HSE Response to Consultation on Chemicals Legislative Reform Proposals

February 2026

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Introduction

1. The UK chemicals regulatory framework regulates the lifecycle of chemicals – manufacture, storage, supply, distribution, use and disposal of chemicals and the protection of people and places where they may be exposed to chemicals. Regulations also cover the export and import of chemicals and implement the UK's pre-existing commitments under international agreements.

2. This document provides a summary of responses to a HSE consultation on proposals to make legislative changes to the chemicals regulatory framework which ran from 23 June 2025 until 18 August 2025 on the HSE Consultation Hub. **This consultation response is designed to be read in conjunction with the consultation document**[1].

[1] HSE Chemicals Legislative Reform Proposals Consultation - https://consultations.hse.gov.uk/hse/chemicals-legislative-reform-proposals/

Legislative background

3. HSE has responsibility for three EU regulations assimilated into domestic law by the Retained EU Law (Revocation and Reform) Act 2023[2] ('the REUL Act')' following EU Exit:

    - 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[3] is commonly known as the **Great Britain Biocidal Products Regulation ('GB BPR')**. GB BPR provides a framework for the authorisation and approval of biocidal active substances and the products containing them.

    - Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[4] is commonly known as the **Great Britain Classification, Labelling and Packaging Regulation ('GB CLP')**. GB CLP requires suppliers of chemicals to classify and label their chemicals in accordance with an internationally agreed system, the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS)[5].

    - Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012[6] concerning the export and import of hazardous chemicals is commonly known as the **Export and Import of Hazardous Chemicals Regulation (GB PIC)**. GB PIC regulates the export and import of certain hazardous chemicals and is applicable to chemicals on a list (the GB PIC list[7]) that are exported from GB. The GB PIC list is maintained by HSE.

4. GB BPR, GB CLP and GB PIC (referred to in this document as "the chemicals regimes") apply in England, Scotland and Wales.

5. In order to facilitate dual access to both the UK Internal Market and EU Single Market, Northern Ireland continues to apply EU rules relating to chemicals under the terms of the Windsor Framework[8]. However, the Government intends to take the necessary steps to avoid any new regulatory barriers between Northern Ireland and the rest of the UK, in line with the manifesto commitment to protect the UK Internal Market while reducing barriers to trade between the UK and EU.

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[2] Retained EU Law (Revocation and Reform) Act 2023 - https://www.legislation.gov.uk/ukpga/2023/28/contents/enacted

[3] 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 - https://www.legislation.gov.uk/eur/2012/528/contents

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 - https://www.legislation.gov.uk/eur/2008/1272/contents

[5] About the GHS | UNECE - https://unece.org/about-ghs

[6] Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals - https://www.legislation.gov.uk/eur/2012/649/contents

[7] GB PIC list of chemicals - https://www.hse.gov.uk/pic/pic-list.htm

[8] The Windsor Framework – https://www.gov.uk/government/publications/the-windsor-framework

6. HSE is committed to maintaining the current standards of health and environmental protection. Currently the standards are aligned to those in the EU. Section 14 of the REUL Act states that "A relevant national authority may by regulations revoke any secondary retained EU law and replace it with such provision as the relevant national authority considers to be appropriate and **to achieve the same or similar objectives**"[9]. HSE interprets "similar objectives" as requiring the maintenance of a standard that is no lower than what is being replaced. To that end, and noting the responses to the consultation, HSE will only recognise the EU as a trusted jurisdiction.

7. Furthermore HSE must align with the non-regression commitments set out in the UK/EU and EAEC: Trade and Cooperation Agreement (TCA)[10]. Under Article 387[11], the UK is committed to maintain labour and social protections, while Article 391[12] commits the UK to ensure levels of environmental protection are not weakened or reduced. This includes a commitment to "not weaken or reduce, in a manner affecting trade or investment between the Parties, its environmental levels of protection or its climate level of protection below the levels that are in place at the end of the transition period".

[9] Section 14 of the Retained EU Law (Revocation and Reform) Act 2023 - https://www.legislation.gov.uk/ukpga/2023/28/section/14

[10] Trade and Cooperation Agreement between the United Kingdom of Great Britain and Northern Ireland, of the one part, and the European Union and the European Atomic Energy Community, of the other part - https://www.gov.uk/government/publications/ukeu-and-eaec-trade-and-cooperation-agreement-ts-no82021

[11] Article 387 of the Trade and Cooperation Agreement between the United Kingdom of Great Britain and Northern Ireland, of the one part, and the European Union and the European Atomic Energy Community, of the other part - https://assets.publishing.service.gov.uk/media/608ae0c0d3bf7f0136332887/TS_8.2021_UK_EU_EAEC_Trade_and_Cooperation_Agreement.pdf#page=487

[12] Article 391 of the Trade and Cooperation Agreement between the United Kingdom of Great Britain and Northern Ireland, of the one part, and the European Union and the European Atomic Energy Community, of the other part - https://assets.publishing.service.gov.uk/media/608ae0c0d3bf7f0136332887/TS_8.2021_UK_EU_EAEC_Trade_and_Cooperation_Agreement.pdf#page=491

Purpose of Consultation

8. In March 2025, the Government published the *'New approach to ensure regulators and regulation support growth'*[13] referred to as the Regulation Action Plan ('RAP'). This policy paper sets out the ambition for regulation to support growth, be targeted, proportionate, transparent, predictable and adaptive to keep pace with innovation.

9. HSE's proposals align with the three key principles in the RAP which are to:

    - Tackle complexity and the burden of regulation
    - Reduce uncertainty across our regulatory system
    - Challenge and shift excessive risk aversion in the system

10. The consultation sought stakeholder views on the proposals summarised below. The proposals were developed to assist HSE to become increasingly adaptive and ambitious in how it regulates chemicals by removing duplication, streamlining processes, taking a more risk-based approach to regulation and promoting growth and innovation.

11. The proposals are intended to enable HSE to remain an effective GB regulator, better situated to pass efficiencies on to business whilst still supporting HSE's strategic goal to increase and maintain trust to ensure people feel safe where they live, where they work, and in their environment. The overall aim is to reduce burdens whilst maintaining existing levels of health and environmental protection as per legal obligations set out in the legislative background section above.

12. HSE is also cognisant of the outcome of the UK-EU Summit 2025[14] setting out a new strategic partnership between the UK and EU which builds on the foundation of the Withdrawal Agreement[15], including the Windsor Framework[16], and UK/EU and EAEC: Trade and Cooperation Agreement[17]. Though the proposals for the chemicals regimes are not directly affected by the outcome of the UK-EU Summit 2025, HSE has taken the existence of that strategic partnership into consideration due to the similarity in particular between pesticides (which is in scope of the proposed

[13] Government Policy paper – 'New approach to ensure regulators and regulation support growth' - https://www.gov.uk/government/publications/a-new-approach-to-ensure-regulators-and-regulation-support-growth/new-approach-to-ensure-regulators-and-regulation-support-growth-html

[14] UK-EU Summit 2025 - Joint Statement - https://www.gov.uk/government/publications/ukeu-summit-key-documentation/uk-eu-summit-joint-statement-html

[15] Withdrawal Agreement - https://www.gov.uk/government/publications/withdrawal-agreement-and-political-declaration

[16] The Windsor Framework – https://www.gov.uk/government/publications/the-windsor-framework

[17] Trade and Cooperation Agreement between the United Kingdom of Great Britain and Northern Ireland, of the one part, and the European Union and the European Atomic Energy Community, of the other part - https://www.gov.uk/government/publications/ukeu-and-eaec-trade-and-cooperation-agreement-ts-no82021

European Union-United Kingdom Sanitary and Phytosanitary Agreement[18]) and biocides (it is unclear at this time if biocides is in scope of that agreement).

13. A summary of the proposals for each of the chemical regimes is outlined below.

Summary of GB BPR proposals

- **Proposal 1:** Introduce a system which allows the recognition of approvals and, where appropriate, authorisations given in foreign jurisdictions with similar standards. This proposal addresses the Government's commitment that HSE would consult on how international approvals can be recognised to reduce the time and cost to bring chemical products, including biocides, to the GB market, which was made as part of the RAP to ensure regulators and regulation support growth. This proposal is detailed in section 3.4 of the consultation document.

- **Proposal 2:** Replace the system of active substance renewals[19]. Approvals would no longer have fixed expiry dates. Instead, active substances would be "called in" for review by HSE using a risk-based approach and in a manner which facilitates the smooth flow of goods across the whole UK Internal Market. This proposal is detailed in section 3.5 of the consultation document.

- **Proposal 3:** Introduce powers to permit the Secretary of State to allow biocidal active substances and biocidal products which are essential to society to be made available on the GB market where needed, whilst safeguarding against possible abuse of the system by means of specific conditions. This proposal is detailed in section 3.6 of the consultation document.

