Title: The Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc. Regulations 2024	Impact Assessment (IA)
IA No: HSE-IA2024-001	**Date:** 2nd October 2023
RPC Reference No: N/A	**Stage:** Final
Lead department or agency: Health and Safety Executive	**Source of intervention:** Domestic
Other departments or agencies: N/A	**Type of measure:** Secondary legislation
	Contact for enquiries: andrew.low@hse.gov.uk

Summary: Intervention and Options

RPC Opinion: N/A (de minimis)

Cost of Preferred (or more likely) Option (in 2019 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
-£0.6m	-£0.6m	£0.1m	Nil (de minimis)

What is the problem under consideration? Why is government action or intervention necessary?

Annexes II and III of the assimilated Great Britain Biocidal Products Regulation 2012[1] (GB BPR) contain data requirements to support the approval of active substances and biocidal products. Some of the current data requirements are now out of date due to technical and scientific progress. An update of these Annexes is required so that they reflect current scientific standards and minimise animal testing requirements by adopting new testing methods and encouraging the use of in vitro studies rather than in vivo animal studies.

What are the policy objectives of the action or intervention and the intended effects?

Current data requirements, which must be met by businesses making Great Britain (GB) active substance approval and biocidal product authorisation applications, are set out in the above-mentioned Annexes. This will make the Health and Safety Executive's (HSE) current published data requirement guidance, which recommends the use of these test methods, a GB regulatory requirement. This is to:

- Keep up with technical and scientific progress, ensuring the GB competent authority has access to the most scientifically up to date information, to be able to assess the risks associated with the use of biocidal products and their active substances, so it can effectively identify and control risks to human and animal health and the environment before products reach the GB market
- Improve biocidal product safety and the ability for HSE to maintain world-leading safety standards
- Articulate unequivocal GB regulatory data requirements, which are clear to businesses making GB active substance approval and biocidal product authorisation applications, and reduce the likelihood of application refusals and challenges relating to test requirements
- Make requests for specific scientific test data to take advantage of scientific advances in endocrine testing and reduce animal testing

The changes will mean that applicant businesses:

- Must ensure that they meet specific data requirements set out in the updated Annexes II and III, including using in vitro studies rather than in vivo animal studies (where specified) from the date that they come into force

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

- Option 0 – Business as usual (baseline)
- Option 1 – GB legislation with tailored changes to GB Annexes II and III (preferred)

Option 1 is preferred because it delivers government priorities to maintain standards in line with technical progress; it tailors the approach to what is appropriate for GB, minimises animal testing and provides the certainty of statutory requirements.

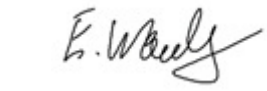
Other options considered, but not taken forward as they do not deliver the objective above: GB legislation mirroring changes to Annexes in the European Union (EU) legislation; and leaving GB BPR as is and ask applicants for further information based on guidance only.

Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)	**Traded:** N/A	**Non-traded:** N/A
Will the policy be reviewed? Informal internal monitoring **If applicable, set review date:** N/A		

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Chief Economist  Date: 2nd October 2023

Summary: Analysis & Evidence

Policy Option 0

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year: 2022	PV Base Year: 2024	Time Period Years: 10	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** N/A

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	**N/A**		**N/A**	N/A
High	**N/A**	1	**N/A**	N/A
Best Estimate	**N/A**		**N/A**	N/A

Description and scale of key monetised costs by 'main affected groups'

This is the business-as-usual baseline against which the other options are compared. As such, there are no additional costs and benefits of Option 0.

Other key non-monetised costs by 'main affected groups'

Doing nothing would mean HSE fail to keep the data requirements in line with scientific and technical progress including the use of non-animal in vitro test methods, and not be aligned with the Government's objectives of eliminating or reducing animal testing.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	**N/A**		**N/A**	N/A
High	**N/A**		**N/A**	N/A
Best Estimate	**N/A**		**N/A**	N/A

Description and scale of key monetised benefits by 'main affected groups'

This is the business-as-usual baseline against which the other options are compared. As such, there are no additional costs and benefits of Option 0.

