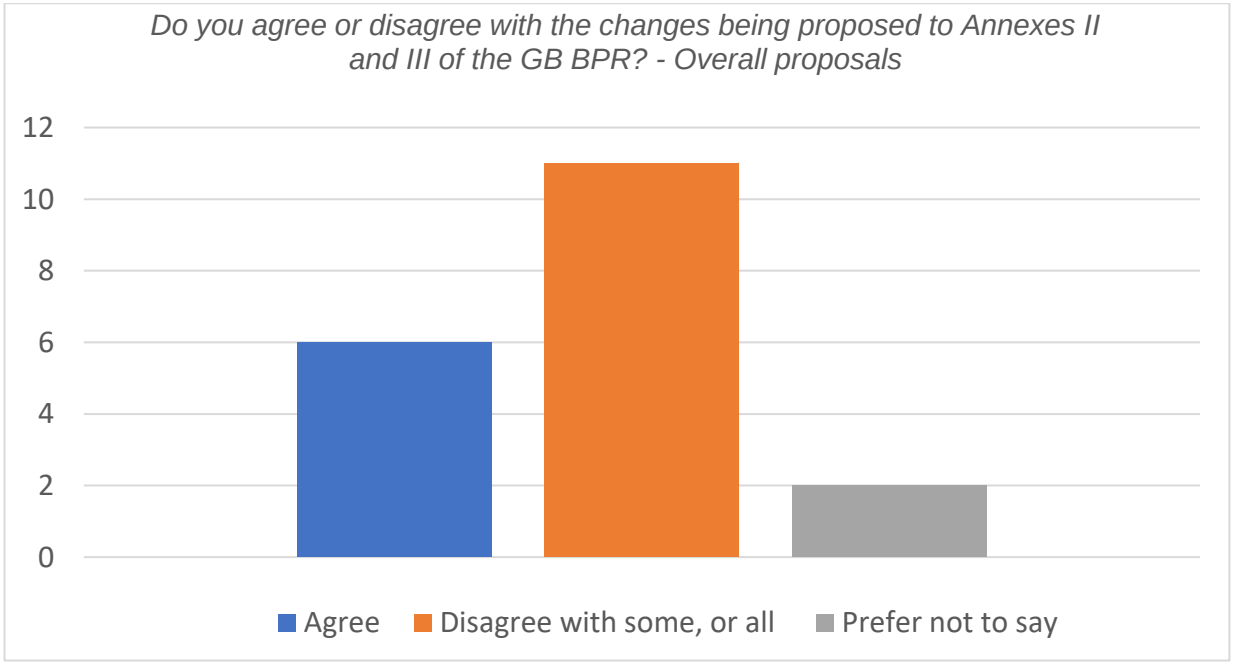
- User of biocidal products
- GB authorisation holder for one or more biocidal products
- EU authorisation holder for one or more biocidal products
- GB active substance approval holder for one of more active substance
- EU active substance approval holder for one of more active substance

18. The same six organisations said they held both GB and EU Biocidal Product authorisations, and GB and EU active substance approvals.

Summary of findings

Responses to proposed changes to the GB Biocidal Products Regulation data requirements

19. More than half (11) of the online consultation respondents disagreed with, or noted impacts of some or all of the overall proposed changes. These respondents included chemicals businesses (3), trade associations (2), non-governmental departments (2), a trade union, a consultancy and two 'other' respondents.

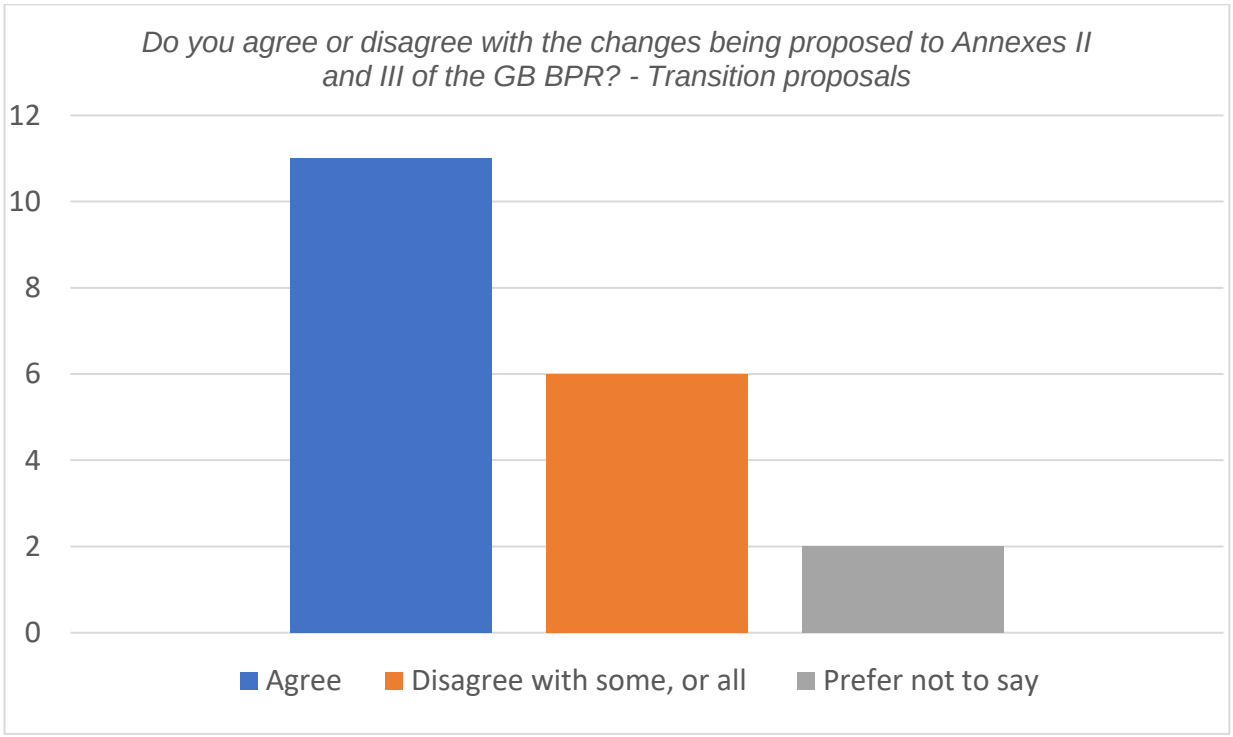


20. Proposed wording changes were provided and have been noted and thematically analysed. Where indications were that policy intent may have been misunderstood, this will be referred to in HSE's response in Section 2.

21. Over half of the 19 online survey respondents welcomed the proposed 12-month transition period but those who disagreed with proposals shared concerns relating to

time taken to generate data and dossiers. One NGO emailed a 'strongly' supportive response. They highlighted the introduction of a tiered approach to safety testing which moves through from literature searches into in vitro testing and animal tests, only if necessary.

22. Of the six respondents who disagreed, four were chemical business – two businesses were active substance manufacturers and biocidal products formulators; one was a formulator, manufacturer and importer of both active substances and biocidal products; and the fourth formulates, imports, distributes, retails and uses BPs, and manufactures and imports active substances. All four businesses held GB and EU authorisations and approvals.



Responses related to potential impacts of the proposed changes on specific areas of industry

Chemical business highlight concerns

23. The chemical businesses (3) in disagreement with the proposed changes were operating in both the active substance and biocidal products businesses and were EU (European Chemicals Agency[4] (ECHA)) and GB authorisation and approval holders. They were all engaged in biocidal product formulation; two were engaged in active

[4] European Chemicals Agency - https://echa.europa.eu/

substance manufacturing; and one was engaged in the importation of active substances. Concerns included sufficiency of specific endocrine activity tests to draw conclusive results, related implications and uncertainty, as well as economic viability of additional tests if not already being provided to the EU.

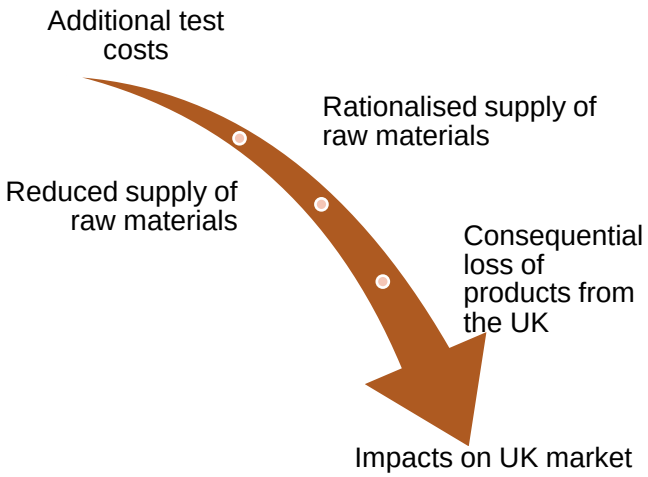
Consultant highlight concerns

24. One consultant respondent disagreed with some aspects of the proposals and submitted detailed technical comments via email.

'Other' respondent type highlight concerns

25. Proposed wording changes related to genotoxicity testing left some respondents feeling uncertain about its meaning. However, there was support for an implication of a degree of consultation with HSE over testing proposals before a study is conducted, which was supported as it is not always clear to a non-expert what would be the most appropriate in vivo study to follow-up in vitro positive results.

26. This respondent type also raised concerns about the economic impacts of changes, including issues relating to effects on business and supply of raw materials.



Non-Government Organisations and Trade Association highlight concerns

27. Some issues related to ambiguous wording and wording appearing to 'lock in' animal testing which risks outdating of Annex II as a transition is made to non-animal methods. The use of more animals in active substance registrations was raised. There is appetite for greater use of existing data; and views were shared on consideration of changes relating to other endpoints within the new requirement for additional studies to assess endocrine disruption.