- **Proposal 4:** Introduce powers to make further amendments in secondary legislation to the detailed procedures in GB BPR, making it possible to improve the efficiency and effectiveness of that particular regime in future in a more agile way. This proposal is detailed in section 3.7 of the consultation document.

Summary of GB CLP proposals

- **Proposal 1:** Consolidate Article 37 and Article 37A of GB CLP into a single procedure for GB mandatory classifications and break the automatic link requiring HSE to consider all Committee for Risk Assessment (RAC) opinions published by the European Chemicals Agency (ECHA). This proposal is detailed in section 4.3 of the consultation document.

[18] UK-EU Summit – Common understanding - https://www.gov.uk/government/publications/ukeu-summit-key-documentation/uk-eu-summit-common-understanding-html. The proposed Sanitary and Phytosanitary Agreement is set out at paragraphs 23 to 33.

[19] HSE guidance on active substance approvals - https://www.hse.gov.uk/biocides/active-substances/active-substance-approval.htm

- **Proposal 2:** Revoke the GB notification database and requirement for GB duty holders to submit notifications to HSE as the GB CLP Agency, thereby reducing burdens on duty holders[20] and the regulator. This proposal is detailed in section 4.4 of the consultation document.

- **Proposal 3:** Relocate explanatory notes relating to entries in the GB Mandatory Classification and Labelling (GB MCL) List from Part 1 of Annex VI to the Regulation to HSE's website. This proposal would enable the Agency to make future revisions to notes pertaining to GB MCL entries in an administrative capacity, rather than through a Statutory Instrument. This proposal is detailed in section 4.5 of the consultation document.

- **Proposal 4:** Introduce powers to make future amendments to GB CLP and its supporting regulations to implement general updates and international obligations. This would ensure the timely reflection of wider political, technological and scientific developments and establish continuous means by which the UK can meet new or revised international commitments. This proposal is detailed in section 4.6 of the consultation document.

Summary of GB PIC proposals

- **Proposal 1:** Remove redundant procedures such as the Special Reference Identification Number (Special RIN or SRIN) procedure for small quantities of chemicals being exported for research or analysis in quantities unlikely to affect human health or the environment. This proposal is detailed in section 5.2 of the consultation document.

- **Proposal 2:** Amend the "waiver" process whereby the Designated National Authority can waive for one year the requirement for the explicit consent of the importing country to be in place before export takes place, streamlining the waiver conditions so that the same conditions would apply to all qualifying chemicals. This proposal is detailed in section 5.3 of the consultation document.

- **Proposal 3:** Introduce powers to make future amendments and updates to GB PIC and its supporting regulations to implement general updates and international obligations. This would ensure that the UK can continue to implement its international obligations. This proposal is detailed in section 5.4 of the consultation document.

Protecting Northern Ireland's place in the UK Internal Market

14. The consultation sought views on the operation of two distinct CLP regimes in GB and NI following recent amendments to the requirements of EU CLP that are detailed

[20] Duties and responsibilities: Overview - https://www.hse.gov.uk/chemical-classification/what-to-do/overview.htm

in section 4.8 of the consultation document. In line with the Government's commitment to protect the UK Internal Market in all circumstances, it committed to explicitly consult on applying a consistent regime across the UK, should this be required to safeguard the UK Internal Market.

15. HSE will amend GB CLP to safeguard the UK Internal Market by applying a consistent regime across the United Kingdom to address the impact of associated changes in classification and labelling from recent revisions to EU CLP and the Action Plan on the chemicals sector (6th Simplification Omnibus[21]) as a result of the Windsor Framework. The legislation to implement these changes will be made with the intention to provide at least a minimum of six months prior to the labelling changes taking effect in Northern Ireland and the EU.

[21] Simplification of certain requirements and procedures for chemical products - https://single-market-economy.ec.europa.eu/publications/simplification-certain-requirements-and-procedures-chemical-products_en

Consultation methodology

16. The consultation ran online on the HSE Consultation Hub for eight weeks from 23 June 2025 until 18 August 2025. The consultation document made clear that the scope of certain proposals across the chemicals regimes included some that are considered ambitious, and if progressed, would require a future primary legislative vehicle (i.e. a Parliamentary Bill) for them to be implemented.

17. The consultation was promoted via HSE e-bulletins (with a total of 119,834 subscribers). Respondents were encouraged to respond to the online consultation to aid response analysis. A Word document version of the consultation was also made available for those who preferred to respond to a shared inbox or by post.

Informal stakeholder engagement prior to consultation

18. The online consultation followed a period of informal stakeholder engagement between March 2024 to June 2025. HSE officials met with representatives from industry, non-governmental organisations (NGOs) and trade unions, who were given the opportunity to provide early views on the proposed changes. This positioned HSE to receive valuable insight on the key issues and wider impacts of its proposals.

19. Ongoing stakeholder engagement has been an integral part of understanding the implications of the proposed amendments. It has provided HSE with valuable insight on primary issues, wider impacts, and potential implementation costs. HSE sought to explore similar issues further and gather evidence during its public consultation.

Respondent demographics

20. HSE received 237 complete and partial responses via the online consultation form and 45 complete responses via email. An additional 7 responses were received by email which were analysed qualitatively (as partial responses) as respondents did not follow the format of questions in the consultation. Not all respondents answered every question, and not all gave comments to support their response.

21. For those analysed quantitatively and qualitatively (complete responses), the response breakdown was as follows; 152 members of the public, 38 employees, 29 ‘other businesses’, 20 trade associations, 15 consultants, 11 ‘other’, 7 national NGOs, 6 contractors, 2 international NGOs and 1 Government member. 1 respondent provided an invalid response by selecting more than one answer.

22. Respondents who selected ‘other’ tended to be from political parties, general practitioners, or academics with ties to environmental research.

23. For the 7 respondents who could only be analysed qualitatively as they provided partial responses, the response breakdown was as follows: 2 business representative

bodies/trade associations, 1 international NGO, 1 trade union and 3 ‘others’ (a learned society/professional association; an independent think tank and charity; and a conservation charity).

24. The majority of the respondents were based in England (225) and a smaller portion were based in Scotland (21) and Wales (13). None reported that they were from Northern Ireland. Those who reported they were from ‘other’ places (19) included respondents based across the whole of the UK or from the rest of the world, including Australia, EU, Finland, France, Germany, the Netherlands, Spain, Switzerland and USA.

25. Respondents reported they operated in several markets, with many supplying goods in GB (123), NI (90), EU (102) and the rest of the world (83).

26. For GB BPR, businesses involved with the supply of biocidal active substances included responses from downstream users[22] (50), importers (39), manufacturers (32), research facilities (29), distributers (28) and exporters (27). Businesses involved with the supply of biocidal products included responses from downstream users (55), manufacturers (53), importers (44), distributors (42), exporters (37) and research facilities (23).

27. GB CLP was the regime which most respondents identified with, with manufacturers most commonly responding (67) followed by downstream users (65), importers (59), exporters (54), distributors (46) and research facilities (29).

28. For GB PIC, exporters responded most commonly (35) followed by importers (33), downstream users (32), distributors (30), manufacturers (28) and research facilities (2).

Consultation analysis methodology

29. The HSE Consultation Hub is based on a system which produces a raw data set and basic charted responses. HSE’s social researchers and economists collaborated with policy teams in its Engagement and Policy Division and subject matter experts from its Chemicals Regulations Division to systematically analyse this data and consider qualitative consultation responses. Qualitative responses were each considered in detail on their own and have been subsequently summarised thematically in this response.

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

[22] ‘Downstream user’ is defined in Article 2 of the assimilated GB CLP Regulation as “any natural or legal person established, […] other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.” - https://www.legislation.gov.uk/eur/2008/1272/article/2

and to assist policy decision-making in making a rounded assessment. HSE's social researchers apply principles and methods set out in central government guidance on evaluation, The Magenta Book[23], and Social Research Association Ethics Guidance[24].

31. This response includes a quantitative overview of responses to the multiple-choice questions in the consultation, as well as a thematic analysis of free text fields to identify key themes and sentiments.

32. This response categorises businesses by size. 'Micro business' describes a business with 0-9 employees other than the respondent, 'small business' describes a business with 10-49 employees other than the respondent, 'medium business' describes a business with 50-249 employees other than the respondent, and 'large business' describes a business with 250+ employees other than the respondent.

33. **Due to the differing nature of the three chemicals regimes under consideration, this response provides a summary of consultation responses for each regime followed by a policy response.**

[23] The Magenta Book - https://www.gov.uk/government/publications/the-magenta-book

[24] Social Research Association Research Ethics Guidance - https://the-sra.org.uk/SRA/SRA/Ethics/Research-Ethics-Guidance.aspx

Protecting Health and Environmental Standards in GB

34. Prevalent as an overall theme against all proposals – but especially the proposal on use of trusted jurisdictions (see GB BPR proposal 1) – were concerns that HSE would regress from current levels of health and environmental protection as part of its reforms.