Other key non-monetised benefits by 'main affected groups'

This is the business-as-usual baseline against which the other options are compared. As such, there are no additional costs and benefits of Option 0.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5%
N/A		

BUSINESS ASSESSMENT (Option 0)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: N/A
Costs: N/A	**Benefits:** N/A	**Net:** N/A	

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year: 2022	PV Base Year: 2024	Time Period Years: 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£0.5m	**High:** -£0.9m	**Best Estimate:** -£0.7m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£0.4m	1	£0.02m	**£0.5m**
High	£0.4m		£0.06m	**£0.9m**
Best Estimate	£0.4m		£0.04m	**£0.7m**

Description and scale of key monetised costs by 'main affected groups'

The costs are anticipated to fall to the manufacturers of biocidal active substances and products. HSE estimate the majority of businesses in scope will incur the costs anyway through compliance with similar requirements in the EU. Around 2,950 businesses will incur one-off familiarisation costs of around £400,000. In addition, businesses undertaking additional required tests for new and renewal biocidal active substance dossiers will incur ten-year present value costs of between around £150,000 and £550,000.

Other key non-monetised costs by 'main affected groups'

None.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Unquantified		Unquantified	**Unquantified**
High	Unquantified		Unquantified	**Unquantified**
Best Estimate	Unquantified		Unquantified	**Unquantified**

Description and scale of key monetised benefits by 'main affected groups'

None

Other key non-monetised benefits by 'main affected groups'

The changes ensure that the data requirements in GB BPR keep up with scientific and technical progress, reduce the need for animal testing in line with wider government goals, and reflect the latest internationally validated test methods. The changes will provide legal certainty to businesses applying for biocidal product authorisations and active substance approvals in Great Britain.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5%

HSE estimates that the majority of dossiers submitted to us will not be subject to additional costs due to baseline compliance with similar EU requirements and the characteristics of the substances themselves. Specifically, HSE estimates that <1% of new active substance dossiers will incur additional costs. This is based on a comparative analysis GB and EU approval and authorisation lists and whether companies are selling their actives and products into both markets.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: Nil (de minimis)
Costs: £0.1m	**Benefits:** Nil	**Net:** £0.1m	

Evidence Base

Problem under consideration and rationale for intervention

1. Biocidal active substances and products (products and substances which are intended to kill or otherwise control harmful organisms) are assessed for their safety and effectiveness before approvals and authorisations can be granted.

2. Annexes II and III of the assimilated Great Britain Biocidal Products Regulation (EU Regulation 528/12) (GB BPR) contain the information requirements for active substances (Annex II) and biocidal products (Annex III). Applicants are required to submit dossiers of scientific data, containing studies meeting these requirements, to allow assessments to be carried out.

3. On 26 March 2021 EU Regulation 2021/525 was published in the Official Journal with amendments to Annexes II and III of the EU Biocidal Products Regulation (EU BPR) for EU-27 countries and Northern Ireland with effect from 15 April 2022.

4. This EU Regulation does not apply to Great Britain (GB), where a separate assimilated Biocidal Products Regulation (GB BPR) applies. HSE specialists were involved in developing the updated data requirements while the UK was part of the EU. Having considered the amendments from a GB perspective, operational and specialist colleagues believe that GB BPR should be modified to adopt changes which meet the needs of GB.

5. These changes include adopting new testing methods and requiring the use of in vitro studies rather than in vivo animal studies, in order to keep pace with scientific and technical progress. In vivo ('in the body') testing is performed using live animals, whereas in vitro ('in glass') testing is performed using cell samples or other techniques that do not involve live animal testing. In most cases the new tests replace old ones, however there is one new test (the Developmental Neurotoxicity Test (DNT)) which was not previously required.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

6. The evidence used in this final stage Impact Assessment is from a combination of sources. It includes internal estimates of numbers of biocidal products and active substances that are likely to be affected, estimates by HSE experts on the likely costs of testing requirements, and internal data analysis. Estimates of numbers of businesses which may be affected, and likely numbers of businesses who will need to comply with EU requirements as well as those in GB, have been triangulated from information from HSE chemicals regulation experts; synthesised intelligence from published and bespoke industry, government and market intelligence sources; and compared published lists of active substances and products that are approved and authorised in GB and the EU (see paragraph 25).

7. Assumptions made in the consultation stage IA[1]were tested through consultation[2]; workshops with HSE toxicologists and sector experts; and augmented with HSE-commissioned market analysis of the biocides sector.

[1] Revision of GB Biocidal Products Regulation Annexes II and III - Health and Safety Executive - Citizen Space (hse.gov.uk)

[2] The report of the consultation is available at https://consultations.hse.gov.uk/crd-biocides/rev-gb-bpr-annexes-ii-and-iii/

Description of options considered

Option 0 – business as usual

8. The default option in any comparison is 'business as usual', whereby no changes are made to GB BPR and the current versions of Annexes II and III continue to apply. EU Regulation 2021/525 would continue to apply to Northern Ireland (as is the case for all options).

