

HSE Chemicals Legislative Reform Consultation Document 2025

CONSULTATION BY THE HEALTH AND SAFETY EXECUTIVE	2
OVERVIEW.....	2
HOW TO SUBMIT RESPONSES	3
ONCE THE CONSULTATION CLOSES	3
CONFIDENTIALITY AND GDPR.....	3
QUALITY ASSURANCE AND COMPLAINTS	4
1. INTRODUCTION.....	5
ABOUT YOU	7
DEMOGRAPHIC QUESTIONS	9
2. BACKGROUND	14
PURPOSE OF THIS CONSULTATION	15
3. BIOCIDAL PRODUCTS	16
3.1 BACKGROUND – BIOCIDAL PRODUCTS AND GB BPR	16
3.2 TRANSITION FROM EU BPR TO GB BPR	16
3.3 BPR ACTIVE SUBSTANCE REVIEW PROGRAMME	17
3.4 CHANGES TO GB BPR TO SUPPORT THE RECOGNITION OF INTERNATIONAL BIOCIDES APPROVALS	18
3.5 REMOVAL OF ACTIVE SUBSTANCE APPROVAL DATES AND CALLING IN ACTIVE SUBSTANCES FOR REVIEW.....	25
3.6 EXPANDED ESSENTIAL USE PROVISIONS	28
3.7 POWERS TO AMEND GB BPR AND ITS SUPPORTING REGULATIONS	31
3.8 BIOCIDES COST ESTIMATES	32
4. CLASSIFICATION, LABELLING AND PACKAGING	35
4.1 BACKGROUND – THE GREAT BRITAIN CLASSIFICATION LABELLING AND PACKAGING (GB CLP) REGULATION	35
4.2 TRANSITION FROM EU CLP TO GB CLP	35
4.3 MAKING GB CLP EVALUATION MORE AGILE AND PREDICTABLE.....	36
4.4 CHANGES TO GB CLP SUBSTANCE NOTIFICATION.....	44
4.5 RELOCATION OF TECHNICAL PROVISIONS.....	47
4.6 POWER TO MAKE GENERAL UPDATES	49
4.7 CLP COST SUMMARY.....	50
4.8 PROTECTING NORTHERN IRELAND’S PLACE IN THE UK INTERNAL MARKET.....	51
5. PRIOR INFORMED CONSENT	58
5.1 BACKGROUND – THE EXPORT AND IMPORT OF CERTAIN HAZARDOUS CHEMICALS UNDER GB PIC.....	58
5.2 REMOVAL OF THE SPECIAL REFERENCE IDENTIFICATION NUMBERS PROCEDURE ...	59
5.3 AMENDMENT OF THE WAIVER FROM REQUIREMENT FOR EXPLICIT CONSENT TO IMPORT PROVISION.....	60
5.4 POWER TO MAKE GENERAL UPDATES	62
5.5 PIC COST SUMMARY.....	63

Consultation by the Health and Safety Executive

Overview

The Health and Safety Executive (HSE) undertakes a wide range of regulatory functions fundamental to enabling a safe and healthy workplace. We are dedicated to protecting people and places and helping everyone lead safer and healthier lives. Our role goes beyond worker protection to include public assurance. We work to ensure people feel safe where they live, where they work and in their environment which we achieve in part through our role as the appointed authority to regulate chemicals.

Great Britain (GB) has one of the best workplace health and safety performances in the world and achieves some of the lowest rates of occupational injury and fatality in Europe.

HSE's work supports innovation, productivity and economic growth in GB and businesses that adopt effective, proportionate health and safety practices increase productivity and employee engagement. HSE's strategy – [Protecting people and places: HSE strategy 2022 to 2032](#) – commits HSE to reviewing its regulatory framework to keep pace with social, political, environmental and technological developments.

This consultation document is issued by the Health and Safety Executive (HSE) in line with the [Government's Consultation Principles](#) for consulting with stakeholders. It outlines the proposals for changes to HSE led chemicals policy and seeks views on: Biocides, Classification, Labelling and Packaging, and the export and import of hazardous chemicals (Prior Informed Consent).