35. The cornerstone of HSE's regulation is to provide a safe and effective route for the supply of and use of chemicals for the GB market. As set out in the legislative background of this response, the levels of protection are set both in the assimilated regulations which were adopted in GB following EU Exit and in existing domestic legislative provisions predating EU Exit. Similarly, the UK/EU and EAEC: Trade and Co-operation Agreement[25] requires non-regression on labour, social and environmental levels of protection. The Chemicals Annex of that Agreement commits (amongst other things) the UK and the EU to ensure high levels of protection for the environment, human health and animal health, and to co-operate to do so. The proposed next steps set out in HSE's policy responses below do not alter these requirements, meaning the current high levels of protection will remain extant. It is HSE's policy to maintain high levels of protection analogous to those in the EU and **HSE will continue to align with these standards, with divergence occurring only in exceptional circumstances.**

[25] UK/EU and EAEC: Trade and Co-operation Agreement - https://assets.publishing.service.gov.uk/media/608ae0c0d3bf7f0136332887/TS_8.2021_UK_EU_EAEC_Trade_and_Cooperation_Agreement.pdf

GB Biocidal Products Regulation (GB BPR)

36. **For detailed background on the GB BPR proposals and consultation questions please see pages 16 to 34 of the Chemicals Legislative Reform proposals document**[26]. The GB BPR proposals are primarily driven by the need to include greater flexibility into the regulatory system to manage the backlog of regulatory assessments inherited from the EU.

37. Biocides are products which are supplied with the intention of killing or controlling harmful organisms. They include a wide range of product types including insecticides, rodenticides, wood, fabric and construction material preservatives, disinfectants, water treatment chemicals and anti-fouling coatings on ships.

38. Biocides are essential to society to control pests and to protect public health and infrastructure. However, they can also pose risks to people, animals and the environment if they are improperly used. To mitigate these risks, GB BPR puts in place a two-step process to ensure that biocides may only be supplied and used when the risks are demonstrated to be at an acceptable level.

39. In GB, HSE must review approximately 330 active substance/product type combinations which were resubmitted after leaving the EU, alongside renewing an increasing number of approvals that are approaching their expiry date (88 for which renewal applications had been received as of November 2025). Based on current resourcing estimates it could take decades to complete the 330 new approvals, which is not a sustainable regulatory position, making it right to consider reforms to better manage the workload.

40. Proposals to address this issue included provisions to recognise foreign regulatory approvals to reduce the time and cost of bringing biocidal active substances and products to the GB market and replacing mandatory active substance renewals with a system based on calling in active substances for review on risk-based criteria. Other changes to enhance the flexibility and operability of the regime were also proposed.

41. For each GB BPR proposal below, HSE has aggregated consultation responses to provide summaries, which are followed by HSE's policy response.

[26] GB BPR proposals and consultation questions (pages 16-34) - https://consultations.hse.gov.uk/hse/chemicals-legislative-reform-proposals/user_uploads/hse-chemicals-legislative-re7 form-consultation--word-version.docx

Proposal 1 – Changes to GB BPR to support the recognition of international biocides approvals

Summary of consultation responses

42. Questions in this section (1-9a) concerned a proposal to introduce a system that would allow recognition of biocide approvals in foreign jurisdictions, where there is assurance that the foreign jurisdiction has similar standards for evaluation.

43. In terms of enabling approvals of active substances and biocidal products via recognition of foreign jurisdictions (questions 1 and 2), about two-thirds disagreed with this approach, with about a third agreeing with the proposal. Those identifying as NGOs or members of the public strongly disagreed, whereas employees and businesses were more supportive. However, micro businesses largely disagreed.

44. Respondents were also asked to provide reasons for their answers, what practical difficulties and unintended consequences, if any, could result from the changes, and if they had any additional information to provide. The responses contained similar themes, with potential benefits of the proposal including:

    a. A reduction in workload as a result of streamlined processes which cut down on complexity, time costs and financial costs. Respondents reported that this proposal could reduce administrative, economic and technical burdens for applicants.

    b. A potential increase in UK trade and the promotion of scientific development.

    c. Particularly concerning biocidal products, feedback in certain areas suggested some regulatory burdens currently exist which do not ultimately benefit health or the environment and could be reduced.

45. Those who disagreed highlighted similar concerns, including:

    a. Apprehension around the jurisdictions that could be in scope, in large part due to concerns about their health, safety and environmental standards being considered lower than the UK, as well as local deviations in foreign jurisdictions which would make those standards differ. There were concerns that recognition of approvals and authorisations would result in a lack of autonomy and governance in GB decision-making and that there may be insufficient transparency in non-GB processes. This included concerns with the robustness of testing standards and issues of data accessibility.

    b. Concerns that recognition of international decisions would lead to an overall reduction in standards.

c. Some respondents were concerned that this process could introduce additional time, effort and cost into the regulatory process. There were questions about the timelines surrounding regulatory decisions.

d. Concerns that the recognition of non-EU decisions would ultimately result in a deviation from high standards seen in the EU. This concern was often underpinned by a strong drive for regulatory alignment with the EU. The impact of regulatory divergence on NI was noted as a key concern.

e. There was a notable difference between concerns expressed by businesses and members of the public: businesses expressed practical concerns centred around delays, such as on processes and the potential impact on trade, while members of the public expressed ethical concerns centred around trust, such as the risk of exploitation, weakened governance, and adverse impacts on health and the environment.

f. Notably, large businesses expressed fewer concerns than their medium, small and micro counterparts in certain areas.

46. Those who neither agreed nor disagreed provided the following feedback:

a. In principle, the proposal could be supported as long as GB maintains strong regulatory standards and the process supporting the recognition of international approvals and authorisations was clear and transparent.

b. The criteria a jurisdiction would need to meet to become a recognised jurisdiction would need to be clear, with reassurance of their standards provided through appropriate testing, before recognition of their approvals would be acceptable.

47. On how subsequent decisions in recognised foreign jurisdictions should be handled in GB, including renewal, restriction or non-renewal of an active substance, three different approaches were proposed (Question 9).

48. The two preferred options were:

a. ‘Renewals are recognised in GB but restrictions or bans in recognised foreign jurisdictions trigger a separate review in GB’. Feedback from respondents who preferred this option suggested it demonstrated flexibility and due diligence, promoting autonomous decision-making and a more precautionary approach. This was the preferred option for micro businesses.

b. ‘Subsequent decisions in recognised foreign jurisdictions (renewals, non-renewals and restrictions) are normally recognised in GB, but where there has been a ban or restriction in a recognised foreign jurisdiction, applicants who disagree with that decision are allowed to submit a data package and pay for

re-evaluation in GB and an independent GB decision is taken'. Feedback from respondents who preferred this option also suggested this approach demonstrated flexibility and due diligence, promoting autonomous decision-making and a more precautionary approach. Notably, this tended to be the preferred option of businesses, employees and those who identified as 'other', and was the preferred option across most sectors.

49. The least preferred option was:

    a. 'Subsequent decisions in recognised foreign jurisdictions (renewals, non-renewals and restrictions) are recognised in GB (similar to initial approvals)'. Feedback from respondents who preferred this option suggested it demonstrated flexibility and due diligence, would promote time, effort and cost savings, and supported a more cautious and autonomous approach which may promote alignment with the EU.

HSE policy response

50. Consultation on this proposal supported a commitment in the RAP which set out that '*HSE and Defra will consult on how international approvals can be recognised to reduce the time and cost to bring chemical products including biocides, to the GB market'.*

51. There are benefits to business that could be brought about by this proposal, in terms of reducing workloads and increasing trade. The strong views expressed by respondents regarding the lack of clarity on which foreign jurisdictions would be applicable are also noted. This is particularly in relation to how the standards of any given foreign jurisdiction would be appropriately tested or measured to engender trust that these jurisdictions can be recognised in GB. Business would also wish to recognise jurisdictions in a way that would streamline the regulatory burden and not add to it. Alongside these views, HSE recognises that divergence from the EU, with a potential for increasing divergence with NI, is unfavourable.

52. Following the 19 May 2025 UK-EU Summit-Common understanding[27], HSE is mindful that changes made in this policy area should be, where possible, harmonious with the ongoing work to establish a Common Sanitary and Phytosanitary Area ('SPS Agreement'). It is unclear at this time if biocides will be in scope of the SPS Agreement, however there are links to agriculture and food (for example, use of biocides in food contact materials or to disinfect food preparation areas).