Option 1 – GB legislation with tailored changes (where deemed appropriate for GB) to GB BPR Annexes II and III

9. Make legislative changes applying most of the Annex II and III changes to new applications and active substance approval renewals that the EU made, omitting those aspects with which GB does not agree. HSE disagrees with the need to change the requirements to include obligatory developmental neurotoxicity studies and the need for data to demonstrate the efficacy of treated articles.

10. Other options were considered at the policy development stage but have been rejected and are not assessed further in this IA. These are discussed below.

Options considered at policy development stage, but not taken further

11. Other options were considered at the policy development stage but have been rejected and are not assessed further in this IA. They include:

- **GB legislation mirroring EU changes:** Legislation making exactly the same changes to Annexes II and III as were made in the EU. The only exception to this would be if something were inoperable, e.g. a reference to an EU database to which GB does not have access or an inappropriate cross-reference in the context of GB BPR. This option has not been pursued as there are a small number of areas where HSE does not agree with the EU's changes. This is either because HSE experts consider the data required by the EU is not needed to effectively conduct the evaluation, or that the test requirements can be made more targeted to reduce testing on animals, or in one case that some additional information is needed to inform evaluations. Under this option, the opportunity would be missed to adopt changes that fully meet the needs of GB. Full details are in Consultation Document available at https://consultations.hse.gov.uk/crd-biocides/rev-gb-bpr-annexes-ii-and-iii/.

- **Leave GB BPR as is and ask applicants for further information based on guidance only (no legislation):** Leave GB BPR unamended and HSE would instead rely on publicising any extra information requirements that it agrees with via guidance, probably in the form of content on HSE's website. Existing provisions in Article 62 of GB BPR allow HSE to require submission of non-animal tests in favour of animal tests where they exist (see paragraph 19). This would mean that HSE could only encourage submission of new data requirements (i.e. the DNT test referred to below) as it would not be a legal requirement. This was not pursued as failure to incorporate the updated requirements into law could lead to practical problems if businesses choose not to comply. It would also mean that changes to reduce animal testing would not be fully implemented in law.

- **Apply the new testing requirements retroactively to existing product and active substance applications:** There are around 340 active substance submissions already submitted to HSE for review; and around 330 for products. These include active substances grandfathered into BPR from the previous Control of Pesticides Regulations 1986 (COPR)[3], other reviews and renewals. HSE considered the application of the new testing requirements retrospectively to these

[3] The Control of Pesticides Regulations 1986 (SI 1986 No 1510)

submissions, and this was rejected on the grounds of significantly high costs, the fact that this would go beyond what the EU are enacting and that it would be unfair to businesses affected as it would mean applying different, unforeseeable requirements to those which were in place at the time they applied. As an alternative, HSE believes it is fairer and more proportionate to apply the requirements at the time when active substance approvals are renewed, rather than at first review.

Policy objective

12. Current data requirements which must be met by businesses making GB active substance approval and biocidal product authorisation applications are set out in GB BPR Annexes II[4] and III[5]. They will be updated to make HSE's current published data requirement guidance a GB regulatory requirement. This is to enable the GB Competent Authority to:

- Keep up with technical and scientific progress, ensuring the GB competent authority has access to the most scientifically up to date information to be able to assess the risks associated with the use of biocidal products and their active substances so it can effectively identify and control risks to human and animal health and the environment before products reach the GB market
- Improve biocidal product safety and the ability for HSE to maintain world-leading safety standards
- Articulate unequivocal GB regulatory data requirements, which are clear to businesses making GB active substance approval and biocidal product authorisation applications, and reduce the likelihood of application refusals and challenges relating to test requirements
- Make requests for specific scientific test data to take advantage of scientific advances in endocrine testing and reduce animal testing

13. The changes will mean that applicant businesses:

- Must ensure that they meet specific data requirements set out in Annexes II and III, including using in vitro studies rather than in vivo animal studies from the date that they come into force

Summary and preferred option with description of implementation plan

14. The preferred option (Option 1) is to prepare legislation to make tailored amendments to Annexes II and III.

15. Subject to consent from Ministers in Scotland and Wales, the Secretary of State has the power to make these changes using a negative resolution statutory instrument under powers delegated in Article 85 of GB BPR (adaptation to scientific and technical progress).