28. Trade associations had concerns which centred around the proposed changes in a post-EU Exit landscape.

29. Concerns homed in on the following core issues:

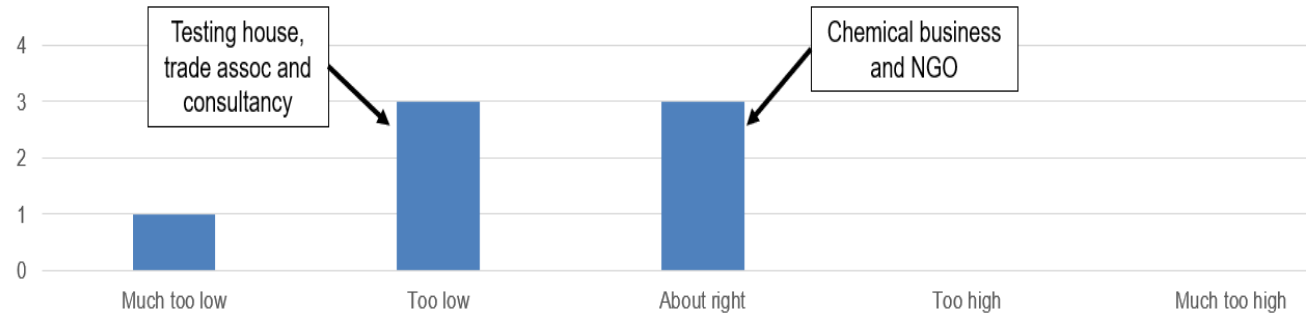
    - The implications of new costly testing requirements impacting the British chemical industry's ability to compete with companies in the EU.
    - UK regulators should complete the GB BPR review programme for existing active substance/product type combinations before enhancing requirements and introducing further change.
    - Once active substance/product type combinations have been approved, further regulatory enhancements might then be considered at renewal.
    - Likewise, for brand new regulatory active substance /product type combinations, the enhancements might then be contemplated.

Response to current and proposed biocidal active substance and product test costs

30. Of the 19 online survey responses, seven reported that they were willing to answer some questions on typical test costs. Nine respondents were not willing and three said that they were unsure. Only those who responded that they were willing were routed to the following cost questions which are set out in more detail. The following analysis of cost questions summarises responses. Where respondents identified their sector, this is noted in the response bar charts.

31. For most of the test types HSE asked about in the consultation (skin irritation, eye irritation, skin sensitisation and genotoxicity), HSE identified during the consultation period that HSE was already requiring these tests to be submitted in particular for biocidal products under Article 62. Therefore, the costs were not included in the final stage Impact Assessment (IA). The only test costs taken forward in the final stage IA were those related to Developmental neurotoxicity (DNT).

32. Survey questions 16 and 17:
    We estimate that skin irritation tests currently required under the Great Britain Biocidal Products Regulation EU No 528/2012 (GB BPR) cost around £2,000 per active substance/ product submission. This is based on an in vivo rabbit test.
    Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? And, What would be a estimate, and why?

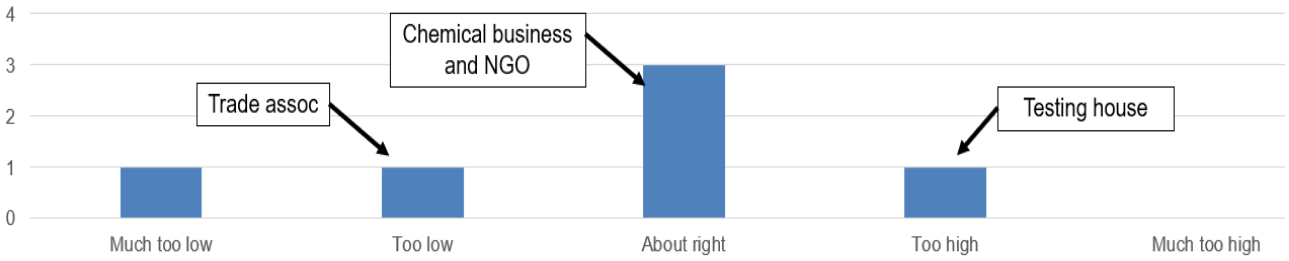


Of those who disagreed (4) with the IA estimate of £2,000, an individual and a trade association each suggested an alternative figure of £4,000. HSE toxicologists accept these alternative estimates as being in the same range as the initial estimate.

33. Survey questions 18 and 19:

We estimate that eye irritation tests currently required under GB BPR cost around £2,000 per active substance/ product submission. This is based on an in vivo rabbit test.

Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?

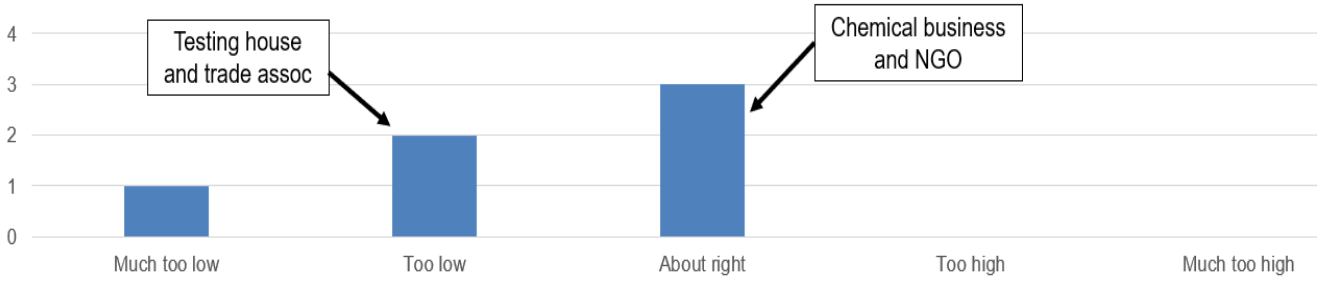


Of those who disagreed (3) with the IA estimate of £2,000, a trade association suggested an alternative figure of £3,500; and an individual of £4,000. HSE toxicologists accept these alternative estimates as being in the same range as the initial estimate.

34. Survey questions 20 and 21:

We estimate that skin sensitisation tests currently required under GB BPR cost around £5,000 per active substance/ product submission. This is based on a local lymph node assay in a mouse.

Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?

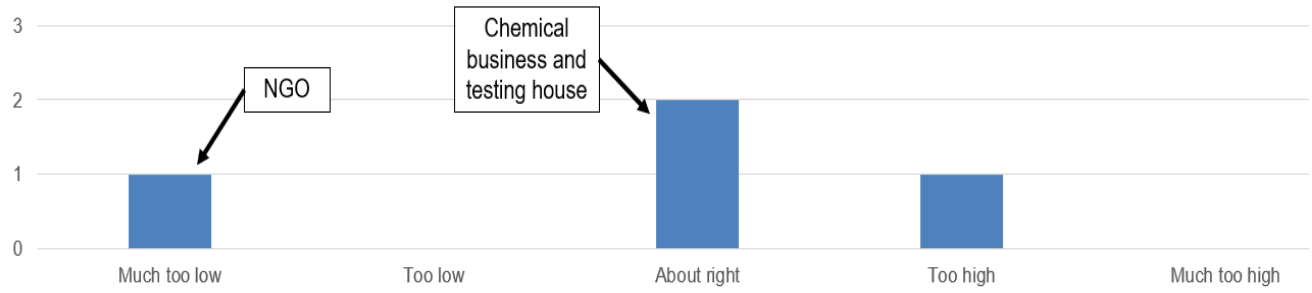


Of those who disagreed (3) with the IA estimate of £5,000, a trade association suggested an alternative figure of £6,000; and an individual of £9,000. HSE toxicologists accept these alternative estimates as being in the same range as the initial estimate.

35. Survey questions 22 and 23:

We estimate that genotoxicity tests currently required under GB BPR cost around £9,000 per active substance submission. This is based on a liver UDS assay.

Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?



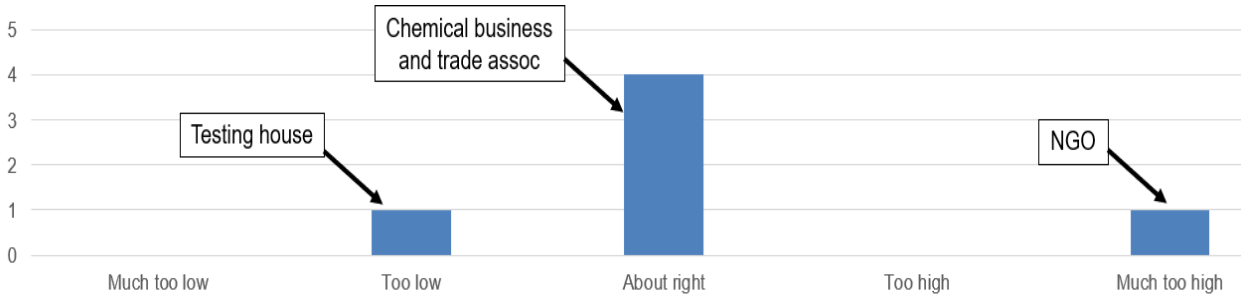
Of those who disagreed (2) with the IA estimate of £9,000, an individual suggested an alternative figure of £6,800; HSE toxicologists accept this alternative estimate as being in the same range as the initial estimate.

Additionally, an NGO suggested an alternative estimate of £20,000. HSE toxicologists accept that these are approximations and there will be variability among different contract research organisations and across the globe.

36. Survey questions 24 and 25:

We estimate that skin irritation tests required to fulfil the new GB BPR requirements would cost around £11,000 per active substance/ product submission. This is based on carrying out two in vitro tests per submission.

Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?

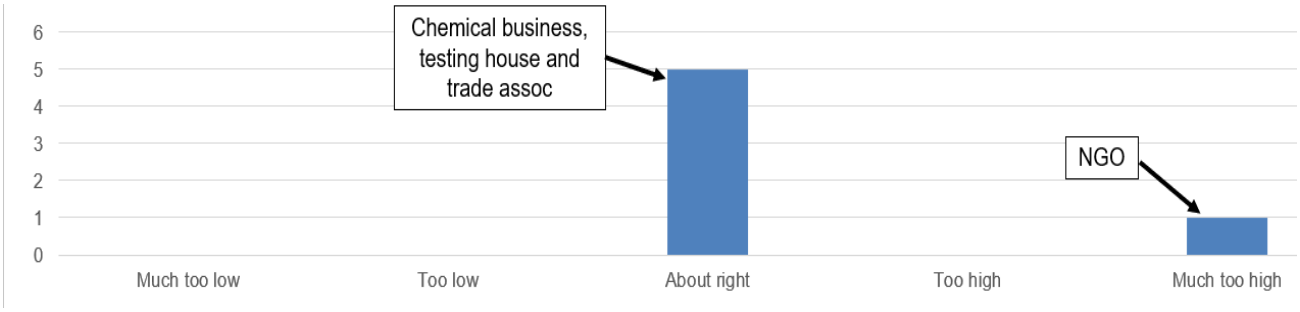


Of those who disagreed (2) with the IA estimate of £11,000, an NGO suggested an alternative figure of around £5,700. HSE toxicologists accept that these are approximations and there will be variability among different contract research organisations and across the globe.