53. It is important to recognise that the recognition proposals have several important objectives. First, they would help address the backlog of 330 active substance/product type evaluations which GB inherited from the EU, which HSE will find immensely challenging to tackle unilaterally. Second, they would significantly

[27] UK-EU Summit - Common Understanding - https://www.gov.uk/government/publications/ukeu-summit-key-documentation/uk-eu-summit-common-understanding-html

enhance the efficiency of the regulatory system by reducing by an estimated 97% the substantial costs to businesses of evaluation fees for active substance approvals (currently estimated at £160,000 per evaluation) and (if applied to biocidal products) between 96% and 99% of the cost of biocidal product authorisations (currently estimated at £25,000 per evaluation).

54. It is proposed that GB BPR should adopt decisions from foreign jurisdictions that can be assessed as being at least as high as GB standards and follows from HSE's commitment set out in paragraph 35. In other words, where it can be demonstrated that adopting approvals from that jurisdiction does not lower standards compared to those already in place in GB. This means that the benefits of the recognition proposals would be achieved without the lowering of standards of protection to people and the environment.

55. Concerns were raised that the recognition proposals would mean that GB could diverge from the high standards set in the EU. These were often allied with a strong desire to align with the EU's decisions. Therefore, it is important to note the EU will be the only jurisdiction from which GB would recognise approvals. It is helpful to promote alignment with the EU where it is deemed appropriate for GB because the proposals mean that EU approvals could be adopted without a time-consuming separate GB evaluation.

56. This would help to mitigate concerns on deviation from the GB system from requirements in Northern Ireland. However, inclusion of exceptional rejection criteria, which set out when the Secretary of State may decide not to adopt a foreign approval, will maintain GB autonomy and the current system of governance in place and will allow freedom to deviate from EU decisions in exceptional circumstances.

57. The decision to recognise approvals in the EU would not be at odds with the SPS Agreement negotiations or the RAP commitment. On the latter, HSE is committed to working with Defra to ensure a coherent approach particularly across the pesticides and biocides regulations. This work is ongoing via a separate workstream.

58. **Next steps:** HSE's preferred approach is to introduce legislative changes allowing for the recognition of EU approvals. The EU will be the only jurisdiction included on the list of recognised jurisdictions. HSE will explore opportunities to introduce this proposal via primary legislation.

Proposal 2 – Removal of active substance and biocidal products expiry dates and calling in active substances and biocidal products for review

Summary of consultation responses

59. Questions in this section (10-13a) concerned a proposal to replace the current system of active substance renewals. Approvals would no longer have fixed expiry dates.

Instead, active substances would be “called in” for review by HSE using a risk-based approach and in a manner which facilitates the smooth flow of goods across the whole UK Internal Market**.**

60. Approximately six in ten respondents (question 10 and question 13) disagreed with this approach, with about a third agreeing with the proposal. Overall, those who disagreed identified as members of the public and NGOs. Business representative bodies/trade associations, other businesses, business paid advisory services and employees tended to agree. Most businesses sizes also agreed, with the exception of micro businesses who disagreed.

61. Those who agreed with the proposal highlighted potential benefits, including:

    a. More flexibility in the system which could result on savings in time, cost and effort for duty holders.

    b. A more risk-proportionate approach to regulation, removing unnecessary compliance burdens without compromising human or environmental health.

62. Those who disagreed provided the following feedback:

    a. There were concerns that the proposed approach could present practical issues, such as increased time, effort and cost demands. Concerns around the notice periods that would be provided if a substance or product was called in for review were also prevalent. There was an overall concern with the lack of clarity on the process and timelines, with transparency in these areas being highlighted as necessary to support innovation.

    b. There were also concerns that insufficient assessment and safeguarding could result in decreased quality of substances and products on the market, which could raise ethical issues related to public safety. Some respondents believed this presented a risk of exploitation, and others suggested that regular reviews provide an incentive to maintain quality.

63. Respondents were asked to what extent they agreed or disagreed that industry should be required to provide information so that evidence-based decisions could be made to call-in active substances for review (Question 11-11a). Nearly three-quarters of those responding agreed with this proposal and just over one in ten disagreed.

64. The majority of respondents across all roles, business sizes and sectors strongly agreed or agreed that industry should be required to provide information. Responses were typically of the views that it is good practice to ensure that regulatory decision-making is informed by scientific evidence. Other responses noted that this approach could be better but only if call-ins remain proportionate to risk.

65. Respondents also noted the importance of a legal requirement to enforce this measure, including setting penalties for non-compliance. Views suggested that the

approach would need to be independently reviewed to ensure the process remains transparent and ultimately promotes safety. There were also concerns that a duty to provide information could increase time, effort and cost burdens and respondents noted there would need to more clarity on how this process would work in practice.

66. HSE also asked for suggestions on how the system could operate (Question 12-12a). Respondents suggested that:

    a. This approach would need to be underpinned by clear expectations, timelines and notice periods to ensure that businesses could provide the correct information in a timely manner.

    b. Information provided must be science-based and quality-assured, providing a clear foundation for a risk-proportionate regulatory approach.

    c. Some respondents felt that adopting standards similar to the EU would be the safest approach.

    d. Others, primarily trade associations, 'other' businesses, contractors and employees, suggested that engaging stakeholders in the process, particularly around timelines and processes, would support compliance.

HSE policy response

67. HSE is aware that recognition of EU approvals alone will not resolve the issue of the backlog of new and existing approvals approaching their renewal dates. In line with the RAP, it is important that the fixed approach to renewals is challenged, and more flexibility introduced to the system.

68. There is a strong case that the focus of effort should be on those active substances that have not yet been evaluated and therefore may present the greatest risk rather than substances that have already been thoroughly evaluated and deemed acceptable. For the approvals of very hazardous substances there is already provision by which the approval period is curtailed, meaning these substances would more regularly be subject to review and activity is arguably already proportionate to risk. This proposal would embody this approach more broadly across the portfolio of renewals.

69. The combination of this proposal with the first, under which GB will recognise approvals in recognised jurisdictions, provides safeguards against standards being lowered. The details are still being considered, but if a recognised jurisdiction identifies new risks and introduces restrictions to an approved active substance, this may either be directly recognised in GB or would trigger a review through call-in arrangements.

70. It is planned that the EU will be a recognised jurisdiction this could provide a means for GB to respond appropriately to new restrictions placed on active substances in the EU following a renewal evaluation. Therefore, it is disagreed that this proposal

will reduce standards. Instead, it gives HSE the flexibility to focus on active substances with a higher risk profile, ensuring that reviews are driven by a change in the evidence base rather than an arbitrary expiry date.

71. In relation to concerns over potential practical issues and costs associated with a call-in approach, HSE agrees that more clarity on this proposal setting out how the call-in system will work is necessary to address these points. This will need to include practical matters such as the criteria for call-in, information requirements from businesses, both when an active substance or biocidal product is called in and any requirements during interim periods, and the process and timeline for call-ins. Potential costs to business are likely to depend on how the details are implemented, but a key objective for HSE will be to design a system that is consistent with the objectives of the RAP, namely to reduce burdens and complexity for businesses, to make requirements predictable and to reduce excessive risk-aversion.

72. **Next steps:** HSE will not seek to make this change under REUL Act powers. Instead, the preferred approach is that a change to replace expiry dates with a call-in system could be made via primary legislation. Only if considered necessary or desirable, details of the call-in system could be subject to further consultation. Further consideration will be given to whether this system should be extended to biocidal products.

73. In the interim, HSE will seek to postpone the expiry dates of up to 173 active substances from January 2027 for a period of five years using REUL Act powers. This will provide time for the completion of the call-in system, including, if necessary or desirable, for the criteria for the call-in system to be consulted on.

Proposal 3 – Expanded essential use provisions

Summary of consultation responses

74. Questions in this section (14-15a) concerned a proposal to introduce powers to permit the Secretary of State to allow biocidal active substances and biocidal products which are essential to society to be made available on the GB market where needed, whilst safeguarding against possible abuse of the system by means of specific conditions.

75. Just under four in ten responses agreed with the proposal that the Secretary of State should have the power to issue a ‘societally’ essential use derogation for any active substance which meets the criteria, with a similar number of responses disagreeing (just above four in ten). Those identifying as NGOs and members of the public strongly disagreed. Business representative bodies/trade associations, business paid advisory services and employees tended to agree, although agreement rates were smaller for small and micro businesses.

76. Those who agreed suggested that the proposal could:

a. Provide more flexibility to make decisions which prioritise the protection of human health.

b. Increase market resilience in an uncertain risk landscape, allowing the Secretary of State to make quick decisions in response to emerging risks.

77. Those who disagreed, and those who highlighted potential unintended consequences, provided the following feedback:

a. Critical regulatory decisions should be grounded in scientific evidence or made by an independent body or group of experts.

b. There were concerns that expanded delegated powers could be exploited and subject to lobbying, presenting a risk of lowering standards and compromising safety.

c. There were also concerns that suppliers could intentionally exploit this mechanism to avoid the standard approval process. The lack of appropriate scrutiny was also highlighted as a potential risk to environmental protections.

d. Some were concerned that this proposal would have implications for trade, with some companies being unintentionally favoured.

e. Further information would be required to determine whether this was an effective solution to the problem presented.