16. This option is low-cost to GB businesses, in line with Government priorities around reduction in animal testing, and it is proportionate to the needs of GB.

17. This would be accompanied by an interim measure of issuing guidance to applicants requesting that they provide the further information that will later become statutory once legislation comes into force , at which point the guidance will be updated to make clear the changed requirements are legally required for future applications.

18. Some of the additional data (toxicological data to assess whether a chemical is an endocrine disruptor, updates to ecotoxicological data, and chemistry data) are already included in guidance

[4] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products – Annex II

[5] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products – Annex III

and as such are already being requested by HSE to evaluate active substance and biocidal product applications. Some changes (such as changes to text on efficacy) are points of clarification rather than new requirements. Therefore, in these cases applicants are already effectively complying with the requirements; the effect of changes will simply be to bring the law in line with current practice. In these cases, the amended data requirements are baseline and HSE has not further assessed their impact.

19. In other cases, there are new fully validated alternative test methods that are already available and required by other regimes (in particular of the EU). This suggests a high likelihood of compliance as soon as the requirements enter force. Therefore, other than updating guidance HSE does not consider further action is required to implement the new requirements.

20. It is planned that the legislation introducing the new data requirements will enter force on 6 April 2024, with an 18-month transitional period before they are fully mandatory. This will apply to all the requirements and is being specifically introduced to give applicants adequate time to commission new testing where this is required. In this cost analysis, it is assumed that test costs and familiarisation will begin to be incurred from April 2024 (when the proposed legislative changes come into force) prior to the conclusion of the transition period. This is a reasonable model of actual costs as active substance and product tests will be booked and paid for well in advance of the submission of a dossier to HSE.

Monetised and non-monetised costs and benefits of Option 1

Numbers of biocide active substance and product submissions

21. In the consultation stage impact assessment, HSE estimated that the changes to the testing requirements would affect a range of submissions concerning both active substances and products, including both new submissions and renewals. However, since consultation and further review of the policy and current practices, HSE considers that the majority of 'new' tests required in the consultation stage IA are already required of applicants under Article 62 of GB BPR. Article 62 requires that animal testing is undertaken only as a last resort and therefore that applicants provide testing dossiers to HSE consistent with the latest in technical progress, which already covers many of the tests that Option 1 proposes to make explicit in GB BPR. As a result, the making of the following tests a specific requirement will impose no additional costs:
    a. Skin irritation testing for both new and renewal active substance submissions and renewal product submissions
    b. Eye irritation testing for both new and renewal active substance submissions; and product submissions
    c. Skin sensitisation testing for both new and renewal active substance submissions and product submissions
    d. Genotoxicity testing for new and renewal active substance submissions

22. This leaves only developmental neurotoxicity (DNT) testing for new active substances and renewals incurring additional costs in this final stage IA. HSE expect to receive between nil and one application for approval for a new active substance per annum over the next ten years; and between ten and eleven applications for active substance renewals per annum over the same period.

23. As discussed in the consultation stage IA, not all the new and renewal active substance submissions will be in scope of additional testing costs under these proposals. As the EU has already implemented these additional testing requirements, any active substance for which approval or authorisation is already being sought in the EU will bear no additional costs, as they will undertake the tests under the baseline as part of their EU submission.

24. To estimate the proportion of active substance approval applicants likely to apply for the EU as well as GB, HSE economic and social research analysts conducted a three-stage analysis to arrive at estimates of the proportions of unique applicant/ authorisation holder businesses which were:

    a. active in both GB and EU, which has already implemented the new test requirements; or,
    b. active in GB only and therefore may be less likely to be meeting the new GB BPR test requirements.

25. The analysis gathered knowledge and estimates from HSE chemicals regulation experts; synthesised intelligence from published industry, government and market intelligence sources; and compared published lists of active substances that are approved and authorised in GB and the EU. This allowed HSE to estimate the proportion of active substances approved in GB that have also been processed through the EU system. There is some level of uncertainty in this analysis, as it required some interpretation of substances and companies with similar names and some additional research into whether they were in fact the same on both lists.[6] This analysis has led HSE to conclude that for active substances, between 1% and 3% might be expected to seek GB approval without also seeking EU approval and would therefore expect to incur additional testing costs.

26. Further, also as discussed in the consultation stage IA, HSE toxicologists estimate that around a third of new active substances would display the attributes that would lead to a requirement for DNT testing.