37. Survey questions 26 and 27:

We estimate that eye irritation tests required to fulfil the new GB BPR requirements would cost around £10,000 per active substance/ product submission. This is based on carrying out two in vitro tests per submission.

Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?



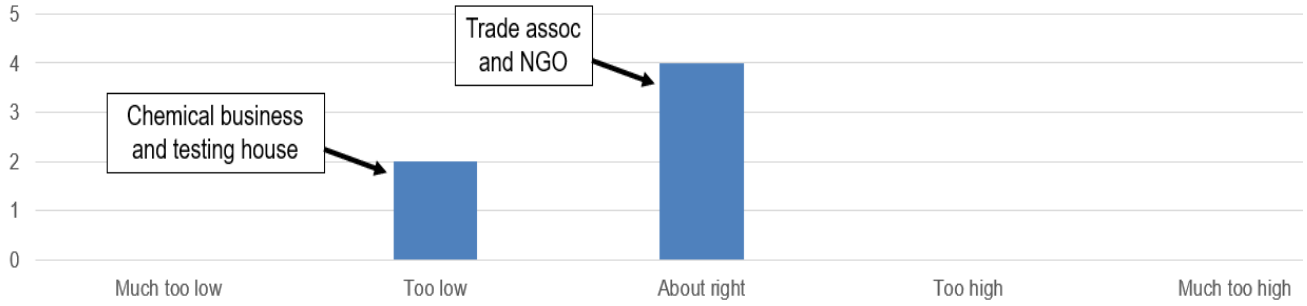
One respondent, an NGO, disagreed with the IA estimate of £10,000. They suggested an alternative figure of around £5,300. HSE toxicologists accept that these are

approximations and there will be variability among different contract research organisations and across the globe.

38. Survey questions 28 and 29:

    We estimate that skin sensitisation tests required to fulfil the new GB BPR requirements would cost around £15,000 per active substance/ product submission. This is based on an in vitro DASS test.

    Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?

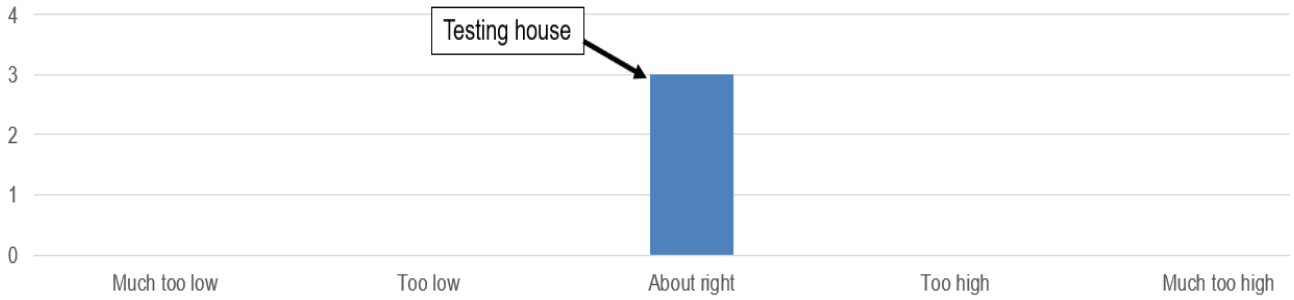


    Of those who disagreed (2) with the IA estimate of £15,000, a chemical business suggested an alternative figure of £20,000. HSE toxicologists accept that these are just approximations and there will be variability among different contract research organisations and across the globe.

39. Survey questions 30 and 31:

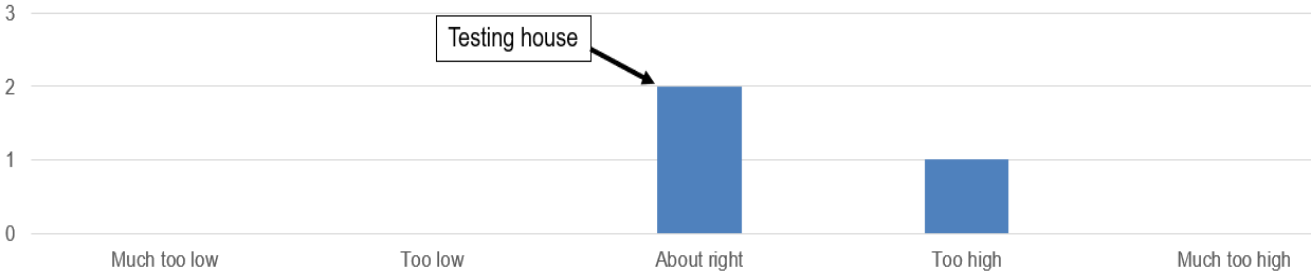
    For genotoxicity, we anticipate that the test required to fulfil the new GB BPR requirements might be either a rodent comet assay (three tissues) or a transgenic rodent mutation test involving two tissues and three dose levels. For the rodent comet assay (three tissues), we estimate that the cost would be around £35,000 per active substance.

    Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?



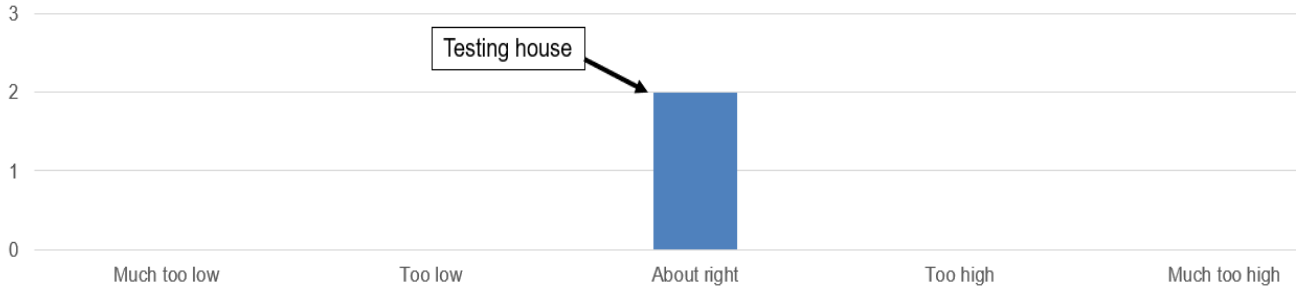
All three respondents who answered this question agreed with the estimate and no alternatives were offered.

40. Survey questions 32 and 33:
For the transgenic rodent mutation test involving two tissues and three dose levels, we estimate that the cost would be around £211,000 per active substance.
Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?



Although one respondent thought the IA estimate of £211,000 was too high, no alternatives were offered.

41. Survey questions 34 and 35:
We estimate that developmental neurotoxicity (DNT) tests required to fulfil the new GB BPR requirements would cost around £533,000 per active substance submission.
Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?



Both respondents who answered this question agreed with the estimate and no alternatives were offered. As such, the figure of £533,000 was retained and used in the analysis in the final stage IA.

42. Survey questions 36 and 37:

Do you anticipate any additional costs of interpreting DNT test results for integration into your active substance submission to HSE; additional costs being over and above the cost of commissioning the test itself?

What additional costs do you anticipate and why?

Two respondents to this question believed there would be additional costs to integrate the DNT test into the submission. We received only one suggestion from an individual who suggested that this might come to £4,000 for a weight of evidence analysis. This figure was adopted in the final stage IA, following verification of its reasonableness with HSE toxicologist and policy specialists.

43. Survey questions 38 and 39:

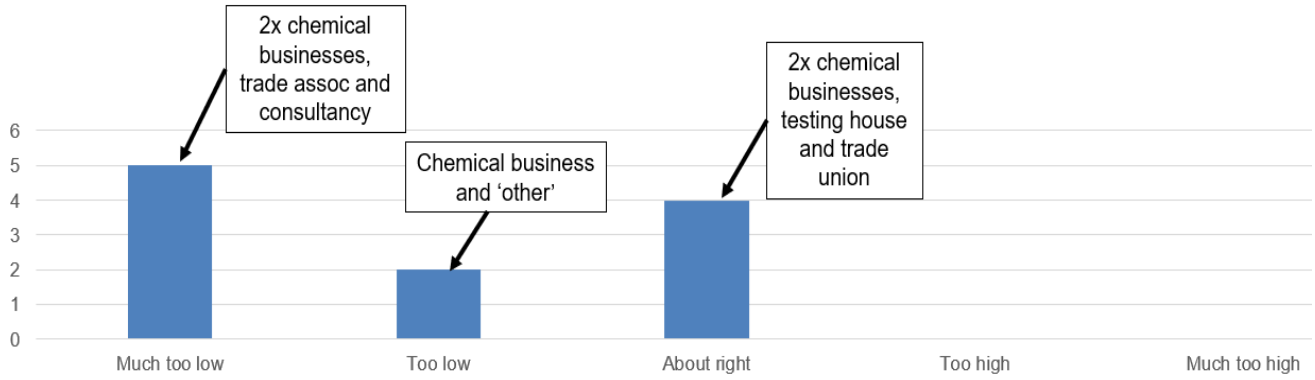
We believe that most applicants will already be complying with the proposed GB testing requirements because they:

- *have already applied to an EU Member State or ECHA for active substance approval; or,*

- *are planning to apply to an EU Member State or ECHA for active substance approval.*

As such, we estimate that between 1-3% of active substance applications will incur additional costs for GB BPR.

Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?



Four respondents thought the estimate of 1-3% was about right, and seven thought it too low or much too low. Four respondents suggested alternative figures. Four respondents suggested alternative figures: 25% (individual), >30% (chemical business), 75% (trade association) and >75% (consultancy). Various reasons were given for these higher estimates including additional data being typically requested during evaluations, leading to extra testing costs; the figure not taking into account data-sharing costs; and the fact that many substances have not yet been through a full evaluation. However, although these are valid reasons for why extra costs may be incurred by businesses during the evaluation process, HSE believes they are not directly attributable to the proposed changes in the data requirements and are instead part of the baseline as they would be incurred even in the absence of the changes. Therefore, HSE does not consider that evidence has been provided to amend the original estimate.