78. Those who neither agreed nor disagreed suggested that there was a need to balance health outcomes with potential costs (e.g. business costs).

HSE policy response

79. The concerns on the potential to exploit this power are noted. The stringent conditions in Article 5(2) of GB BPR set out what counts as essential:

a. it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment;

or

b. not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

80. It is imperative that HSE as the independent GB regulator can act under certain circumstances to approve an essential active substance or product that may not currently be authorised or otherwise permitted under transitional arrangements, but

has a critical societal use. There are good reasons why this may be the case, for example if a supplier no longer acts as a supporter for an active substance. It is right that HSE has a mechanism by which it can intervene preventing supply failure on essential substances/products whose unavailability could cause significant disruption to everyday life.

81. Regarding concerns raised over potential implications for trade and the potential for derogations to favour some companies over others, it is acknowledged that this is a risk. To mitigate this, HSE intends to retain the current requirement (from the similar, but more restricted essential use derogation in Article 22 of the GB BPR Review Regulation[28]) that there must be a consultation on any proposed essential use derogations, which would allow any potential concerns over fairness to be identified and mitigated before a decision is taken. HSE also intends to make any derogations subject to requirements that alternatives are sought, or an application is prepared to approve the active substance, to ensure that they are issued for the minimum necessary time. In practice derogations would be subject to specific time-bound conditions and would expire if relevant actions were not taken by the suppliers, reducing the potential for exploitation or abuse.

82. HSE is currently managing the situation by issuing 'critical situation permits' under derogation powers in Article 55(1) of GB BPR. Under these powers, the competent authority is able to permit an unauthorised biocidal product for up to 180 days where there is a danger to public health, animal health or the environment which cannot be contained by other means. These derogations can then be extended for up to 550 days by the Secretary of State or ministers in Scotland and Wales as relevant. However, in practice these have in some cases required repeated re-issue to maintain critical products in legal use, which was not the intended purpose of the derogation powers.

83. **Next steps:** HSE's preference is to seek to introduce powers to permit the Secretary of State to make the necessary derogations for essential use biocides via primary legislation.

84. In the interim, using REUL Act powers, HSE proposes to amend the power in Article 55(1). Doing so would allow that if there is likely to be an ongoing need to use a critical but unauthorised product, derogations can run until the product is authorised. It would also allow the Secretary of State or devolved ministers to set deadlines for applications to be received and for derogations to be withdrawn if the deadlines are not met. This would be intended to allow proportionate action to be taken to keep essential products legally in use without repeated extensions while applications are prepared and evaluated for the products in question to be fully authorised under the Regulation.

[28] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products - https://www.legislation.gov.uk/eur/2014/1062/contents

Proposal 4 – Powers to amend GB BPR and its supporting regulations

Summary of consultation responses

85. Questions in this section (16-16a) concerned a proposal to introduce powers to amend GB BPR through secondary legislation.

86. Of those responding, just under a third agreed (either 'agreed' or 'strongly agreed') with this proposal to introduce powers to amend GB BPR using secondary legislation, whilst over four in ten disagreed (with the vast majority responding 'strongly disagree'). Those identifying as NGOs and members of the public strongly disagreed. Business representative bodies/trade associations, business paid advisory services and employees tended to agree, although micro businesses disagreed.

87. Agreement centred around time, effort and cost savings associated with this approach without compromising safety and oversight, as well as increased flexibility.

88. Key areas of disagreement centred around a lack of oversight, control and clarity, as well as concerns around deviation from EU standards. Some were concerned that this approach could lower standards and be open to exploitation, which led to safety concerns. Others felt that this should be contained in primary, rather than secondary, legislation.

89. Members of the public had many concerns over this proposal but were mainly concerned about the lack of clarity and oversight associated with this approach, which was echoed by national NGOs. Business felt that it increased flexibility, resilience, the opportunity for innovation and saved time effort and costs, but could lead to lack of oversight and clarity and should be primary legislation.

HSE policy response

90. HSE's preference is to seek to introduce a general power to update GB BPR and its supporting regulations via primary legislation. This is a necessary measure which will permit GB BPR to be more flexible and responsive for example to changes in the EU.

91. HSE disagrees that allowing changes to GB BPR through secondary legislation would lead to a lower level of oversight than is appropriate or could lead to reductions in levels of protection. As set out in paragraph 35, HSE will continue to maintain current standards of protection. This measure is necessary to make sure the regulatory framework can continue to function effectively without compromising HSE's overarching commitment to maintain high levels of protection for the environment, and human and animal health. Using primary legislation to make even minor updates to GB BPR would make it unwieldy and very difficult to achieve.

92. However, it is right that fundamental changes to the objectives and principles of GB BPR should require primary legislation. Therefore, any powers to amend the Regulation through secondary legislation must be suitably defined and circumscribed so they cannot be used to alter these objectives and principles.

93. **Next steps:** HSE's preference is to seek to introduce appropriate amendment powers via primary legislation.

GB Classification, Labelling and Packaging (GB CLP)

94. **For detailed background on the GB CLP proposals and consultation questions please see pages 35 to 50 of the Chemicals Legislative Reform proposals document[29].** The GB CLP proposals seek to improve operability of the Regulation for duty holders and HSE as the GB CLP Agency. Proposals included practical amendments to enhance the efficiency with which future changes to the regime are delivered and to remove burdensome requirements for duty holders and HSE.

95. HSE also consulted on the effectiveness of the current regulatory approach across GB and NI, where EU CLP applies under Annex 2 of the Windsor Framework.

96. For each GB CLP proposal below, HSE has aggregated consultation responses to provide summaries, which are followed by HSE's policy response.

Proposal 1 – Consolidate Article 37 and Article 37A into a single procedure and remove the statutory link requiring HSE to consider all Committee for Risk Assessment (RAC) opinions published by the European Chemicals Agency (ECHA), thereby making GB CLP evaluation more agile and predictable

Summary of consultation responses

97. Questions in this section (1-3a) concerned a proposal to consolidate the Article 37 and Article 37A procedures into a single procedure, removing the statutory link between the publication of a RAC opinion by ECHA and GB Mandatory Classification and Labelling (MCL) activity.

98. There were mixed responses to this proposal (GB MCL evaluation fast-track) with about a quarter of respondents agreeing, four in ten respondents disagreeing and a final third of respondents either answering 'don't know' or 'do not agree nor disagree'. Those identifying as NGOs and members of the public strongly disagreed. Agreement was marginal for micro, small and large businesses, but more substantial for medium-sized businesses. Business representative bodies, paid advisory services and employees agreed.

99. Those who agreed with this proposal suggested:

[29] GB CLP proposals and consultation questions (pages 35-50) - https://consultations.hse.gov.uk/hse/chemicals-legislative-reform-proposals/user_uploads/hse-chemicals-legislative-reform-consultation--word-version.docx

a. This approach could streamline processes and make them less burdensome. Many respondents were supportive of making the process more efficient for HSE.

b. Some highlighted the importance of stakeholder consultation to inform decision-making.

100. Those who disagreed, and those who highlighted potential unintended consequences, provided the following feedback:

a. While the proposal could make the process more efficient, there were concerns that the approach could compromise quality and potentially introduce safeguarding of existing standards issues.

b. Some felt there needed to be reviews to ensure decisions were robust, scientifically sound and transparent.

c. Alignment with EU decisions was also noted as a key priority for some respondents, who had concerns that this proposal could further increase regulatory divergence and cause unnecessary delays.

d. Respondents noted the importance of public consultation. There were also concerns with clarity, potential classification issues and issues with transparency and language barriers.

e. Others reported that further information was required to make an informed decision on this proposal.

101. HSE asked to what extent respondents agreed or disagreed with HSE's proposal that the criteria for fast-track evaluation should be based on a jurisdiction's adoption of the United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS), rather than publication of an ECHA RAC opinion (Question 2).

102. Nearly half of those responding disagreed (with the majority responding 'strongly disagree'). In terms of the remaining responses, approximately one in five either 'agreed', answered 'don't know' or 'neither agree nor disagree', respectively. Alongside members of the public disagreeing, other businesses and trade associations also disagreed. As for business size, only medium businesses agreed with the proposal, with micro, small and large businesses disagreeing.

103. Reasons for disagreement focused around issues such as a drive to align with EU regulations, concerns around driving efficiency at the expense of quality, having a robust decision review, not having a public consultation and concerns around not trusting other jurisdictions. Some were concerned about classification issues, and others felt that divergence from the EU would cause further delays. Some felt that GB should align with UN GHS, and respondents noted safeguarding of existing standards and transparency as essential to ensure sufficient protections.

