Title: Revision of GB Biocidal Products Regulation Annexes II and III	Impact Assessment (IA)
IA No:	**Date:** 16th September 2022
RPC Reference No:	**Stage:** Consultation
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:

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**
-£2.7m	-£2.7m	£0.3m	Nil (de minimis)

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

Annexes II and III contain the 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 Some of the current data requirements are now out of date due to technical and scientific progress.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, 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 GB active substance approval and biocidal product authorisation applications are set out in the above-mentioned Annexes. They will be updated to make HSE's current published data requirement guidance a GB regulatory requirement. This is to enable the GB authority to:

- Keep up with technical and scientific progress, ensuring the GB regulatory 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 human, animal and environmental hazards 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 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 SI with tailored changes to GB Annexes II and III (preferred)

Option 1 is preferred because it delivers on government priorities to maintain standards in line with technical progress, 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 SI mirroring changes to Annexes in the EU; and leaving GB BPR as is but ask applicants for further information based on guidance only.

Will the policy be reviewed? It will/will not be reviewed. **If applicable, set review date:** Month/Year

Is this measure likely to impact on international trade and investment?		Yes / No		
Are any of these organisations in scope?	**Micro** Yes/No	**Small** Yes/No	**Medium** Yes/No	**Large**Yes/No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:**	**Non-traded:**	

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 SELECT SIGNATORY: ..... Date: .....

Summary: Analysis & Evidence

Policy Option 0

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2022	PV Base Year 2023	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**	1	**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 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 we fail to keep the data requirements in line with scientific and technical progress including the use of non-animal in vitro test methods, which would fail to align 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%

BUSINESS ASSESSMENT (Option 0)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: Nil (de minimis)
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 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£5.6m	**High:** -£0.9m	**Best Estimate:** -£3.2m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£0.1m	1	£0.1m	**£0.9m**
High	£0.4m		£0.6m	**£5.6m**
Best Estimate	£0.3m		£0.3m	**£3.2m**

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. We estimate the majority of businesses in scope will incur the costs anyway through compliance with similar requirements in the EU. Around 1,140 businesses will incur one-off familiarisation costs of between around £150,000 and £440,000. In addition, businesses undertaking additional required tests for biocidal active substance and product dossiers will incur ten-year present value costs of between around £770,000 and £5.1 million.

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

For the only entirely new test (Developmental Neurotoxicity Test) there may be some costs associated with translating the test result into a suitable format for the dossier and drawing appropriate conclusions in addition to the costs of undertaking the test. This has not been quantitatively estimated in this IA and we will gather evidence during consultation.

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%

We estimate that the majority of dossiers submitted to HSE will not be subject to additional costs due to baseline compliance with similar EU requirements. Specifically, we estimate that only 1-3% of active substance and 3.8% of product 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. We will explore methods to refine this estimate during consultation.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: Nil (de minimis)
Costs: £0.4m	**Benefits:** Nil	**Net:** £0.4m	

Evidence Base

Problem under consideration and rationale for intervention

1. Annexes II and III of the Biocidal Products Regulation (EU Regulation 528/12) (GB BPR) contain the information requirements for active substances (Annex II) and biocidal products (Annex III).

2. 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.

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

4. These amendments include adopting new testing methods and encouraging 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, but there is one new test (the Developmental Neurotoxicity Test) which was not previously required.

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

5. The evidence used in this consultation 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. Estimates of numbers of businesses 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 chemicals regulation experts; synthesised intelligence from published 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).

6. We have not sought to gather additional data during the development of this consultation stage Impact Assessment. This is mainly because in areas where there is less certainty (for example estimating the proportion of businesses which will apply to the EU as well as GB) it is unlikely we could improve on the accuracy of the estimates without incurring substantial costs which are disproportionate to the costs associated with the changes, which are anticipated to be relatively small.

7. The assumptions will be tested through consultation; and we are also commissioning market research on the biocides sector, though this latter research might not be complete in time to inform the development of the final Impact Assessment.

Description of options considered

Option 0 – business as usual

8. The default option in any comparison is 'business as usual'. EU Regulation 2021/525 would then only apply to Northern Ireland.

Option 1 – GB SI with tailored changes (where we agree) to GB Annexes II and III

9. Prepare a GB SI making most of the changes to Annexes II and III that the EU made but 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. They include:

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 SI mirroring EU changes:** Prepare a GB SI 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 was 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. The opportunity would be missed to adopt changes that fully meet the needs of GB. Full details are in Consultation Document CDXXX.