27. Taken together, these assumptions indicate that it will be a rare new active substance submission that incurs additional DNT testing costs – between around 0.033 and 0.12 submissions per annum, with a mid-estimate of around 0.073.

Additional test costs

28. As discussed above, most of the additional tests' costs discussed in the consultation stage IA have since been found to be baseline and so are not estimated further in this final stage IA (although updated evidence on their costs is discussed in Annex 2).

29. Test costs have been estimated by HSE toxicologists with reference to Organisation for Economic Cooperation and Development (OECD) reference costs.

30. For DNT, no tests are required under the baseline. For actives, the DNT cost is estimated at around £533,000. We tested this cost estimate in consultation and responses indicated that it was about right.

31. During consultation HSE also explored whether dutyholders would incur further costs associated with translating the DNT test result into a suitable format for the dossier and drawing appropriate conclusions to include in the active substance dossier. Evidence from consultation indicated that this would be covered by a 'weight of evidence' analysis costing around £4,000, which was agreed as reasonable by HSE toxicologists.

32. This gives a total cost of DNT testing per active substance submission of around £537,000.

33. Across the in-scope new active substances given in paragraph 27, this would give an estimated annual cost of between around £18,000 and £64,000, with a mid-estimate of around £39,000.

34. This gives an **estimated present value cost of DNT tests** of between around £150,000 and £550,000, with a **mid-estimate of around £340,000**.

[6] This analysis is described further in Annex 1.

Familiarisation

35. HSE anticipates that dutyholders would have to take some time to familiarise with the changes proposed to GB BPR. Although the new testing requirements are already being applied by HSE under Article 62 (see paragraph 21), we would expect dutyholders to review the changes making these explicit in GBBPR Annexes II and III.

36. In the consultation stage IA, HSE policy leads estimated that it would take each organisation between around 3 and 9 hours to read and familiarise with the changes, with a mid-estimate of around 6 hours. This was based on expectations of the length of the guidance that would be issued by HSE. In understanding that the practical effect of the changes will be reduced given the pre-existing Article 62 testing requirements, HSE policy leads have estimated that familiarisation is likely to be at the lower end of the range – that is, 3 hours.

37. Based on the data review discussed in paragraph 25, HSE estimated in the consultation stage impact assessment that there are around 1,140 biocidal product manufacturers or active substance suppliers in GB that could need to familiarise. Subsequent market research purchased by HSE indicates that this figure could be higher at around 2,950. The disparity between the two numbers appears to be due to not all businesses having products that have yet come up for authorisation. To take a robust approach in this final stage IA, HSE considered the higher estimate of 2,950.

38. This gives a total of around 8,900 hours spent familiarising.

39. HSE believes that this familiarisation would be undertaken by a science manager. To estimate the cost of their time, HSE have used the average wage for Professional, Scientific And Technical Activities, Managers, Directors And Senior Officials (SOC code M1) from the Annual Survey of Hours and Earnings.[7] This hourly wage is £36.46. The full value of the manager's time to their employer will include additional 'on-wage' costs, such as pension, National Insurance and other costs. HSE estimates that these account for a further 18% on top of the wage. This gives a full economic cost of the manager's time of £43.02 per hour.

40. This gives a **total one-off cost of familiarisation of around £380,000**.

Benefits

41. Updates to Annex II and III of GB BPR will bring the data requirements for biocidal active substances and products up to date in line with scientific and technical progress, providing the most accurate and up to date information for regulators to base their decisions on, leading to better protection of human health and the environment.

42. The change from in vivo to in vitro testing for some requirements will lead to a reduction in animal testing in line with broader government policies.

43. Clarity about the requirements being present in the legislation will remove doubt over their applicability compared to the current system of the tests being recommended in guidance. This may make the application process smoother by reducing the likelihood that HSE would need to request further information during the course of the evaluation in the areas covered by the changes, by making the data requirements obligatory rather than stated in guidance.

[7] Annual Survey of Hours and Earnings (ASHE) - Estimates of earnings for the UK, by industry and occupation, UK, April 2021 provisional SOC 2020 - Office for National Statistics (ons.gov.uk)

Summary of quantified costs and benefits

44. The quantified costs are summarised below in Table 1. They come to a present value cost over ten years of between around £530,000 and £940,000, with a mid-estimate of around £720,000. These costs all fall directly to businesses.

45. The equivalent annual net direct cost to business (estimated in 2019 prices and 2020 present value baseline) is £0.1 million, well below the £10 million de minimis for the current (as of September 2023) Better Regulation Framework.