Responses covering other potential impacts of the proposed test requirements for biocidal active substance and products

44. Survey questions 40 and 41:

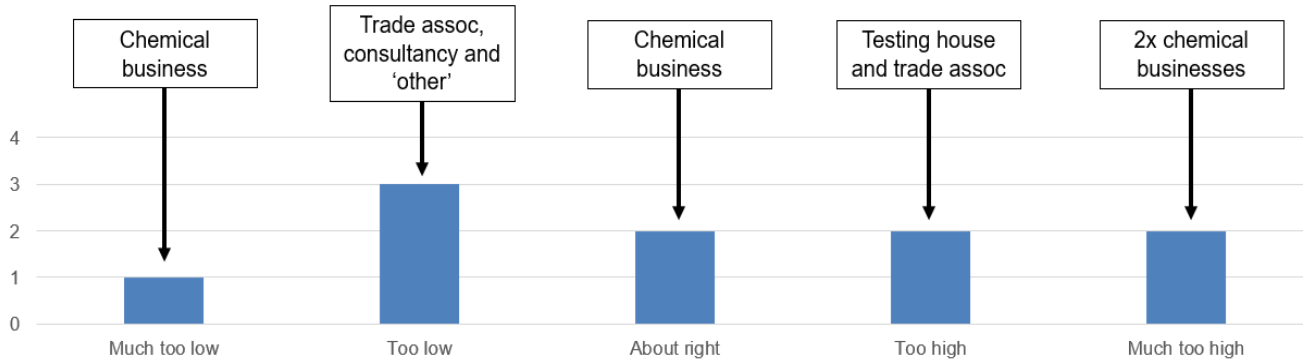
Similarly, we estimate that most applicants will already be complying with the proposed GB testing requirements because they:

- *have already applied to an EU Member State or ECHA for biocidal product authorisation; or,*

- *plan to apply to an EU Member State or ECHA for biocidal product authorisation.*

As such our estimate is that up to 38% of biocidal product authorisation applications will incur additional costs for GB BPR.

Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?



There was a fairly even spread of responses on this question.

In the consultation stage IA, HSE estimated that up to 38% of product applications would potentially incur additional costs as a result of **not** also applying for authorisation in the EU. We further estimated that, of those 38%, 90% would also not incur costs as they would be able to be assessed via the calculation method in the GB CLP Regulation[5], which would mean that only 3.8% of product would incur additional costs.

A trade association which said the estimate was 'too high'; and a chemical business which said it was much too high had misinterpreted Question 40 and suggested that the reference to 38% was a typo and it should read 3.8%.

Other respondents who suggested alternative figures also seemed to have misinterpreted the question. Two respondents (a testing house and a chemicals business who said that 38% as too high and much too low, respectively) appear to have read the question as stating that there would be a 38% increase in cost for biocidal products (rather than an increase in cost for 38% of biocidal product authorisation holders). The remaining respondents (a chemical business which said it

[5] Classification, Labelling and Packaging Regulation - www.hse.gov.uk/chemical-classification/legal/clp-regulation.htm

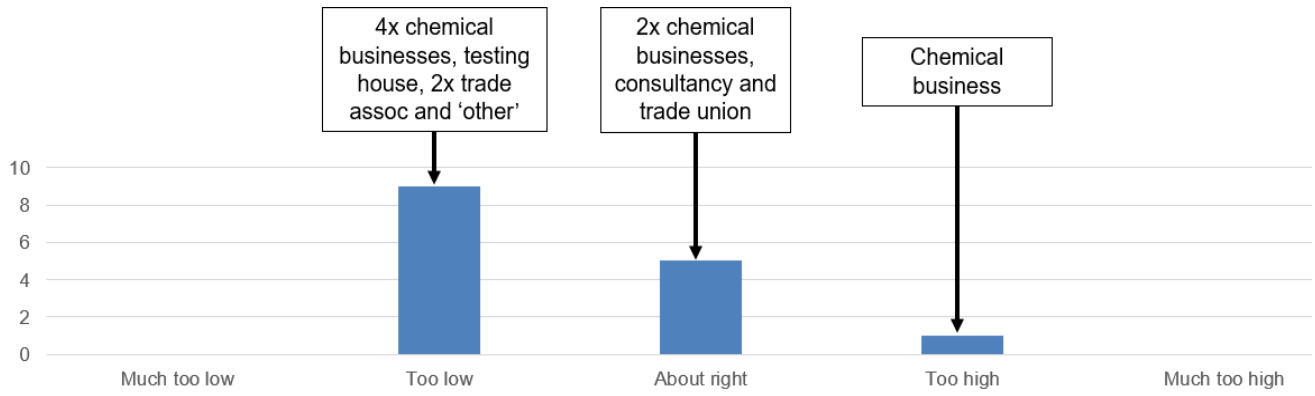
was ‘much too high’, a consultancy which said that it was ‘too low’ and a trade association which said it was ‘too low’ trade association) did not provide any evidence that HSE could relate to the number of GB biocidal product applications which could incur additional costs as a result of not having been made in the EU.

This figure was not used in the IA so we have made no further attempt to update the original estimate. It should be noted that analytical complexities arose where data quality, company subsidiaries and business registrations may have led to double counts of businesses which may not be operating in the EU.

45. Survey questions 40 and 41:

We estimate that it could take around 6 hours for each active substance and product manufacturer to familiarise themselves with the proposed test requirements for the GB BPR.

Do you think this estimate is: much too low/ too low/ about right/ too high/ much too high? What would be a better estimate, and why?



Although five respondents thought the figures of around 6 hours was about right, nine believed it was too low. One believed that the estimate of around 6 hours was too high.

In the consultation stage IA, HSE estimated that familiarisation time would take between 3 and 9 hours, but in the consultation we asked about a point estimate for the mid-point of that range. Of those who suggested alternative figures:

- One suggested three hours as the GB BPR is not too different from the EU version
- One suggested eight hours due to HSE’s guidance being less accessible than that of ECHA and HSE having a ‘poor’ helpdesk service; to account for increased divergence between the GB and EU regimes; and to account for the reduced capability of many small and medium-sized enterprises (SMEs).

- One believed that six hours might be about right for experienced companies, but that SMEs and new entrants might need nine or more hours
- Two suggested 12 hours, one noting that additional time would be needed to compare the GB and EU regimes
- One suggested 24 hours to read the new guidance in conjunction with technical guidance and apply the requirements to individual products and actives
- Two suggested 30 hours – one noted that specialists might take 6 hours, but that generalists would take longer; and the other that several people per organisation would need to familiarise, which would raise the time

As noted above in the final stage IA, HSE considers that most of the in vitro tests will in fact be baseline and so not additional. This led HSE to conclude that the familiarisation time would not be as great as in the consultation stage IA as the only new tests would relate to DNT for new active substances. As such, HSE policy experts estimated that the bottom of the original range (i.e., 3 hours per business) would be sufficient.

Section 2 – Health & Safety Executive responses

HSE considered the views of consultees and provided responses in the table below.

Issue and Summary	Response
New test costs A number of comments that were received were about the costs involved in carrying out new testing. Some specific concerns were raised regarding the new testing requirements for endocrine disruption, which it was believed would be inconclusive and lead to additional testing at substantial cost. A number of responses also raised concerns about the costs of generating new studies for existing applications.	While HSE accepts that new testing involves very small extra costs in some cases, as outlined in the IA, HSE does not consider these excessive and believes they are justified because they reflect the most recent scientific updates to test requirements. The new data requirements will ultimately lead to reductions in animal testing and improved human health and environmental safety. In addition, as the changes to the data requirements HSE is proposing will make the data requirements more aligned with those currently applicable in the EU, in most cases HSE believes that testing will have already been carried out to satisfy EU regulatory requirements as most companies engage with both the EU and GB regulatory systems. In relation to testing for endocrine disrupting properties, there may have been some misunderstanding over the degree to which the updated requirements are new. Many of the tests are already required under other endpoints, and others are already prescribed in existing EU guidance, which HSE is already applying. The requirements formalise requirements which are effectively already being applied and HSE does not believe they will lead to substantial extra costs compared with the status quo.

	In relation to the generation of studies for new applications, HSE has amended its approach following the consultation. The new data requirements will only apply to new applications (new active substances and renewals of existing active substance approvals) and not to applications and review dossiers already submitted. Therefore, these costs will not be incurred.
Use of non-animal testing methods A number of respondents made comments suggesting that HSE should move away from animal testing to non-animal methodologies (NAMs) in other areas than those already proposed. Some respondents made detailed technical suggestions regarding changes to the proposed data requirements. There were also concerns that changes could 'lock in' animal testing requirements or could require the use of more animals in active substance evaluations.	HSE has considered the specific suggestions made to further move away from animal testing. In some cases, HSE will strengthen wording to clarify that alternatives to animal testing should be used where possible and appropriate. However, in other cases HSE believes the wording is appropriate as proposed, either because: - there are no validated in vitro alternatives or other sufficiently well-developed or reliable non-animal methods for investigating the endpoint in question, especially complex endpoints; or - HSE can already request non-animal data using such methods when they become available without having to formally revise the data requirements under existing provisions in Article 62 of GB BPR (Article 62 permits animal testing to be carried out for the purposes of GB BPR only as a last resort.) The provisions of Article 62 can also be applied to permit approaches such as read-across and other methodologies (e.g. in silico approaches) to be used where these are appropriate. It should also be noted that while for some endpoints the majority of the updated data requirements are aimed at reducing the need for animal testing, for other

	endpoints it is to ensure adaptation to technical and scientific progress and to improve human health and environmental safety.
Proposed text changes Two specific suggestions were made by consultees regarding the proposed text outlining testing requirements for skin sensitisation, specifically to align the text more closely with OECD guidance (OECD Test Guideline 497). A number of other technical suggestions were made to details of the data requirements.	The text will be amended to refer to OECD guidance (OECD 497). No robust justification was provided in most cases for deviating from the technical proposals. However, we will make minor clarifications to address some of the points raised. The technical changes HSE has made to the data requirements following the consultation are shown at Annex 1.
Transition period A number of comments were received suggesting that the proposed 12-month transitional period is not long enough to allow the generation of new studies.	In light of these comments, HSE has revised the proposed transitional period so that the new data requirements will not become applicable until 18 months after the legislation comes into force on 6th April 2024. As previously noted, these requirements will apply to new applications only and will not be retrospectively applied to existing applications.
Divergence from EU requirements 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.