- **Leave GB BPR as is but ask applicants for further information based on guidance only (no statutory instrument):** Leave GB BPR unamended and HSE would instead simply rely on publicising any extra information requirements that it agrees with via guidance, probably in the form of content on HSE's website. Probably we could only encourage submission of the amended data rather than indicate it is strictly required, as it would not be a legal requirement. This has not been pursued as HSE could not legally require submission of data according to the updated requirements, which 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.

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 the above-mentioned Annexes. They will be updated to make HSE's current published data requirement guidance a GB regulatory requirement. This is to enable the GB authority to:

- Keep up with technical and scientific progress, ensuring the GB regulatory 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 human, animal and environmental hazards 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 above) is to prepare a GB SI 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 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 be required once the SI is completed. Once the SI enters force the guidance will be updated to make clear the changed requirements are legally required for future applications.

18. Some of the additional data (in particular relating to endocrine disrupting chemicals) is already being requested by HSE because it is required to evaluate active substance and biocidal product applications. Therefore, applicants are already effectively complying with the requirements, but the changes will include the data requirements in law. 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 we do not consider further action is required to implement the new requirements.

19. The details of when the amended data requirements will be applied are still under consideration, to ensure that appropriate data are available to the regulator while avoiding unnecessary costs to industry by requiring updated tests where existing data are adequate. In this cost analysis, we have assumed that test costs and familiarisation will begin to be incurred from 2023 (the time of the proposed legislative change) without allowing for a transition period until HSE would require submissions to include the new data. This is probably a reasonable model of actual costs as active substance and product tests will be booked and paid for well in advance of the submissions of a dossier to HSE.

Monetised and non-monetised costs and benefits of Option 1

Numbers of biocide active substance and product submissions

20. We have estimated future numbers of active substance and product submissions that could attract additional test costs. These estimates are based on recently observed data on actual submissions projected into the future. The figures are expected to be broadly stable over the ten years of the appraisal period, although the ranges reflect the scope for expected variation. Figures are summarised in Table 1.

Table 1: Estimated number of submissions under BPR per annum over the next ten years

	Low	Mid	High
Active substances			
New	Nil	0.5	1.0
Renewals	10.0	10.5	11.0
Total	**10**	**11**	**12**
Products			
New	10	55	100
Renewals	50	175	300
Total	**60**	**230**	**400**

21. Not all of these submissions will be in scope of additional testing costs under these proposals. For example, as the EU has already implemented these additional testing requirements (and more), any active or product 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.

22. In addition, products can be assessed through a process called 'CLP calculation', whereby the hazard of the product ingredients is assessed via their classification under the 'Classification, Labelling and Packaging Regulations' (CLP); and the proportion of product made of the hazardous ingredient assessed to consider and potentially rule out any adverse effects. For example, if a product contains a substance that is classified as an eye irritant under CLP, but the proportion of the product that this substance makes up is very low, then CLP calculation might lead HSE to conclude that further tests for the eye irritation of the whole product were disproportionate.

23. These two effects (baseline EU compliance and CLP calculation) will serve to reduce the number of BPR submissions to HSE for actives and products that will incur additional test costs.

24. 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 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 and products that are approved and authorised in GB and the EU. This allowed us to estimate the proportion of actives and products approved and authorised in GB 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.[1] This analysis has led us to conclude that:
    a. For active substances, between 1% and 3% might be expected to seek GB approval without also seeking EU approval
    b. For products, no more than 38% might be expected to seek GB authorisation without also seeking EU Member State authorisation

26. In addition, HSE toxicologists estimate based on their own experience assessing products that around 90% of products in GB are assessed using the CLP calculation method (and so, only 10% will incur additional test costs). Combining this with the estimate of 38% of products also seeking EU Member State authorisation, we therefore estimate that:

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

a. For active substances, between 1% and 3% will incur additional test costs, with a mid-estimate of 2%
b. For products, around 3.8% will incur additional test costs

27. Numbers of active substance and product submissions expected to incur additional test costs are summarised below in Table 2.

Table 2: Estimated numbers of BPR submissions incurring additional test costs per annum

	Low	Mid	High
Active substances			
New	Nil	0.01	0.03
Renewals	0.1	0.21	0.3
Total	**0.10**	**0.22**	**0.36**
Products			
New	0.4	2.1	3.8
Renewals	2.3	8.6	15.0
Total	**2.6**	**10.7**	**18.8**

Additional test costs

28. In some cases, active substance and products will already be undertaking tests that the new requirements will displace. For example, where tests are changing from being conducted on animals ('in vivo'[2]) to being conducted on cell samples ('in vitro'[3]), these tests can be more expensive. As such, the additional cost will be only the difference between the new test costs and the old.

29. Test costs have been estimated by HSE toxicologists with reference to OECD reference costs.

30. For **skin irritation**, the baseline cost is estimated at around £2,000 per active/ product, based on an in vivo rabbit study. The (two) in vitro tests cost around £11,000. This gives an additional cost per active/ product of around £9,000.