104. Members of the public were more concerned about safeguarding existing standards and EU alignment, whereas trade associations and other businesses shared concerns around issues like classification, UN GHS adoption, divergence causing delays and confidence in decisions made by non-EU jurisdictions. Manufacturers were more likely to agree but had concerns around EU alignment, which jurisdictions would be used, and the robustness of the review.

HSE Policy Response

105. It is considered that this change is a necessary structural amendment to the framework that will streamline processes and permit focus on substances that are of relevance to the GB market. The requirement to consider RAC opinions that are not relevant to GB inhibits HSE being an effective GB regulator and prevents the timely delivery of mandatory classifications in a way that takes account of EU CLP. In line with the RAP, it is right that HSE addresses this source of burden and complexity.

106. The new fast-track evaluation pathway will provide a more efficient route in providing mandatory classifications reducing the overall time taken to complete the process. It is targeted at assessing classification proposals from territories that have adopted the UN GHS and have a transparent classification process. This will be restricted to the EU. This means HSE will not have to repeat the evaluation of EU classifications proposals except under exceptional circumstances (see paragraphs 112 to 115) where HSE may wish to conduct further evaluation.

107. HSE expects fast-track evaluation to be the primary mechanism through which it continues to consider relevant RAC opinions, enabling faster alignment with the corresponding EU system. The transparency criterion governing the classification proposals considered under fast-track evaluation will require the outputs of evaluation and consultation conducted by other countries to be available in English or Welsh to avoid language barriers.

108. The transparency with which GB MCL changes are made at present will be maintained through provision of a publicly available technical assessment which evidences the scientifically robust foundation upon which decisions will be made. Moreover, stakeholders will be able to challenge classification proposals through presentation of new information to HSE. The introduction of a GB MCL workplan will facilitate greater transparency as to HSE's evaluation activity and promote informal public consultation as stakeholders will have increased awareness of the classification proposals HSE intends to consider and the timing of this activity. This will enable stakeholders to make timely contributions to the evaluation process.

109. This change does not obviate HSE's obligation under Article 36(1) of GB CLP to evaluate substances with carcinogenic, mutagenic, reproductive toxic and respiratory sensitisation hazards. This legal requirement ensures that HSE will continue to consider and prioritise RAC opinions featuring hazards that are recognised by the UK and the EU as being the most severe.

110. Removal of the obligation to consider RAC opinions will not hinder HSE's ability to produce GB MCLs featuring the following hazard classes that are exclusive to EU CLP: endocrine disruption for human health and the environment; persistent, bioaccumulative, toxic; very persistent, very bioaccumulative; persistent, mobile, toxic; and very persistent, very mobile. Article 36(3) of GB CLP[30] provides a sufficient basis for the evaluation of RAC opinions featuring these six EU CLP hazard classes on a case-by-case basis. Nevertheless, HSE is cognisant of the divergence caused by differences in the hazard classes of EU CLP and GB CLP and is working to establish how best to address this divergence and minimise (where possible) additional burdens to duty holders. This work is ongoing and would not be affected by the implementation of GB CLP reforms proposed in the consultation.

111. HSE will consider how to incorporate the six EU CLP hazard classes into GB CLP. However, HSE notes the addition of new hazard classes in GB CLP could generate burdens for duty holders. An additional consideration is that the hazard classes may be subject to change given the recent action by the EU to simplify EU CLP through the removal of burdensome requirements. Furthermore, the EU has committed to following the outcome of UN GHS consideration on the six hazard classes which could involve the removal or significant amendment of the six hazard classes and their criteria in EU CLP.

112. Minimising the potential for divergence, especially across the UK Internal Market, is of importance to HSE, however as a general principle there must be scope, in exceptional circumstances, to allow for outcomes that are in the interests of GB. Divergence between the GB and EU remains minimal. Divergence between the 206 chemical substances that have received GB MCLs since the UK's EU Exit and the corresponding entries on the EU Harmonised Classification and Labelling List is around 11%.

113. For the great majority of GB MCLs (89%), HSE has agreed with and recommended all of the proposed hazard classifications in the published RAC opinions on scientific and technical grounds in the proposed GB MCLs for Ministerial Decision. Where HSE has disagreed with the published RAC opinion, this is often for only one or two hazard classes, noting that a RAC opinion can sometimes cover up to twenty hazard classes for active substances. This does not necessarily mean that the overall classification proposed in the GB MCL is less protective for human health and the environment than that proposed in the RAC opinion, and, on occasion, the GB MCLs have proposed more severe hazard classifications.

114. However, there may also be circumstances where divergence is necessary. As set out in the rest of the consultation document, divergence should be limited to clearly defined, exceptional circumstances. By providing a mechanism to be used in

[30] **Article 36(3) of the GB CLP Regulation:** Where a substance fulfils the criteria for other hazard classes or differentiations than category 1 respiratory sensitisation; and category 1A, 1B and 2 carcinogenicity, germ cell mutagenicity and reproductive toxicity or is not an active substance, a mandatory classification and labelling in accordance with Article 37 or Article 37A may also be added to the GB mandatory classification and labelling list on a case-by-case basis, if justification is provided demonstrating the need for such action.

exceptional circumstances, it will allow suitable mitigation measures to be considered in relevant downstream legislation dependent on the requirements of GB CLP. Nevertheless, HSE understands that regulatory certainty is important for duty holders and that any divergence should only be permitted in exceptional circumstances.

115. The preferred way forward is to use REUL powers to break the link with RAC opinions, introducing more flexibility into GB CLP. HSE will recognise classifications from the EU, however under exceptional circumstances HSE may conduct further evaluation. As an additional amendment at the request of Devolved Governments (DGs) it is proposed that duplicative procedures for seeking DG consent to GB MCL proposals be removed.

116. **Next steps:** HSE will aim to progress this proposal and make legislative changes to consolidate Article 37 and Article 37A using the REUL Act. The law will also be amended to remove the duplicative DG consent process.

Proposal 2 – Revoke the GB notification database and requirement for GB duty holders to submit notifications to HSE as the GB CLP Agency, thereby reducing burdens on duty holders and the regulator

Summary of consultation responses

117. Questions in this section (4-5a) concerned a proposal to remove the Article 40 duty for suppliers to notify HSE, as the GB CLP Agency, of new chemical substances or changes to previously notified substances that they place on the GB market.

118. Of those answering this question, 45% agreed that the removal of the Article 40 requirement to notify the GB CLP Agency would save businesses time. This compares with just under a quarter who disagreed. A fifth of respondents indicated that they simply didn't know. Those identifying as members of the public tended to disagree. Business representative bodies/trade associations, business 'other', business paid advisory services and employees tended to agree.

119. Those who agreed reported that the proposal would reduce administrative burdens, streamline processes that are currently burdensome and inefficient, and introduce greater flexibility. However, it was noted that GB should continue to follow international standards.

120. Those who disagreed and those who highlighted potential unintended consequences felt that increased efficiency would be realised at the expense of quality, noting that this could have an impact on public safeguards. There were also concerns with diverging from the current EU approach. There were concerns that this approach would present less oversight and transparency concerning substances on the market in GB, ultimately leading to lower safety standards, leading to a lack of trust.

HSE policy response

121. GB CLP notification requirements replicate the supplier obligations in EU CLP to notify to ECHA's Classification and Labelling Inventory and often prove to be a duplicative and burdensome task for suppliers owing to the existence of similar GB regulatory requirements. As the classification and labelling information notified to HSE is determined by the supplier, notifications often contain inaccurate information rendering them largely unusable by HSE for regulatory purposes. As such, HSE's view is that there is little value in retaining these notification requirements in GB.

122. HSE acknowledges that NGOs consider the removal of GB CLP notification requirements a potentially regressive step. However, HSE asserts that the oversight and transparency that notification is perceived to provide can be maintained through existing provisions in GB legislation. GB CLP supplier obligations require the information notified to HSE to also be present on the chemical's label and for that information and the data supporting decision making to be made available at the request of HSE or GB CLP enforcing authorities. Similar information requirements also exist in other chemical regimes, for example the chemical substance registration and safety data sheet provisions of the assimilated Regulation (EC) No 1907/2006 ('UK REACH'). Furthermore, there is no suggestion to remove self-classification or GB MCL list requirements for hazardous substances.

123. For classification and labelling information, GB CLP stakeholders can continue to access ECHA's publicly available Classification and Labelling Inventory database which contains 7 million classifications and data on approximately 350,000 substances. This information is provided by ECHA free of charge and on a publicly accessible electronic basis in accordance with statutory requirements set out in Article 42(1) of EU CLP[31] and Article 119(1) of EU REACH[32].

124. **Next steps:** HSE will aim to use REUL powers to revoke the GB notification database and the requirement for GB duty holders to submit notification to HSE.