Section 3 Next steps

HSE acknowledges the support from all respondents and organisations who took part in this consultation. All responses have been considered within the overall analysis.

The evidence and data gathered have been fed into a final stage IA which analyses and assesses the impacts, costs and benefits of the proposals. The consultation responses have been fully considered and have led HSE to refine the detail of the proposed regulations to implement the amended data requirements.

HSE will bring forward legislation which will bring the proposed changes to the data requirements into law, following the normal parliamentary and legislative procedures and timescales. The planned entry into force date of the changes is 6 April 2024 with an 18-month transitional period until they become mandatory on 6 October 2025; this is subject to parliamentary procedures and will be confirmed in further communications from HSE. An updated IA will be published alongside the legislation on the Legislation.gov[6] website.

[6] Legislation.gov website: https://www.legislation.gov.uk/uksi/2024/352/contents/made

Consultation Report

Changes to Biocidal Product Regulations Annexes II and III

Annex 1

All references to EU Regulations are to be read as referring to the GB assimilated versions of those Regulations.

This Annex contains tables that summarise the provisions in GB BPR Annexes II and III as they currently stand (left hand column), alongside the new proposed text (right hand column).

Underlined text shows proposed additions to the text following the consultation and ~~strikethrough~~ text shows proposed deletions to the text post-consultation.

Note: This draft text is provided for only. Only the final legal text will be a definitive statement of the law.

Changes to Annex II

	Current GB BPR Wording	New wording
Point 2 Paragraph 5	The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set down in Article 62(2), applicants may also consult with the competent authority with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.	The applicant ~~shall~~ must initiate a pre-submission consultation with the prospective evaluating body. In addition to the obligation set out in Article 62(2), the applicant may also consult with the competent authority ~~that will evaluate the dossier~~ with regard to the proposed information requirements and in particular the strategy for avoiding new testing on vertebrates alongside any testing on vertebrates that the applicant proposes to carry out. The applicant ~~shall~~ must document such pre-submission consultations and their outcomes and ~~shall~~ must include the relevant documents in the application.
Point 5	3. Tests submitted for the purpose of the approval of an active substance shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ([1]). However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate, whenever possible internationally recognised, and their appropriateness must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations/ adjustments that have been made in order to respond to the specific characteristics of these materials.	Tests submitted for the purpose of the approval of an active substance shall be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ([1]) Where a revised version of a test method described in Commission Regulation (EC) No 440/2008 is available, but not included in that Regulation, the revised version may be used with the agreement of the competent authority ~~or any revised version of these methods not yet included in that Regulation~~. However, if a method is inappropriate or not described in Commission Regulation (EC) No 440/2008, other methods shall be used which are scientifically appropriate and their appropriateness shall be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of these materials.

Title one table

	Current GB BPR Wording			New wording		
Heading of column 3	Information required	All data is CDS unless indicated as ADS	Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates	Information required	All data is CDS unless indicated as ADS	Specific rules for adaptation from column 1
row 2	IDENTITY OF THE ACTIVE SUBSTANCE - For the active substance, the information given in this Section shall be sufficient to enable the active substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated			IDENTITY OF THE ACTIVE SUBSTANCE (AND ITS PRECURSOR~~(S)~~ OR PRECURSORS IF THE ACTIVE SUBSTANCE IS GENERATED *IN SITU*) - For the active substance and, if applicable, its precursor or precursors, the information given in this Section ~~shall~~ must be sufficient to enable the active substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items listed in this Section, the reasons ~~shall~~ must be clearly stated		
row 2.5	Molecular and structural formula (including SMILES notation, if available and appropriate)			Molecular and structural formula (including SMILES notation, if available and appropriate). For precursor~~(s)~~ or precursors and for active substances generated in situ, information about all generated chemical substances (intended and unintended)		~~In case it is not possible to exactly define the molecular structure of the precursor(s) and/or active substance, the molecular and structural formulas do not need to be provided.~~ The molecular and structural formula does not need to be provided in cases where it is not possible to exactly define the molecular structure of the precursor~~(s)~~ or precursors or the active substance.
row 2.8	Method of manufacture (syntheses pathway) of active substance			Method of manufacture (syntheses pathways) of active		

	including information on starting materials and solvents including suppliers, specifications and commercial availability			substance including information on starting materials and solvents including suppliers, specifications and commercial availability. For active substances generated in situ, a description of the reaction schemes including all intermediate reactions and their associated chemical substances (intended and unintended) ~~shall~~ must be provided		
row 2.11.1	N/A - NEW INSERTION			Analytical profile of at least five representative samples taken from the in situ generated substance~~(s)~~ or substances, providing information on the content of the active substance~~(s)~~ or substances, any other constituent above 0.1 % w/w, including residues of precursor~~(s)~~ or precursors, and where relevant any additional impurities referred to in 2.10.		
row 6.6	Efficacy data to support these claims on biocidal products and, where label claims are made, on treated articles, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate			Efficacy data to support~~:~~ ~~–~~the innate activity of the active substance for the intended use~~(s)~~ or uses.~~, and~~ Efficacy data ~~shall~~ may include any available standard protocols, laboratory tests or field trials and performance standards where appropriate, or data similar to those available for suitable reference products		

row 6.7.2	Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms			Observations on undesirable or unintended side effects on non-target organisms or on objects and material to be protected		
8.1.	Skin irritation or skin corrosion The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/Corrosion (Annex B.4. to Regulation (EC) No 440/2008)			Skin corrosion or irritation The assessment ~~shall~~ must comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) skin corrosion*, in vitro* testing; (c) skin irritation, *in vitro* testing; (d) skin corrosion or irritation, *in vivo* testing		The stud~~y/~~ies in column 1 do~~(es)~~ not need to be conducted if: - the available information indicates that the substance meets the criteria for classification for skin corrosion or irritation, - the substance is a strong acid (pH≤ 2~~,~~.0) or base (pH≥ 11~~,~~.5), - the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, - the substance meets the classification criteria for acute toxicity (Category 1) by the dermal route, or - an acute toxicity study by the dermal route provides conclusive evidence on skin corrosion or irritation adequate for classification. If results from one of the two studies listed in point (b) or point (c) in column 1 of this row already allow conclusive decision on the classification of a substance or on the absence of skin irritation potential, the second study does not need to be conducted.

						An *in vivo* study for skin corrosion or irritation ~~shall be considered if~~ must not be conducted unless the *in vitro* studies listed in points (b) and (c) in column 1 of this row are not applicable, or the results of these studies are not adequate for classification and risk assessment. *In vivo* studies for skin corrosion or irritation that were ~~carried out or~~ initiated before ~~[IMPLEMENTATION DATE]~~ 6th October 2025 ~~shall~~ will be considered appropriate to address this information requirement
8.2.	Eye irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008)			Serious eye damage or eye irritation The assessment ~~shall~~ must comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) serious eye damage or eye irritation, *in vitro* testing; (c) serious eye damage or eye irritation, *in vivo* testing		The stud~~y/~~ies in column 1 do~~(es)~~ not need to be conducted if: - the available information indicates that the substance meets the criteria for classification for eye irritation or causing serious damage to eyes, - the substance is a strong acid (pH≤ 2~~,~~.0) or base (pH≥ 11~~,~~.5), - the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or - the substance meets the classification criteria for skin corrosion leading to classification of the substance as "serious eye damage" (category 1). If results from a first *in vitro* study do not allow a conclusive decision on the classification of the substance or on the absence of eye irritation potential

						~~(an)~~other~~(s)~~ *in vitro* stud~~y~~(ies~~)~~ for this endpoint ~~shall~~ must be considered. An *in vivo* study for serious eye damage or eye irritation ~~shall only be considered if~~ must not be conducted unless the *in vitro* stud~~y~~(ies~~)~~ listed in point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment. *In vivo* studies for serious eye damage or eye irritation that were ~~carried out or~~ initiated before ~~[IMPLEMENTATION DATE]~~ 6th October 2025 ~~shall~~ will be considered appropriate to address this information requirement
8.3.	Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. *in vivo* testing The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for *in vivo* testing. If another skin sensitisation test is used justification shall be provided.		Step 2 does not need to be conducted if: — the available information indicates that the substance should be classified for skin sensitisation or corrosivity, or — the substance is a strong acid (pH < 2,0) or base (pH > 11,5)	Skin sensitisation The information ~~shall~~ must allow ~~to conclude~~ a conclusion as to whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Category 1A). The information should be sufficient to perform a risk assessment where required. The assessment ~~shall~~ must comprise the following tiers: (a) assessment of the available human, animal and non-animal data;		The stud~~y/~~ies in column 1 do(es) not need to be conducted if: - the available information indicates that the substance meets the criteria for classification for skin sensitisation or skin corrosion, - the substance is a strong acid (pH≤ 2~~,~~.0) or base (pH≥ 11~~,~~.5), or - the substance is spontaneously flammable in air or in contact with water or moisture at room temperature. ~~If information from test method(s) addressing one or two of the key events described under point (b) in column 1 of this row allows for classification of the substance and~~

				(b) skin sensitisation, *in vitro* testing according to OECD TG 497. ~~Information from in vitro or *in chemico* test method(s) referred to in point 5 of the introductory part of this Annex and addressing each of the following key events of skin sensitisation:~~ ~~(i) molecular interaction with skin proteins;~~ ~~(ii) inflammatory response in keratinocytes;~~ ~~(iii) activation of dendritic cells;~~ (c) skin sensitisation *in vivo* testing. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for *in vivo* testing. Another skin sensitisation test may only be used in exceptional cases. If another skin sensitisation test is used, justification ~~shall~~ must be provided		~~risk assessment, studies addressing the other key event(s) do not need to be conducted.~~ ~~An *in vivo* study for skin sensitisation shall be conducted only if the *in vitro* or *in chemico* test methods of OECD Test Guideline 497 described under point (b) in column 1 of this row are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment~~ In vitro tests do not need to be conducted if: - an in vivo study referred to in point (c) of column 1 of this row is available, or - the available in vitro or in chemico test methods of OECD Test Guideline 497 are not applicable for the substance An in vivo study for skin sensitisation must not be conducted unless the in vitro or in chemico test methods of OECD TG 497 are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment. *In vivo* skin sensitisation studies that were ~~carried out or~~ initiated before ~~[IMPLEMENTATION DATE]~~ 6th October 2025 ~~shall~~ will be considered appropriate to address this information requirement