46. As discussed in paragraphs 41 to 43, there are accompanying benefits that have not been possible to quantify.

Table 1: Summary of quantified costs (ten-year present values, £thousands)

	£thousands		
	Low	**Mid**	**High**
Additional test costs	£150	£340	£550
Familiarisation	£380	£380	£380
Total	**£530**	**£720**	**£940**

Note: *totals may appear not to sum due to rounding*

Risks and assumptions

47. In the analysis, HSE has assumed that recent observation of the numbers of submissions will serve as a useful guide to submission numbers over the appraisal period of this assessment. In reality, future figures could vary in unpredictable ways, such as due to long-term market changes, such as Brexit; and shorter-term market shifts, such as changes in product uses due to the pandemic. However, significant fluctuations of this type are not anticipated.

48. Estimates of test costs (both for the baseline and for the proposed changes) are based on best available data. For DNT testing, we were able to confirm that respondents believed our estimates are about right.

49. Limitations of the social research analysis of published sources and rationale for analytical decisions are outlined in detail in Annex 1.

Impact on small and micro businesses

50. HSE does not propose to exempt small and micro businesses (i.e., those employing fewer than 50 employees) from these requirements; nor medium-sized businesses (i.e. those employing between 50 and 499 employees). The hazards that BPR exists to regulate relate to the properties of the hazardous substances that manufacturers produce and these are no less hazardous for having been produced by a smaller company.

51. Since the consultation stage impact assessment, HSE commissioned and received a bespoke market research report on the sector, which allows for the refinement and verification of the initial estimates on sector business size.

52. According to the Interdepartmental Business Register (IDBR)[8], there are 85 businesses in SOC code 2020[9] 'Manufacture of pesticides and other agrochemical products'. This is well below the approximately 2,950 manufacturers HSE policy estimate are in scope of these regulations (see

[8] UK business: activity, size and location - Office for National Statistics (ons.gov.uk)

[9] Standard Occupational Classification (SOC) - Office for National Statistics (ons.gov.uk)

paragraph 37). This could be due to not all businesses in the chemical supply chain being involved in the making and submitting of submissions to GB BPR. According to IDBR, 88% of these businesses are small or micro.

53. Looking more widely at chemical manufacturers, SOC code 20 in IDBR 'Manufacture of chemicals and chemical products' contains 3,230 businesses; and 82% are small or micro.

54. HSE's bespoke commissioned market research indicates that around 5% of businesses in the sector are large.

55. These estimates indicate that it is likely that the proportion of small and micro biocidal active substance and product manufacturers is very high. Although the number of manufacturers is not synonymous with the number of products, this would seem to imply that exempting small and micro businesses from the BPR requirements would leave a large proportion of the market unregulated. For the specific changes that this impact assessment appraises, exempting such a large portion of the market from the new requirements would mean HSE failed to deliver on the strategic objectives of maintaining world-leading safety standards and limiting the scope of in vivo testing.

56. There is no reason to believe that the costs enumerated in this impact assessment would be disproportionate for small and micro businesses. The costs of the tests are expected to be the same (on average) for each substance. Costs for a business will vary based on the number of biocidal active substances and products for which they apply for approval or authorisation; and the hazard that they present (e.g., whether they present a genotoxicity or developmental neurotoxicity hazard).

Wider impacts (consider the impacts of your proposals)

57. HSE does not assess that the proposed changes would have any wider effects:

- The changes are not anticipated to have equality impacts on people with protected characteristics

- The changes will not affect incentives for businesses to compete, nor their ability to do so.

A summary of the potential trade implications of measure

58. No impacts on trade are anticipated.

59. Under BPR, businesses must be established in the UK to hold biocides authorisations or to be on the 'Article 95 List' of approved active substance suppliers. This is unaffected by these changes. To the extent that non-UK businesses can apply for biocides product authorisations and approvals (e.g., if a foreign company has a subsidiary based in the UK), the requirements will be the same for UK and foreign businesses both before and after these changes.

60. Both before and after these changes, UK companies will still have to comply with the local requirements of the different countries in which they wish to trade (including GB, EU and rest of the world).

61. Overall, the changes will bring GB requirements closer to those in place in the EU than they are at present and in most cases the new requirements will be identical those in the EU, which also apply in Northern Ireland under the Northern Ireland Protocol and the Windsor Framework. However, this is not expected to lead to divergent regulatory outcomes between GB and the EU or Northern Ireland, or to have any impact on trade. This is because the scientific criteria for assessing biocides will remain the same as those applying in the EU and Northern Ireland with only minor differences in evidence requirements against a small number of those criteria which are not expected to affect regulatory decision-making.