31. These costs would be incurred by new active substance submissions; and both new and renewal product submissions.

32. Across the new active substance numbers in Table 2, annual costs would be minimal - between nil and around £270, with a mid-estimate of around £90. For products (both new and renewal), annual costs would be between around £24,000 and £170,000, with a mid-estimate of around £96,000.

33. This gives an estimated present value cost of additional skin sensitivity irritation tests of between around £200,000 and £1.5 million, with a mid-estimate of around £830,000.

34. For **eye irritation**, the baseline cost is estimated at around £2,000 per active/ product, based on an in vivo rabbit study. The (two) in vitro tests cost around £10,000. This gives an additional cost per active substance of around £8,000.

35. These costs would be incurred by new active substance submissions; and both new and renewal product submissions.

[2] "In a living body".

[3] "In glass" (i.e., in a test tube or other vessel).

36. Across the new active substance numbers in Table 2, annual costs would be minimal - between nil and around £240, with a mid-estimate of around £80. For products (both new and renewal), annual costs would be between around £21,000 and £150,000, with a mid-estimate of around £86,000.

37. This gives an estimated present value cost of additional eye irritation tests of between around £180,000 and £1.3 million, with a mid-estimate of around £740,000.

38. For **skin sensitisation**, the baseline cost is estimated at around £5,000 per active/ product, based on a local lymph node assay in a mouse. The in vitro Defined Approaches for Skin Sensitisation (DASS) test costs around £15,000. This gives an additional cost per active/ product of around £10,000.

39. These costs would be incurred by new active substance submissions; and both new and renewal product submissions.

40. Across the new active substance numbers in Table 2, annual costs would be minimal - between nil and around £300, with a mid-estimate of around £100. For products (both new and renewal), annual costs would be between around £26,000 and £190,000, with a mid-estimate of around £110,000.

41. This gives an estimated present value cost of additional skin sensitisation tests of between around £230,000 and £1.6 million, with a mid-estimate of around £920,000.

42. For **genotoxicity**, the baseline cost is estimated at around £9,000 per active for a liver Unscheduled DNA Synthesis (UDS) assay. The in vitro test costs between around £35,000 for a rodent comet assay (three tissues) (to detect DNA damage); and around £211,000 for a transgenic rodent mutation (TGR) test involving two tissues and three dose levels (using rodents that are bred to include genes to help detect mutations).

43. During consultation, we will explore whether it is possible to estimate the proportions in which one or the other test could be required (or, indeed, if in some circumstances both tests could be required). However, for this consultation stage IA, we will simply assume these test costs give a high/ low range. This gives an additional cost per active of between around £26,000 and £202,000, with a mid-estimate of around £114,000.

44. These costs would be incurred by new and renewal active substance submissions. No costs will be incurred in respect of product submissions.

45. Across the active substance numbers in Table 2, HSE toxicologists estimate only around one-third will be liable for genotoxicity tests. This would give an estimated annual cost of between around £870 and £24,000, with a mid-estimate of around £8,400.

46. This gives an estimated present value cost of genotoxicity tests of between around £7,500 and £210,000, with a mid-estimate of around £72,000.

47. For **developmental neurotoxicity (DNT)**, no tests are required under the baseline. For actives, the DNT cost is estimated at around £533,000.

48. These costs would be incurred by new and renewal active substance submissions. No costs will be incurred in respect of product submissions.

49. Across the active substance numbers in Table 2, HSE toxicologists estimate only around one-third will we liable for DNT tests. This would give an estimated annual cost of between around £18,000 and £64,000, with a mid-estimate of around £39,000.

50. 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.

51. Across all additional tests, costs are summarised below in Table 3. **Total present value costs over ten years of additional tests** are estimated at between around £770,000 and £5.1 million, with a mid-estimate of around £2.9 million.

52. There may be some 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. This has not been quantitatively estimated in this IA and we will gather further evidence during consultation.

Table 3: Total additional present value test costs over ten years (£thousands)

	£thousands		
	Low	**Mid**	**High**
Skin sensitivity irritation	£200	£830	£1,500
Eye irritation	£180	£740	£1,300
Skin sensitisation	£230	£920	£1,600
Genotoxicity	£7.5	£72	£210
Developmental neurotoxicity (DNT)	£150	£340	£550
Translating DNT test result into dossier	NQ	NQ	NQ
Total	**£770**	**£2,900**	**£5,100**

Note: totals may appear not to sum due to rounding. NQ = not yet quantified

Familiarisation

53. We anticipate that dutyholders would have to take some time to familiarise with the changes proposed to BPR (although, as discussed in paragraphs 21 to 26, we anticipate that dutyholders will already be carrying out these tests for EU compliance in the majority of cases). HSE policy leads estimate 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 is based on expectations of the length of the guidance that would be issued by HSE.