8.6.	In vivo genotoxicity study The assessment of this endpoint shall comprise the following consecutive steps: — If there is a positive result in any of the in vitro genotoxicity studies and there are no results available from an in vivo study already, an appropriate in vivo somatic cell genotoxicity study shall be proposed/conducted by the applicant — If either of the in vitro gene mutation tests is positive, an in vivo test to investigate unscheduled DNA synthesis shall be conducted — A second in vivo somatic cell test may be necessary, depending on the results, quality and relevance of all the available data — If there is a positive result from an in vivo somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence to demonstrate that the substance reached the tested organ. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered	ADS	The study/ies do(es) not generally need to be conducted if: — the results are negative for the three in vitro tests and if no metabolites of concern are formed in mammals or — valid in vivo micronucleus data is generated within a repeat dose study and the in vivo micronucleus test is the appropriate test to be conducted to address this information requirement — the substance is known to be carcinogenic category 1A or 1B or mutagenic category 1A, 1B or 2.	*In vivo* genotoxicity study The assessment ~~shall~~ must comprise the following tiers: (a)If there is a positive result in any of the *in vitro* genotoxicity studies as listed in 8.5 and there are no reliable results available from an appropriate *in vivo* somatic cell genotoxicity study, an appropriate *in vivo* somatic cell genotoxicity study ~~shall~~ must be conducted; (b)A second *in vivo* somatic cell genotoxicity study may be necessary depending on the *in vitro* and *in vivo* results, type of effects, quality and relevance of all available data; (c)If there is a positive result from an *in vivo* somatic cell genotoxicity study available, the potential for germ cell mutagenicity should be considered based on all available data, including toxicokinetic evidence to demonstrate whether the substance has the capacity to reach germ cells. If no clear conclusions about germ cell mutagenicity can be made, additional	ADS	The stud~~y~~/ies in column 1 do~~(es)~~ not need to be conducted if: —the results are negative for the three *in vitro* tests listed in 8.5 and no other concern has been identified (e.g. metabolites of concern formed in mammals), or —the substance meets the criteria to be classified as a germ cell mutagen category 1A or 1B. The germ cell genotoxicity test does not need to be conducted if the substance meets the criteria to be classified as a carcinogen, category 1A or 1B and a germ cell mutagen category 2 Where in vivo genotoxicity testing is required, repeated dose toxicity studies should be integrated with appropriate genotoxicity tests where possible.

				investigations ~~shall~~ must be considered		
8.10.	Reproductive toxicity For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		The studies need not be conducted if: — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or — the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates there is no or no significant human exposure	Reproductive toxicity For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		The studies do not need to be conducted if: —the substance meets the criteria to be classified as a genotoxic carcinogen (classified both as germ cell mutagen category 2, 1A or 1B and carcinogenic category 1A or 1B), and appropriate risk management measures are implemented including measures related to reproductive toxicity, —the substance meets the criteria to be classified as a germ cell mutagen category 1A or 1B and appropriate risk management measures are implemented including measures related to reproductive toxicity, —the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma or blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates that there is no or negligible human or animal exposure,

						—the substance meets the criteria to be classified as reproductive toxicity category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for sexual function and fertility will be necessary. A full justification must be provided and documented if investigations for developmental toxicity are not conducted, or —the substance is known to cause developmental toxicity, meeting the criteria for classification as reproductive toxicity category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. A full justification must be provided and documented if investigations for sexual function and fertility ~~is~~ are not conducted. Notwithstanding the provisions of this column of this row, studies on reproductive toxicity may need to be conducted to obtain information on endocrine disrupting properties as laid down in 8.13.3.1.
8.10.1	Pre-natal developmental toxicity study, preferred species is rabbit; oral route of administration is the preferred route.			Pre-natal development toxicity study (OECD TG 414) on two species, preferred first species is rabbit (non-rodent) and preferred second species is rat		The study on the second species ~~shall~~ must not be conducted if the study performed on the first species or other available data indicate that the substance causes developmental toxicity meeting the criteria for

	The study shall be initially performed on one species			(rodent); oral route of administration is the preferred route		classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment
8.10.2	Two-generation reproductive toxicity study, rat, oral route of administration is the preferred route. If another reproductive toxicity test is used justification shall be provided. The extended one-generation reproductive toxicity study adopted at OECD level shall be considered as an alternative approach to the multi-generation study			Extended One-Generation Reproductive Toxicity Study (OECD TG 443), with cohorts 1A and 1B and extension of cohort 1B to include the F2 generation with the aim to produce 20 litters per dose group, F2 pups must be followed to weaning and investigated similarly as F1 pups. Rat is the preferred species and oral route of administration is the preferred route. The highest dose level should be based on toxicity and selected with the aim to induce reproductive and/or other systemic toxicity		A two-generation reproductive toxicity study conducted in accordance with OECD TG 416 (adopted 2001 or later) or equivalent information ~~shall~~ will be considered appropriate to address this information requirement, if the study is available and was initiated before [~~IMPLEMENTATION DATE~~] 6th October 2025. Wherever possible, the storage of organ samples (including serum samples) from any of the cohorts and generations of the extended one-generation reproductive toxicity study is highly recommended. These samples may be useful for follow-up investigations, without the need for further animal testing.
8.10.3	Further pre-natal developmental toxicity study. A decision on the need to perform additional studies on a second species or mechanistic studies should be based on the outcome of the first test (8.10.1) and all other relevant available data (in particular rodent reprotox studies). Preferred species is rat, oral route of administration			Developmental neurotoxicity Developmental Neurotoxicity Study in accordance with OECD TG 426, or any relevant study (set) providing equivalent information, or cohorts 2A and 2B of an Extended One-Generation Reproductive Toxicity study (OECD TG 443) with additional investigation for cognitive functions.	ADS	The study ~~shall~~ must not be conducted if the available data: —indicate that the substance causes developmental toxicity and meets the criteria to be classified as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and —are adequate to support a robust risk assessment

						The study ~~shall~~ must only be conducted ~~only~~ if triggered by one of the following: - neurotoxicity occurs in adult animals; or - the active substance interacts with molecules in the nervous system of the target organism; or - thyroid toxicity (including changes in thyroid hormones) occurs in adult animals
8.10.4	N/A – new insertion			Further studies A decision on the need to perform additional studies including those informing on the mechanisms should be based on the outcomes of the studies listed in 8.10.1, 8.10.2 and 8.10.3 and all other relevant available data	ADS	Any additional in vivo study must be scientifically justified.
8.11.2	Carcinogenicity testing in a second species — A second carcinogenicity study should normally be conducted using the mouse as test species — For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route			Carcinogenicity testing in a second species (a) A second carcinogenicity study should be conducted using the mouse as test species; (b) For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		The second carcinogenicity study does not need to be conducted if the applicant can justify on the basis of scientific grounds that it is not necessary
8.12.1 – 8.12.8	8.12.1 Medical surveillance data on manufacturing plant personnel			8.12.1 Information on signs of poisoning, clinical tests, first aid		

are replaced by 8.12.1 – 8.12.3	8.12.2. Direct observation, e.g. clinical cases, poisoning incidents 8.12.3. Health records, both from industry and any other available sources 8.12.4. Epidemiological studies on the general population 8.12.5. Diagnosis of poisoning including specific signs of poisoning and clinical tests 8.12.6. Sensitisation/allergenicity observations 8.12.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known 8.12.8. Prognosis following poisoning			measures, antidotes, medical treatment and prognosis following poisoning 8.12.2 Epidemiological studies 8.12.3 Medical surveillance data, health records and case reports		
8.13.2	Neurotoxicity including developmental neurotoxicity — The preferred test species is the rat unless another test species is justified to be more appropriate — For delayed neurotoxicity tests the preferred species will be the adult hen — If anticholinesterase activity is detected a test for response to reactivating agents should be considered If the active substance is an organophosphorus compound or if there is any evidence e.g. knowledge of the mechanism of action or from repeat dose studies that the active substance may have neurotoxic or developmental neurotoxic properties	ADS		Neurotoxicity If the active substance is an organophosphorus compound or if there is an indication, knowledge of the mechanism of action or knowledge from acute or repeated dose studies that the active substance may have neurotoxic properties, additional information or specific studies (such as OECD TG 424 or OECD TG 418 or 419 or equivalent) will be required. If anticholinesterase activity is detected a test for response to reactivating agents should be considered For evaluation of consumer safety of active substances that	ADS	

	then additional information or specific studies will be required. For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route			may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		
8.13.3	Endocrine disruption If there is any evidence from in vitro, repeat dose or reproduction toxicity studies, that the active substance may have endocrine disrupting properties then additional information or specific studies shall be required to: — elucidate the mode/mechanism of action — provide sufficient evidence for relevant adverse effects For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route	ADS		Endocrine disruption The assessment of endocrine disruption ~~shall~~ must comprise the following tiers: (a)An assessment of the available information from the following studies, where available, and any other relevant information, including *in vitro* and *in silico* methods: (i)8.9.1 A 28-day oral toxicity study in rodents (OECD TG 407); (ii)8.9.2 A 90-day oral toxicity study in rodents (OECD TG 408); (iii)8.9.4 A repeated dose oral toxicity study in non-rodents (OECD TG 409); (iv)8.10.1 A prenatal developmental toxicity study (OECD TG 414); (v)8.10.2 An extended one-generation reproductive toxicity study (OECD TG 443) or two-generation		Where sufficient weight of evidence to conclude on the presence or absence of a particular endocrine disrupting mode of action is available: —further testing on vertebrate animals for that effect ~~shall~~ must be omitted for that mode of action, —further testing not involving vertebrate animals may be omitted for that mode of action. In all cases, adequate and reliable documentation ~~shall~~ must be provided

				reproductive toxicity study (OECD TG 416); (vi)8.10.3 A developmental neurotoxicity study (OECD TG 426); (vii)8.11.1 A combined carcinogenicity study and long-term repeated dose toxicity study (OECD TG 451-3); (viii)A systematic review of the literature including studies on mammals and non-mammalian organisms; (b)If there is any information suggesting that the active substance may have endocrine disrupting properties, or if there is incomplete information on key parameters relevant for concluding on endocrine disruption, then additional information or specific studies ~~shall be required to~~ must be provided which elucidate one or more of the following: (1)the mode or the mechanism of action; and/or (2)potentially relevant adverse effects in humans or animals		