Monitoring and Evaluation

62. HSE's biocides policy and specialist operational teams have regular contact with businesses in the biocides sector and will monitor through formal and informal meetings, interactions with applicants and engagement with trade bodies how the changes are being implemented. HSE will also monitor the experiences of its regulatory scientists in undertaking biocidal active substance and product evaluations using data submitted under the new requirements. Feedback via these various channels will allow HSE to assess the impact of the changes against the original objectives and whether there are any changes required in future.

63. Because of the bespoke and specific nature of the proposed changes to the biocides regulatory regime, and because of the very low estimated costs to businesses of the changes, HSE considers that undertaking a separate evaluation is not cost effective and would be disproportionate to the nature of the changes. Therefore, HSE is recommending that no statutory requirement for a post-implementation review is included in the proposed legislation.

64. The changes will be closely monitored by HSE's biocides staff on an informal and ongoing basis. This approach will allow the maximum flexibility, with issues being captured as and when they arise. It also means that any changes and amendments which are needed would not have to wait until the five-year PIR deadline. The need to monitor for issues and concerns will be clearly communicated both to HSE's biocides staff as well as applicants dealing directly with the changes.

65. The proposed approach of informal monitoring by HSE's biocides staff will ensure maximum flexibility and extra data will not be collected unless specific issues are identified where this would add value. As explained above, HSE considers that this is the most proportionate and cost-effective approach given the nature of the changes.

66. GB BPR will also be reviewed as a whole as part of considering potential regulatory reforms under the powers set out in the Retained EU Law (Revocation and Reform) Act 2023 (REUL). Among other issues, the review will consider whether any amendments are appropriate to the overall approach to data requirements for biocidal product and active substance applications in Annexes II and III of GB BPR (for example, whether it is appropriate for these to be explicitly set out in legislation). This review will be undertaken in time for regulatory changes to be made by the final date on which REUL powers can be exercised of 23 June 2026, where this is decided to be appropriate..

Annex 1: Description of methods used to identify unique applicant/ authorisation holder businesses using GB and EU authorised biocidal product and active substance lists

1. HSE economic and social research analysts conducted a three-stage analysis to arrive at estimates of the proportions of unique applicant/ authorisation holder businesses which were:
    a. active in both GB and the EU, which has already implemented the new test requirements; or,
    b. active in GB only and therefore less likely to be meeting the new GB BPR test requirements

Qualitative analysis: Process and criteria

2. The EU and GB Article 95 lists, and the GB Authorised Biocidal Product list data required cleaning and de-duplicating due to data entry error and differences across lists. This was undertaken in stages:
    a. Initially by simple Excel de-duplication
    b. Comparisons of lists using Excel operations
    c. Manual comparison and de-duplication, mitigating for data entry errors which Excel was not able to identify
    d. Further manual cleaning and verification of unique business details where confidence was not high from the data. This was done through web searches using consistent criteria to make a judgement on whether a business was a unique entity, even if part of an umbrella company. For example, location might have been a defining factor if multiple business entities used very slightly different acronyms but common names. This approach provided a level of validation and increased (qualitative) confidence in the level of accuracy of resulting unique business proportions
    e. After cleaning, remaining companies were further double-checked against the EU and GB lists for entries of any kind so duplicates could be identified with only unique business entities which were active in the UK remaining
    f. Final counts reached using the second stage cleaned data/lists of unique business entities

Rationale for analytical decisions and cleaning criteria

Locations and subsidiaries

3. Decisions for leaving some similar business entries were based on the premise that different locations and subsidiaries may not have centralised processes and can operate in different markets/ product types. Web searches and website checks also confirmed separate entities in some cases. This was subsequently reviewed and rechecked as above after the consultation response was received. The basic premise remained but HSE determined that business registrations did make it difficult to achieve a greater degree of robustness in our original estimate.

List data quality and labelling

4. Based on expert opinion, the following were removed:
    a. Applications labelled 'EU representative to be appointed (representing x company)' and applications appearing to be ones in progress but not followed up, were removed.

Limitations

5. During the original pre-consultation analysis, ECHA's product list was not available due technical issues. As described above, the database was subsequently searched again but added a further layer of complexity and uncertainty surrounding business names and registrations.