Proposal 3 – Relocate explanatory technical notes assigned to entries in the GB Mandatory Classification and Labelling (GB MCL) List from Annex VI to the Regulation to HSE's website

Summary of consultation responses

125. Questions in this section (6-7a) concerned a proposal to remove the explanatory technical notes (essentially guidance) assigned to entries on the GB MCL

[31] EU CLP, Article 42 - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20231201#page=30

[32] EU REACH, Article 119 - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20221217#page=92

List from legislation and publish them on HSE's website. This proposal would enable the Agency to make future revisions to the notes pertaining to GB MCL entries in an administrative capacity, rather than through a Statutory Instrument.

126. Just under half of respondents agreed that changing the location of the GB MCL notes would make it easier to access GB MCL information. This should be balanced against the fact that three in ten people answered 'don't know'. Yet very few people – less than one in ten – disagreed. Overall, all types of respondents (including members of the public) and all sizes of business tended to agree with the proposal.

127. Most respondents felt this proposal would make GB Mandatory Classification and Labelling (GB MCL) information easier to access and more responsive to decisions. Greater adaptability and flexibility could help to avoid delays and streamline processes, but transparency was debated in terms of accountability. It was noted that GB MCL information needed to be made more visible, and that updates to GB MCL notes should be science-based and transparent.

128. Respondents noted potential impacts on other regulatory regimes, as well as potential impact on scrutiny processes, legal action and certainty. It was suggested that updates to the explanatory technical notes should be subject to public consultation, be readily accessed and transparent, and some noted a desire for international alignment.

129. While most respondents reported they were not aware of or were unsure of any unintended consequences (Question 7-7a), those who responded 'yes' reported:

a. There were concerns that there could be issues with data access, such as broken links or outdated resources, as well as a general concern with data security and clarity.

b. There may be issues around legal action and enforcement following the relocation of technical provisions.

c. Some reported transparency concerns and concerns that changes could be made without sufficient scrutiny and oversight.

d. Some raised concerns around inadequacies of the system causing issues for implementation of the UN GHS system as a whole.

e. There was a desire to align with the EU approach and avoid further divergence, both to maintain protections and realise the economic benefits of alignment.

130. Respondents also provided practical feedback on the workability of the new system, making it clear that data and information would need to be prominent, clear and more accessible, with updates that are easily trackable. Feedback suggested that GB explanatory technical notes should align with the wording of EU explanatory

technical notes, and it would be necessary to be able to track legal obligations clearly. There were concerns that changes could result in increased administrative burdens for organisations.

HSE policy response

131. HSE will make changes to relocate the explanatory technical notes associated with some GB MCLs into the same area as the GB MCL List making it easier for suppliers to reference them when classifying and labelling substances and mixtures. This proposal replicates action taken during the UK's withdrawal from the EU to relocate the list of legally binding mandatory classifications and labelling elements present in Annex VI to HSE's website. HSE's experience of operating the GB MCL List evidences the ability to make such changes in a manner that is consistent with current legislative and enforcement frameworks. Prior to the relocation of the notes coming into force, HSE's preferred course of action would be to conduct stakeholder engagement to raise awareness of the impending change, helping to mitigate the risk of confusion amongst stakeholders and avoid the unintended misapplication of GB MCLs.

132. **Next steps:** Using REUL Act powers, HSE will aim to make the necessary changes to relocate the notes from Annex VI to HSE's website.

Proposal 4 – Introduce powers to make future amendments to GB CLP and its supporting regulations to implement general updates and international obligations

Summary of consultation responses

133. Questions in this section (8-8a) asked for details of any unintended consequences which may result from the creation of an ongoing power under which GB CLP and its supporting legislation can be amended. This would ensure the timely reflection of wider political, technological and scientific developments and would establish continuous means by which the UK can meet new or revised international commitments.

134. Respondents reported a number of possible unintended consequences, noting:

a. Concerns around diverging from the EU's regulatory approach, noting that this could have an adverse impact on safety and the economy.

b. Some highlighted the importance of continuing to implement GHS to ensure simple and standardised labelling with trading partners.

c. Others were concerned that there could be a lack of oversight, a reduction in protections, and that changes could be made without the appropriate levels of public scrutiny and consultation.

d. Others noted that the general impact of changes to legislation could be detrimental.

135. However, it was also noted that this approach could be more flexible, allowing GB CLP to adapt to scientific and international regulatory developments without compromising safety.

136. Respondents reported that further information and clarity on potential changes was necessary, with priorities to uphold standards and maintain transparency, as well as consider the impact that changes to GB CLP could have on other legislation.

HSE policy response

137. As set out under the policy response for GB CLP proposal 1, the general powers to update are essential for future amendments to GB CLP. It will also provide the express legal basis by which GB CLP can align with all EU classifications, if doing so is a future policy position. The preference is that this change will be made in a future primary legislative vehicle.

Questions concerning Northern Ireland's place in the UK Internal Market

Summary of consultation responses

138. Questions in this section (9-12a) concerned the operation of two distinct CLP regimes in GB and NI and sought views on incorporating measures in the EU CLP regime into GB CLP to mitigate potential frictions within the UK Internal Market and protect the supply of GB goods to NI.

139. Nearly six in ten people responding agreed that a consistent CLP regime between Great Britain and Northern Ireland is beneficial to safeguard the UK Internal Market (with a fairly even split between those answering 'strongly agree' and those answering 'agree'). On the other hand, only one in ten disagreed. Of the remaining answers, one in six people answered either 'don't know' or 'do not agree nor disagree'.

140. The main benefits of a consistent CLP regime between GB and NI (Question 9a) were identified as follows:

a. A consistent regime would remove burdens and ensure there is certainty and enhanced clarity in regulatory processes. It would facilitate trade and protect the internal market.

b. Some respondents felt that the EU CLP was the most stringent regime and should therefore be followed.

141. Those operating in NI were more likely to say that this approach would facilitate trade, protect the internal market, mitigate costs and simplify compliance.

142. HSE asked whether respondents agreed or disagreed that the current CLP regime between GB and NI was working (Question 10-10a). The majority of respondents (39%) indicated that they didn't know whether the current CLP regime between Great Britain and Northern Ireland was working. In fact, only about one in ten agreed it was working with nearly a third disagreeing. One in five answered that they 'do not agree nor disagree'. Businesses of all sizes and across all sectors disagreed.

143. Respondents reported that they felt current arrangements led to divergence in classification and increased burdens as a result. Some felt that this undermined regulatory certainty, disrupted supply chains and complicated the movement of chemicals within the UK Internal Market.

144. Others felt the arrangements were working for now but that could change in the future. They suggested that the best approach would be to align with EU classifications to address challenges with supply and ensure optimal protections remain in place.

145. Views were sought on whether recent changes to EU CLP should be replicated in GB CLP (Question 11-12). The majority of respondents (61%) agreed that measures should be replicated, including businesses of all sizes across all sectors. Less than ten per cent disagreed, while the remaining third were unsure.

146. While the majority agreed, feedback on specific measures which should be replicated was not forthcoming. Some suggested that all measures should be replicated to ensure a comprehensive regulatory approach that facilitates trade, eases burdens to business, and protects GB citizens.

147. Those who had additional views suggested that alignment would be the best regulatory approach as divergence adds complexity for duty holders, has an adverse impact on trade and would result in lower standards in GB.

HSE Policy Response

148. HSE will amend GB CLP to safeguard the UK Internal Market as it acknowledges the importance of applying a consistent regime across the United Kingdom. In particular, it notes the impact of associated changes in classification and labelling as a result of the European Commission's Action Plan for the chemicals sector. This includes the 6th Simplification Omnibus[33] which aims to reduce regulatory burdens in key EU chemicals legislation. Together with HSE's consideration of how it will apply the new EU hazard classes into GB, the changes brought about by this revision – or rolling back of EU CLP measures – will support a

[33] Simplification of certain requirements and procedures for chemical products - https://single-market-economy.ec.europa.eu/publications/simplification-certain-requirements-and-procedures-chemical-products_en

more consistent regime across NI and GB. The legislation to implement these changes will be made with the intention to provide at least a minimum of six months prior to the labelling changes taking effect in Northern Ireland and the EU.

GB Prior Informed Consent (GB PIC)

149. **For detailed background on the GB PIC proposals and consultation questions please see pages 50 to 55 of the Chemicals Legislative Reform proposals document**[34]**.** GB PIC proposals seek to improve operability by simplifying the administrative procedures for both duty holders and HSE as the PIC Designated National Authority for the export and import of certain hazardous chemicals.

150. For each GB PIC proposal below, HSE has aggregated consultation responses to provide summaries, which are followed by HSE's policy response.

Proposal 1 – Removal of the Special Reference Identification Numbers procedure

Summary of consultation responses

151. Questions in this section (1-3a) concerned a proposal to remove redundant procedures such as the Special Reference Identification Number (Special RIN or SRIN) procedure for small quantities of chemicals being exported for research or analysis in quantities unlikely to affect human health or the environment.