				For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to consider the oral route and conduct animal studies by the oral route		
8.13.3.1	N/A new insertion			Specific additional studies to investigate potential endocrine disrupting properties may include, but are not limited to, the following: (a) the mammalian toxicity studies listed in 8.13.3(a); (b) the *in vitro* assays: (i) Estrogen receptor transactivation assay (OECD TG 455); (ii) Androgen receptor transactivation assay, (OECD TG 458); (iii) H295R steroidogenesis assay (OECD TG 456); (iv) the Aromatase assay (human recombinant) OPPTS 890.1200; (c) Uterotrophic bioassay in rodents (OECD TG 440) and Hershberger bioassay in rats (OECD TG 441); (d) Pubertal development and Thyroid Function in Intact Juvenile or Peripubertal Male Rats (OPPTS 890.1500).	ADS	

				The decision to carry out studies in mammals ~~shall~~ must be taken based on all available information, including a systematic review of the literature (including information on endocrine disrupting effects in non-target organisms) and the availability of suitable *in silico or in vitro* methods		
8.13.4	Immunotoxicity including developmental immunotoxicity If there is any evidence, from skin sensitisation, repeat dose or reproduction toxicity studies, that the active substance may have immunotoxic properties then additional information or specific studies shall be required to: - elucidate the mode/mechanism of action - provide sufficient evidence for relevant adverse effects in humans For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route	ADS		Immunotoxicity and developmental immunotoxicity If there is any evidence from repeat dose or reproductive toxicity studies that the active substance may have immunotoxic properties, then additional information or specific studies ~~shall be required to~~ must be provided which elucidate one or more of the following: (1)the mode or the mechanism of action; ~~and/or~~ (2)potentially relevant adverse effects in humans or animals. For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to consider the oral route and conduct animal studies by the oral route	ADS	~~Immunotoxicity and developmental immunotoxicity~~ ~~If there is any evidence from repeat dose or reproductive toxicity studies that the active substance may have immunotoxic properties, then additional information or specific studies shall be required to elucidate:~~ ~~(1)the mode or the mechanism of action; and/or~~ ~~(2)potentially relevant adverse effects in humans or animals.~~ ~~For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to consider the oral route and conduct animal studies by the oral route~~
8.13.5	Mechanistic data — any studies necessary to clarify effects reported in toxicity studies	ADS		Further mechanistic studies A decision on the need to perform additional studies	ADS	~~Further mechanistic studies~~

				should be based on all relevant data		~~A decision on the need to perform additional studies should be based on all relevant data~~
8.18	Summary of mammalian toxicology Provide overall evaluation and conclusion with regard to all toxicological data and any other information concerning the active substances including NOAEL			DELETED		
9.1.1.	Short-term toxicity testing on fish When short-term fish toxicity data is required the threshold approach (tiered strategy) should be applied		The study does not need to be conducted if: — a valid long-term aquatic toxicity study on fish is available	Short-term toxicity testing on fish When short-term fish toxicity data is required, the threshold approach (tiered strategy) should be applied. Long-term toxicity testing on fish in accordance with point 9.1.6.1 ~~shall~~ will be considered if the substance is poorly water soluble, i.e. below 1 mg/L		The study does not need to be conducted if: —a valid long-term aquatic toxicity study on fish is available, —sufficient weight of evidence including the use of other data such as the Fish Embryo Acute Toxicity (FET, OECD TG 236) ~~and/~~or results obtained from non-animal methods is available for this data requirement.
9.1.6.1	Long term toxicity testing on Fish (a) Fish Early Life Stage (FELS) Test (b) Fish short term toxicity test on embryo and sack fry stages (c) Fish juvenile growth test Fish full life cycle test	ADS		Long term toxicity testing on fish The information ~~shall~~ must be provided from long-term toxicity testing on fish in which early life-stages (eggs, larvae or juveniles) are exposed	ADS	
9.10	Identification of endocrine activity	ADS		Endocrine disruption The assessment of endocrine disruption properties ~~shall~~ must comprise the following tiers:		

				(a) An assessment of the mammalian data set in accordance with 8.13.3 to assess whether the substance has endocrine disrupting properties based on data in relation to mammals; (b) If it cannot be concluded based on the mammalian data in accordance with 8.13.3 or 9.1.6.1 that the substance has endocrine disrupting properties, then studies set out in 9.10.1 or 9.10.2 ~~shall~~ will be considered taking account of any other available relevant information, including a systematic review of the literature.		
9.10.1	N/A New insertion			Endocrine disruption in fish Specific studies to investigate potential endocrine disrupting properties may include, but are not limited to the following data requirements: (a) Medaka extended one-generation test (MEOGRT, OECD TG 240); (b) Fish life cycle toxicity test (FLCTT, OPPTS 850.1500) covering all the 'estrogen-, androgen- and steroidogenic-mediated' (EAS) parameters foreseen		The study does not need to be carried out if: — there is no indication for endocrine activity or endocrine related effects from a sufficient mammalian data set in accordance with 8.13.3 or from any other relevant information (e.g. literature), and — valid *in vivo* data is available, with no information suggesting that the active substance may elicit endocrine activity or effects potentially related to endocrine activity in either the Fish short term reproduction assay (FSTRA; OECD

				to be measured in the MEOGRT study		TG 229), or the 21-days fish assay (OECD TG 230) or Fish sexual developmental test (FSDT, OECD TG 234). If other data are available covering the estrogenic, androgenic and steroidogenic, (EAS) related modalities or parameters investigated in OECD TG 229 or OECD TG 230 or OECD TG 234, then those data can be used instead
9.10.2	N/A New insertion			Endocrine disruption in amphibians Specific additional studies to investigate potential endocrine disrupting properties may include, but are not limited to Larval amphibian growth and development assay (LAGDA; OECD TG 241)		The study does not need to be carried out if: —there is no indication for endocrine activity or endocrine related effects from a sufficient mammalian data set in accordance with 8.13.3 or from any other relevant information (e.g. literature), and —valid *in vivo* data is available, with no information suggesting that the active substance may have endocrine disrupting properties in an Amphibian metamorphosis assay (AMA; OECD 231)
9.10.3	N/A New insertion			If there is information suggesting that the active substance may have endocrine disrupting properties, or if there is incomplete information on key parameters relevant for concluding on endocrine disruption, additional information or specific studies, as necessary, ~~shall be required to~~ must be provided which	ADS	~~If there is information suggesting that the active substance may have endocrine disrupting properties, or if there is incomplete information on key parameters relevant for concluding on endocrine disruption, additional information or specific studies, as necessary, shall be required to elucidate:~~ ~~(a)the mode or the mechanism of action; and/or~~

				elucidate one or more of the following: (a)the mode or the mechanism of action; and/or (b)potentially relevant adverse effects in humans or animals.		~~(b)potentially relevant adverse effects in humans or animals.~~

(3) Title 2 table

	Current GB BPR Wording			Suggested new wording		
Heading of column 3	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from column 1
2.4	Methods, procedures and criteria used to establish the presence and identity of the micro-organism			Specification of the technical grade active ingredient		
2.4.1	N/A new insertion			Content of the active micro-organism and identity and content of relevant metabolites or toxins		
2.4.2	N/A new insertion			Identity and content of impurities, additives, contaminating micro-organisms		
2.4.3	N/A new insertion			Analytical profile of batches		

2.5	Specification of the technical grade active ingredient			Method of production and quality control		
2.6	Method of production and quality control			DELETED		
2.7	Content of the micro-organism			DELETED		
2.8	Identity and content of impurities, additives, contaminating micro-organisms			DELETED		
2.9	Analytical profile of batches			DELETED		
3.5	Information on the production of metabolites (especially toxins)			Information on the production of relevant metabolites and toxins		
4.1	Analytical methods for the analysis of the micro-organism as manufactured			Methods, procedures and criteria used to establish the presence and identity of the micro-organism		
4.2	Methods used for monitoring purposes to determine and quantify residues (viable or non-viable)			Analytical methods for the analysis of the micro-organism as manufactured		
4.3	N/A new insertion			Methods used for monitoring purposes to determine and quantify residues (viable or non-viable)		

Changes to Annex III

Introductory part

	Current GB BPR Wording	Suggested new wording
Point 2 Paragraph 4	For some of the information requirements set out in this Annex, it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by the competent authority in accordance with point (e) of Article 77(2) of that Regulation.	For some of the information requirements set out in this Annex, it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by the Agency in accordance with point (e) of Article 77(2) of that Regulation. However, the information may be not sufficient or adequate to determine whether a non-active substance contained in a biocidal product has hazardous properties and the evaluating body may conclude that further data are required.
Point 2 paragraph 7	The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set out in Article 62(2), applicants may also consult with the competent authority with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.	The applicant ~~shall~~ must initiate a pre-submission consultation with the ~~prospective evaluating body~~ competent authority. In addition to the obligation set out in Article 62(2), the applicant may also consult with the competent authority ~~that will evaluate the dossier~~ with regard to the proposed information requirements and in particular the strategy for avoiding new testing on vertebrates alongside any testing on vertebrates that the applicant proposes to carry out. The applicant ~~shall~~ must document such pre-submission consultations and their outcomes and ~~shall~~ must include the relevant documents in the application
Point 5	5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate, whenever possible internationally recognised, and their appropriateness must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and, where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials.	Tests submitted for the purpose of authorisation shall be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008. ~~or any revised version of these methods not yet included in that Regulation.~~ Where a revised version of a test method described in Commission Regulation (EC) No 440/2008 is available, but not included in that Regulation, the revised version may be used with the agreement of the competent authority. However, if a method is inappropriate or not described in Commission Regulation (EC) No 440/2008, (*1) other methods shall be used which are

		scientifically appropriate and their appropriateness shall be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of these materials.