6. Though manual cleaning and verification was used to good effect to further clean and improve our list data, human intervention does increase the chances of human error; furthermore, Excel limitations led to the need for additional manual checks.
7. Data quality was not excellent and entirely reliable but was of good enough quality to reach estimated proportions which appeared to align to recent market analysis commissioned by HSE. Therefore, the estimate is deemed to be suitable and proportionate to support analysis of potential impacts and costs of the proposed changes.

Annex 2: Updated evidence on biocidal active substance and product tests not analysed in the main body of this impact assessment

1. In the consultation stage IA, HSE discussed the costs of several tests of biocidal active substances and products. In completing the final stage IA, several of these tests have not proved relevant as additional costs brought about by the proposed changes to GB BPR (see paragraph 21 of the main body of this IA). However, HSE reports in this annex on the evidence on these test costs that we gathered during consultation for future reference.

2. During consultation, HSE asked respondents whether they believed the initial cost estimates (based on HSE toxicologist intelligence and OECD reference costs) were too high, too low or about right.

3. In the consultation stage IA, it was estimated that in vivo testing for **skin irritation** would cost around £2,000 per active/ product, based on an in vivo rabbit study. Three respondents believed this estimate was about right, but four believed it was too low and suggested alternative costs of around £4,000.

4. For in vitro testing for skin irritation, in the consultation stage IA HSE estimated costs of around £11,000 per active/ product. Four consultation respondents believed this estimate was about right, but a further two respondents disagreed, one thinking our cost was too low; and another thinking it was too high, suggesting an alternative cost of around £5,700.

5. In the consultation stage IA, HSE estimated that in vivo testing for **eye irritation** would cost around £2,000 per active/ product, based on an in vivo rabbit study. Three respondents believed this estimate was about right, but three disagreed, one thinking it was too high; and another two thinking it was too low, suggesting alternative costs of £3,500 and £4,000 respectively.

6. For in vitro testing for eye irritation, in the consultation stage IA HSE estimated costs of around £10,000 per active/ product. Five consultation respondents believed this estimate was about right, but one respondent thought it was too high, suggesting an alternative cost of around £5,300.

7. In the consultation stage IA, HSE estimated that in vivo testing for **skin sensitisation** would cost around £5,000 per active/ product, based on a local lymph node assay in a mouse. Three respondents believed this estimate was about right, but three believed it was too low, suggesting alternative costs of £6,000 and £9,000 respectively.

8. For in vitro testing for skin sensitisation, in the consultation stage IA HSE estimated costs of around £15,000 per active/ product based on two in vitro skin sensitisation (DASS) test. Four consultation respondents believed this estimate was about right, but two respondents thought it was too low, suggesting an alternative cost of £20,000.

9. In the consultation stage IA, HSE estimated that in vivo testing for **genotoxicity** would cost around £9,000 per active substance, based on a liver unscheduled DNA synthesis (UDS) assay. Two respondents believed this estimate was about right, but two respondents disagreed, one thinking it was too low and suggesting an alternative of £20,000; and another believing it was too high and suggesting an alternative of £6,800.

10. For in vitro testing for genotoxicity, in the consultation stage IA two possible test types were discussed. For a rodent comet assay (three tissues), HSE estimated a cost of £35,000 – of the three respondents who opined, all three thought this was about right. For a transgenic rodent mutation test, HSE estimated a cost of £211,000 – two respondents thought this figure was about right; although a further respondent thought it was too high, they did not suggest an alternative.

11. In the consultation stage IA, HSE discussed that applicants might choose either of these in vitro tests for genotoxicity and that HSE would try to refine our estimates of the proportion that would choose either test for the final stage IA. During discussion with HSE toxicologists, it was understood

that these tests are actually undertaken sequentially, with the rodent comet assay done first, which, if positive, might be followed by a transgenic rodent mutation test if the applicant chooses.

12. In the consultation stage IA, HSE estimated that in around 62% of cases, applicants for GB biocidal products authorisation would also seek authorisation in an EU Member State, and therefore not incur any additional costs for tests as the requirements are already in place in the EU. This was an initial figure based on an assessment of the published product lists of GB and the EU at the time and we committed to develop this assessment during consultation, including assessing further EU product data that was not initially available online. Following further analysis (see Annex 1) HSE has not been able to further refine this estimate due to data quality issues. However, as outlined in paragraph 21 of the IA, it is considered that there are no new costs due to testing for product submissions. Therefore, it is disproportionate to carry out further analysis on this issue. The proportion will be revisited where beneficial for future policy analysis.