54. Based on the data review discussed in paragraph 24, we estimate that there are around 1,140 manufacturers in GB that could need to familiarise. This gives a total of between around 3,400 and 10,300 hours spent familiarising, with a mid-estimate of around 6,800.

55. We estimate that this familiarisation would be undertaken by a science manager. To estimate the cost of their time, we 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.[4] 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. We estimate that these account for a further 20% on top of the wage. This gives a full economic cost of the manager's time of £43.02 per hour.

56. This gives a **total one-off cost of familiarisation** of between around £150,000 and £440,000, with a **mid-estimate of around £290,000**.

Benefits

57. These changes 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.

[4] 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)

58. 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.

59. Clarity about the requirements being present in the legislation should 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.

Summary of quantified costs and benefits

60. The quantified costs are summarised below in Table 4. They come to a present value cost over ten years of between around £920,000 and £5.5 million, with a mid-estimate of around £3.2 million. These costs all fall directly to businesses.

61. The equivalent annual net direct cost to business (estimated in 2019 prices and 2020 present value baseline) is £0.3 million, well below the £5.0 million de minimis for the Business Impact Target.

62. As discussed in paragraphs 57 to **Error! Reference source not found.**, there are accompanying benefits that it has not been possible to quantify.

Table 4: Summary of quantified costs (ten-year present values, £thousands)

	£thousands		
	Low	**Mid**	**High**
Additional test costs	£770	£2,900	£5,100
Familiarisation	£150	£290	£440
Total	**£920**	**£3,200**	**£5,600**

Note: totals may appear not to sum due to rounding

63. We will seek to develop these estimates during consultation, exploring the views of industry on the test costs we have estimated; and to explore methods to triangulate and refine the estimates of the proportion of HSE dossiers that should incur no additional test costs due to baseline EU compliance.

Risks and assumptions

64. In the analysis, we have 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.

65. Estimates of test costs (both for the baseline and for the proposed changes) are based on best available data. We will seek to refine these estimates during consultation.

66. 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

67. We do not propose to exempt small and micro businesses (i.e., those employing fewer than 50 employees) from these requirements. 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.

68. Data on the size distribution of biocidal active substance and product manufacturers is incomplete. HSE understands that for many such manufacturers, biocidal products could be only a small part of their production, making them hard to identify in the published data. We are currently commissioning market research into the biocides industry, which we hope improves the data – it is not currently clear whether this will be ready in time to refine these figures for the final stage impact assessment.

69. According to the Interdepartmental Business Register (IDBR)[5], there are 85 businesses in SOC code 2020 'Manufacture of pesticides and other agrochemical products'. This is well below the approximately 1,140 manufacturers HSE policy estimate are in scope of these regulations (see paragraph 54). 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.

70. 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. Further social research analysis is included in Annex 1.

71. While these two IDBR estimates are not a perfect read for the biocides industry, they do imply 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 so large a 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.

72. 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)

73. We do not assess that the proposed changes would have any wider effects:

- The changes should not affect equalities.
- 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

74. No impacts on trade are anticipated.

75. 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.

76. 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).

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

77. 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. 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

78. 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.

79. The bespoke and specific nature of the proposed changes to the biocides regulatory regime is likely to mean that undertaking a separate evaluation is disproportionate and not cost effective. HSE is therefore considering whether it is appropriate not to include a review clause in the final Statutory Instrument (SI) following the consultation. If no review clause is included this would remove the requirement for a post-implementation review (PIR) five years after the SI's implementation. This will be confirmed in the Final Stage Impact Assessment (IA).

80. Irrespective of whether a review clause is added, 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. If no review clause is added, then 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.

81. The currently 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.

Annex 1: Description of methods used to identify unique applicant/ authorisation holder businesses using GB and ECHA 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 may be less likely to be meeting the new GB-BPR test requirements.

Qualitative analysis: Process and criteria

2. The ECHA 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 done 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, 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 ECHA and GB lists (simple ctrl+F) 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 were 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.

List data quality and labelling

4. Based on expert opinion, the following were removed:
   g. 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. Currently, ECHA's product list is not available due technical issues so a comparison and de-duplication against the ECHA list is not currently possible. We will review if we can identify BP producers that are active in the GB only once/if this is available.

6. It may be possible that some older entries on the lists could have experienced a change in business status.

7. 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 further manual checks

8. Data quality was not excellent and entirely reliable but was of good enough quality to reach proportions which could be verified through consultation and research thus far; this is deemed proportionate to the potential impacts and costs of the proposed changes.