152. Nearly four in ten people disagreed (with a large proportion of these answering 'strongly disagree'); only about one in four people agreed with this proposal. There was also a high level of uncertainty as a third of respondents answered 'don't know'. While 'other' businesses and employees tended to agree with the proposal (along with large and medium sized businesses), members of the public disagreed, alongside micro and small businesses.

153. Those who agreed felt it would reduce workload and streamline processes, removing unnecessary administrative burdens.

154. Those who disagreed raised safety concerns around chemical exports, including potential implications for human and environmental health. There were secondary concerns surrounding a potential decrease in trust from overseas customers which could potentially have a negative economic impact. Some perceived this proposal as a weakening of regulations and suggested it would become more difficult to maintain oversight of the movement of chemicals and apply appropriate scrutiny which could lead to potential exploitation. Respondents were also concerned with diverging from the EU approach and what impact this could have on GB products and trade.

[34] GB PIC background and proposals (pages 50-55) - https://consultations.hse.gov.uk/hse/chemicals-legislative-reform-proposals/user_uploads/hse-chemicals-legislative-reform-consultation--word-version.docx

155. HSE asked respondents approximately how many SRINs their organisations apply for in a typical year (Question 2). Only five respondents reported applying for SRINs:

a. Four respondents reported 2.5 applications per year or less.

b. One large business reported approximately 350 applications per year.

HSE Policy Response

156. It is considered that this proposed change is appropriate as the SRIN is an EU administrative procedure that was retained at the time of EU Exit. It does not inform any regulatory activity under GB PIC, nor is it a requirement under the Rotterdam Convention[35], meaning the UK is still meeting its international obligations. Its removal has no implications for the nature of goods being exported from GB as it serves no function and is not used once generated. However, it does represent an unnecessary administrative burden to businesses and HSE understands that its removal is likely to provide a modest economic benefit.

157. **Next steps**: The preferred course of action is to progress this proposal and make legislative changes to remove SRIN as it is a redundant procedure. This amendment would be made using REUL Act powers.

Proposal 2 – Amendment of the waiver from requirement for explicit consent to import provision

Summary of consultation responses

158. Questions in this section (4-7) concerned a proposal to amend the conditions for applying for a waiver from the explicit consent requirements where no response has been received from the authorities in the importing country to repeated requests for consent.

159. Nearly half of respondents disagreed with the proposal to remove the hazard classification criteria that apply to the Designated National Authority's consideration of a waiver from explicit consent to import for Rotterdam Convention-listed chemicals, with only about one in ten agreeing. A third of responses were 'don't know'. Other businesses and employees tended to agree with the approach. Members of the public overwhelmingly disagreed with the approach, and micro businesses also tended to disagree with the approach.

160. Those who agreed with the proposal suggested that it would alleviate barriers to trade and could introduce more regulatory clarity. The approach could remove delays and increase efficiency with no impact on safety standards.

[35] Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade - https://www.pic.int/

161. Those who disagreed perceived the proposal as a weakening of regulations and noted concerns around safety and environmental impacts, with other feedback suggesting that this was a fundamental consequence of diverging from the EU regulatory approach. Respondents were concerned that this would represent a loss of control for importing countries over hazardous chemicals entering their territory, leading to a negative safety impact for the importing country. There were also concerns that this proposal could have an adverse impact on trade and that speeding up processes could come at the cost of having adequate systems in place to monitor chemical safety.

162. HSE asked respondents approximately how many waivers their organisations apply for in a typical year (Question 5). Only three respondents reported applying for waivers:

a. Two respondents reported applying for 1 waiver per year.

b. One large business reported applying for 3-5 waivers per year.

HSE policy response

163. The response from industry supports HSE's understanding that this will remove barriers to trade, introduce more regulatory certainty, and make the process of exporting hazardous chemicals subject to the requirements of GB PIC more efficient. The issue of a waiver will only be considered after repeated unsuccessful attempts to obtain a response from the importing country and will be restricted to chemicals where there is evidence from official sources that the chemical is licensed, registered or authorised for use there or has been used in or imported into the importing country in the last five years.

164. HSE disagrees this will be a weakening of the regulations but instead the amendment aligns more closely with the implementation of the UK's obligations under the international Rotterdam Convention. This is operated in a similar way in the EU, in so far that EU PIC also derives from the Rotterdam Convention.

165. **Next steps**: The preferred course of action is that REUL Act powers would be used to amend the waiver for explicit consent to import provision.

Proposal 3 – Introduce powers to make future amendments and updates to GB PIC and its supporting regulations to implement general updates and international obligations

Summary of consultation responses

166. Questions in this section (8-8a) concerned a proposal to introduce powers to amend GB PIC through secondary legislation. This would ensure that the UK can continue to implement its international obligations within the required timescales and to better tailor procedures to GB requirements.

167. Over half of respondents to these questions were not sure what, if any, unintended consequences may result from the creation of an ongoing power under which GB PIC and its supporting legislation could be amended. Over three in ten responses, however, did feel that there would be unintended consequences. Members of the public agreed that there would be unintended consequences, whereas other businesses and employees felt there would not be. Micro businesses felt there would be unintended consequences, but medium and large businesses disagreed.

168. Respondents who felt there could be unintended consequences reported concerns related to the dilution of safety measures, noting that subsequent decisions could be at risk of exploitation and lobbying. There were concerns with a lack of oversight, including stakeholder engagement, and appropriate legislative scrutiny. Respondents expressed a clear desire to remain aligned with the EU regulatory approach and suggested powers could be used to weaken regulations, leading to a decline in standards.

HSE policy response

169. HSE disagrees that allowing changes to GB PIC through introducing a general power (by way of primary legislation) would lead to a lower level of oversight than is appropriate or could lead to reductions in levels of protection. As assimilated EU law, GB PIC contains more prescriptive detail around processes, timelines and other administrative matters than is contained in the UK's obligation under the Rotterdam Convention.

170. As reflected in the policy response to PIC proposals one and two, the changes reflect administrative edits to the first proposal, and changes that are better aligning GB PIC to its international obligations. The general powers will provide powers that currently do not exist to, as appropriate, keep pace with our obligations including amendments that may be made by the EU. Any amendments required would be made via secondary legislation which will be subject to full parliamentary scrutiny including consultation with stakeholders.

171. **Next steps:** The preferred course of action is for a general power be introduced to update GB PIC through primary legislation. This is a necessary measure which will permit GB PIC to be more flexible and responsive to international developments, including to ensure that the UK continues to meet its international obligations.

Conclusion

172. HSE acknowledges the support from all stakeholders who shared and promoted this consultation and all those who took time to respond. All responses have been considered within this analysis.

173. Overall, key themes were identified that emerged across all the responses to the consultation. Many respondents were supportive of aligning only with systems that could be considered analogous to GB. The EU was the most favoured option and was considered as the benchmark.

174. Many responses were concerned over the lack of clarity and ambiguity of the proposals with concerns that this could lead to a loss of regulatory compatibility and a decrease in standards, particularly with jurisdictions that are yet to specified. There was also a strong desire for any changes to support streamlining current processes and increasing access to, and trade with, the EU, particularly in light of potential implications for the supply of goods to NI and the protection of the UK Internal Market.

175. HSE reiterates its commitments to maintain the levels of human and animal health and environmental protection across its chemical regimes. HSE notes that the EU serves as a benchmark particularly from an environmental standpoint.

176. It was clear that respondents are keen to ensure that regulatory decisions in GB continue to be informed by relevant information and grounded in scientific evidence. As an independent regulator, HSE recognises the importance of sound, science-based decision-making and remains committed to maintaining high standards of protection.

177. HSE believes that the conclusions set out in this response will continue to provide a safe and effective route for chemicals to enter the GB market without compromising existing standards of protection for health and the environment. Changes to the regulatory framework for chemicals are designed to allow for greater flexibility and agility in regulatory decision-making, ensuring that GB can respond more quickly to regulatory developments. This includes regulatory developments in the EU. It is HSE's policy to ensure that levels of protection in GB remain analogous to those in the EU. **Regulatory decisions will diverge from those made in the EU only in exceptional circumstances.**

178. The consultation findings will feed directly into the development of regulatory amendments to HSE's chemicals regimes. A number of proposals have been identified that could be implemented by secondary legislation made under the REUL Act. Proposals that cannot be taken forward by secondary legislation under the REUL Act are likely to require a suitable primary legislative vehicle. HSE will continue to explore opportunities to make those changes as early as possible, as far as a suitable legislative vehicle is identified and Parliamentary time may allow.

179. The UK Government is committed to protecting the whole UK Internal Market, including mitigating any regulatory barriers between NI and the rest of the UK. Where decisions introduce any regulatory differences between NI and GB, HSE will work with government departments and stakeholders across the UK to identify any potential impacts and any regulatory actions that may be needed to mitigate those differences.

Further information

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Published by the Health and Safety Executive 02/26.