Title 1 table

	Current GB BPR Wording			Proposed new wording		
Heading of column 3	Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates	Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from column 1.
6.6	The proposed label claims for the product and, where label claims are made, for treated articles			The proposed claims for the product and, where claims are made, for treated articles regarding the biocidal properties conferred to the article.		
6.8.2	Observations on undesirable or unintended side effects e.g. on beneficial and other non-target organisms			Observations on undesirable or unintended side-effects on non-target organisms or on objects and material to be protected.		
8.1	Skin corrosion or skin irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/ Corrosion (Annex B.4. to Regulation (EC) No 440/2008)		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects	Skin corrosion or irritation The assessment ~~shall~~ must comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) skin corrosion, *in vitro* testing; (c) skin irritation, *in vitro* testing;		Testing of the product or mixture does not need to be conducted if: —there are sufficient valid data on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between

			between any of the components are not expected	(d)skin corrosion or irritation, *in vivo* testing		any of the components are not expected, —the product or mixture is a strong acid (pH≤ 2~~,~~.0) or base (pH≥ 11~~,~~.5), —the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature, —the product or mixture meets the classification criteria for acute toxicity category 1 by the dermal route, or —an acute toxicity study by the dermal route provides conclusive evidence on skin corrosion or irritation adequate for classification. If results from one of the two studies listed in points (b) or (c) in column 1 of this row already allow a conclusive decision on the classification of product or mixture or on the absence of skin irritation potential, the second study does not need to be conducted. An *in vivo* study for skin corrosion or irritation ~~shall be considered only if~~ must not be conducted unless the *in vitro* studies listed in points (b) and (c) in column 1 of this

						row are not applicable, or the results of these studies are not adequate for classification and risk assessment ~~and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable~~*In vivo* studies for skin corrosion or irritation that were ~~carried out or~~ initiated before ~~IMPLEMENTATION DATE~~ 6th October 2025 ~~15 April 2022 shall~~ will be considered appropriate to address this information requirement only if they lead to a more severe classification than the calculation method of Regulation (EC) No 1272/2008
8.2	Eye irritation ([1]) The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/ Corrosion (Annex B.5. to Regulation (EC) No 440/2008)		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected	Serious eye damage or eye irritation The assessment ~~shall~~ must comprise the following tiers: (a)assessment of the available human, animal and non-animal data; (b)serious eye damage or eye irritation, *in vitro* testing; (c)serious eye damage or eye irritation, *in vivo* testing		Testing on the product or mixture does not need to be conducted if: —there are sufficient valid data available on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected, —the product or mixture is a strong acid (pH≤ 2~~,~~.0) or base (pH≥ 11~~,~~.5),

						—the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature, or —the product or mixture meets the classification criteria for skin corrosion leading to its classification as "serious eye damage" category 1 If results from a first *in vitro* study do not allow a conclusive decision on the classification of the product or mixture or on the absence of eye irritation potential ~~(an)~~other~~(s)~~ *in vitro* stud~~y(~~ies~~)~~ for this endpoint ~~shall~~ must be considered An *in vivo* study for serious eye damage or eye irritation ~~shall be considered only if~~ must not be conducted unless the *in vitro* study(ies) under point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment ~~and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable~~

						In vivo studies for serious eye damage or eye irritation that were carried out or initiated before ~~IMPLEMENTATION DATE~~ 6th October 2025 ~~15 April 2022~~ ~~shall~~ will be considered appropriate to address this information requirement only if they lead to a more severe classification than the calculation method of Regulation (EC) No 1272/2008 ~~as it applies in GB~~
8.3	Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. in vivo testing The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for in vivo testing. If another skin sensitisation test is used justification shall be provided		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected — the available information indicates that the product should be classified for skin sensitisation or corrosivity; or — the substance is a strong acid (pH < 2,0) or base (pH > 11,5)	Skin sensitisation The information ~~shall~~ must allow ~~to conclude~~ a conclusion as to whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Category 1A). The information should be sufficient to perform a risk assessment where required. The assessment ~~shall~~ must comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) skin sensitisation, *in vitro* testing according to OECD TG 497. ~~Information from *in vitro* or *in chemico* test method(s) conducted in accordance with point 5 of the introductory part of this Annex and addressing~~		Testing on the product or mixture does not need to be conducted if: — there are sufficient valid data available on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected, — the available information indicates that the product or mixture should be classified for skin sensitisation or skin corrosion, — the product or mixture is a strong acid (pH≤ 2~~,~~.0) or base (pH≥ 11~~,~~.5), or

				~~each of the following key events of skin sensitisation:~~ ~~(i) molecular interaction with skin proteins;~~ ~~(ii) inflammatory response in keratinocytes;~~ ~~(iii)~~ ~~activation of dendritic cells.~~ (c) skin sensitisation *in vivo* testing. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for *in vivo* testing. Another skin sensitisation test may only be used in exceptional circumstances. If another skin sensitisation test is used, scientific justification ~~shall~~ must be provided.		—the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature. *In vitro* tests do not need to be conducted if: —an *in vivo* study referred to in point (c) in column 1 of this row is available , or —the available *in vitro or in chemico* test methods of OECD TG 497 are not applicable for the product or mixture or the results obtained from these studies are not adequate for classification and risk assessment. ~~If information from test method(s) addressing one or two of the key events described in point (b) in column 1 of this row already allows for classification of the substance and risk assessment, studies addressing the other key event(s) do not need to be conducted~~ An *in vivo* study for skin sensitisation ~~shall only be considered if~~ must not be conducted unless if *in vitro* or *in chemico* studies of OECD TG 497~~79~~ referred to in

						point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable. *In vivo* studies for skin sensitisation that were ~~carried out or~~ initiated before 6th October 2025 ~~15 April 2022 shall~~ will be considered appropriate to address this information requirement.
8.5	Acute toxicity — Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach		Testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected	Acute toxicity — Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach and should include an assessment of ~~of read-across and~~ information from in silico approaches		Testing on the product/mixture does not need to be conducted if: —there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in —~~Directive 1999/45/EC and~~ Regulation (EC) No 1272/2008 and synergistic effects between any of the components are not expected

8.7	Available toxicological data relating to: — non-active substance(s) (i.e. substance(s) of concern), or — a mixture that a substance(s) of concern is a component of If insufficient data are available for a non-active substance(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted test(s) described in Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of		Testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP) Targeted tests, selected from those listed in Section 8 of the table in Title 1 of Annex II shall be carried out, with consideration of reduction of animal use, for the substance(s) of concern or a mixture that a substance(s) of concern is a component of if insufficient data are available and cannot be inferred through read-across, in silico or other accepted non-testing approaches.	Available toxicological data relating to: (a)A non-active substance or substances ~~(s)~~ (i.e. substance or substance~~(s)~~ of concern); and (b)a mixture containing a substance or substances of concern ~~that a substance(s) of concern is a component of~~ Targeted tests listed in Section 8 of the table in Title 1 of Annex II ~~shall~~ must be carried out, with consideration of reduction of animal use, for the substance or substance~~(s)~~ of concern or a mixture ~~that~~ containing a substance or substance~~(s)~~ of concern ~~is a component of~~ if insufficient data are available and cannot be inferred through read-across, *in silico* or other accepted non-testing approaches		Testing on the product or mixture does not need to be conducted if all of the following conditions are met: —there are valid data available on each of the components in the mixture to allow classification of the mixture in accordance with the rules laid down in Regulation (EC) No 1272/2008, ~~as it applies in GB~~ —a conclusion can be made whether the biocidal product can be considered as having endocrine disrupting properties, —synergistic effects between any of the components are not expected.
9.1	Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required — Where there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made			Available ecotoxicological data relating to: (a) A non-active substance or substance~~(s)~~ (i.e. substance(s) of concern); (b)a mixture containing a substance or substances of concern ~~that a substance(s) of concern is a component of~~ Tests listed in Section 9 of Title 1 of Annex II ~~shall~~ must be carried out for the substance or substance~~(s)~~		Testing on the product or mixture does not need to be conducted if all the following conditions are met: —there are valid data available on each of the components in the mixture to allow classification of the mixture in accordance with the rules laid down in Regulation (EC) No 1272/2008, ~~as it applies in GB.~~

	according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/ 2008 (CLP) — Where valid data on the components are not available or where synergistic effects may be expected then testing of components and/or the biocidal product itself may be necessary			of concern or a mixture ~~that~~ <u>containing a substance or</u> substance~~(s)~~ of concern ~~is a component of~~ if insufficient data are available and cannot be inferred through read-across, *in silico* or other accepted non-testing approaches		—a conclusion can be made whether the biocidal product can be considered as having endocrine disrupting properties, —synergistic effects between any of the components are not expected.

Title 2 table

	Current GB BPR Wording			Suggested new wording		
Heading of column 3	Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates	Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from column 1
2.3	Detailed quantitative (g/kg, g/l or % w/w (v/v)) and qualitative information on the constitution, composition and function of the biocidal product, e.g. micro-organism, active substance(s) and product non-active substances and any other relevant components. All relevant information on individual ingredients and the final composition of the biocidal product shall be given			Detailed quantitative (g/kg, g/l, % w/w (v/v), cfu/g, cfu/l or IU/mg or any other appropriate unit) and qualitative information on the constitution, composition and function of the biocidal product, e.g. micro-organism, active substance(s) and non-active substances and any other relevant components All relevant information on individual ingredients and the final composition of the biocidal product ~~shall~~ <u>must</u> be given		

3.6.8	Burning rate — smoke generators			DELETED		
3.6.9	Burning completeness — smoke generators			DELETED		
3.6.10	Composition of smoke — smoke generators			DELETED		
3.6.11	Spraying patterns — aerosols			DELETED		
3.6.12	Other technical characteristics			DELETED		
3.6.8	N/A – new insertion			Spraying patterns – aerosols		
3.6.9	N/A – new insertion			Other technical characteristics		
4.	PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS			4.PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISITICS		
4.1.	Explosives			4.1. Explosives		
4.2.	Flammable gases			4.2. Flammable aerosols		
4.3.	Flammable aerosols			4.3. Flammable liquids		
4.4.	Oxidising gases			4.4. Flammable solids		
4.5.	Gases under pressure			4.5. Oxidising liquids		
4.6.	Flammable liquids			4.6. Oxidising solids		
4.7.	Flammable solids			4.7. Corrosive to metals		
4.8.	Oxidising liquids			4.8. Other physical indications of hazard		
4.9.	Oxidising solids			4.8.1. Auto-ignition temperatures of products (liquids and gases)		

4.10.	Organic peroxides			4.8.2. Relative self-ignition temperature for solids		
4.11.	Corrosive to metals			4.8.3. Dust explosion hazard		
4.12.	Other physical indications of hazard					
4.12.1.	Auto-ignition temperatures of products (liquids and gases)					
4.12.2.	Relative self-ignition temperature for solids					
4.12.3.	Dust explosion hazard					
10.3.	Leaching behaviour	ADS		Leaching behaviour and/or mobility	ADS	

Further information

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