The consultation is in direct support of a key commitment made by the Prime Minister as part of the Government's Policy paper [New Approach to ensure regulators and regulation support growth](#) which is an Action Plan that nests into the broader Government Mission to Kickstart Economic Growth. These changes to the HSE-led areas of the Chemicals Framework should result in reducing costs to business. HSE will need to make these changes through an appropriate legislative route that may give rise to new legislative powers.

How to submit responses

This consultation will last for 8 weeks from 23 June 2025 until 18 August 2025. Responses must be received by 23:59 on 18 August 2025.

You can respond in three ways:

1. Complete the online survey below (our preferred option for ease of analysis)
2. Download the Word document version of this consultation and email it to chemicals.reform@hse.gov.uk
3. Download the Word document version of this consultation and send it to:

Consultation on HSE Chemicals Legislative Reform
Health and Safety Executive
Building 2.3 Redgrave Court

Merton Road
Bootle
Merseyside L20 7HS

If you require a more accessible format of this document, please send details to HSE.Online@hse.gov.uk and your request will be considered.

Once the consultation closes

When the consultation has closed, HSE will consider the views expressed and may further refine the proposals for chemicals legislative reform. A summary of HSE's responses to the views expressed by stakeholders will be published alongside the consultation response. Further communications will be issued for interested parties in advance of any regulatory changes coming into force.

Confidentiality and GDPR

HSE tries to make its consultation procedure as thorough and open as possible. A summary of responses to this consultation document will be made available on the consultation webpage after the close of the consultation period where it can be viewed.

Information provided in response to this consultation may be subject to publication or disclosure in accordance with the access to information regimes – these are primarily the [Freedom of Information Act 2000](#) (FOIA), the [General Data Protection Regulations](#) (GDPR) and the [Environmental Information Regulations 2004](#) (EIR). Statutory Codes of Practice under the FOIA and EIR also deal with confidentiality obligations, among other things.

If you would like us to treat any of the information you provide as confidential, please make this clear in your response. If we receive a request under FOIA or EIR for the information you have provided, we will take full account of your explanation, but we cannot guarantee that confidentiality can be maintained in all circumstances.

An automatic confidentiality disclaimer generated by your IT system will be disregarded for these purposes. Requests for confidentiality should be made explicit within the body of the response.

HSE will process all personal data in accordance with the GDPR. This means that personal data will not normally be disclosed to third parties and any such disclosures will only be made in accordance with the Regulations. See HSE's [Privacy Policy Statement](#).

Quality assurance and complaints

If you have any complaints about the consultation process (as opposed to comments about the issues which are the subject of the consultation) please address them to:

Dipti Kerai
Better Regulation and Policy Unit
Engagement and Policy Division
Health and Safety Executive
4th Floor, 10 South Colonnade

Canary Wharf
London
E14 4PU

or send an email outlining your concern to: Dipti.Kerai@hse.gov.uk.

HSE aims to reply to all complaints within 10 working days. If you are not satisfied with the outcome, you can raise the matter with the Information Commissioner's Office:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

or HSE's Chief Executive, Sarah Albon, at:

Sarah Albon
Chief Executive
Health and Safety Executive
Redgrave Court
Merton Road
Bootle
Merseyside
L20 7HS

You can also write and ask your MP to take up your case with us or with ministers. Your MP may also ask the independent Parliamentary Commissioner for Administration (the Ombudsman) to review your complaint.

1. Introduction

1. The chemicals sector is at the heart of GB's manufacturing industry. It consists of more than 4,100 businesses – including large global multinationals, medium sized companies, and small enterprises. Between them they span the whole supply chain, from energy and feedstocks to pharmaceuticals and consumer products. The chemicals sector makes a key contribution to the UK economy, generating [£46.3bn industry turnover](#) and [£12.2bn Gross Value Added](#). The sector is responsible for thousands of highly skilled and well-rewarded jobs located in parts of the country where they are essential to the local economy. It is estimated that the chemicals sector directly employs [104,600 people](#), and industry sources report that for every employee around three more jobs are supported in purchased services and supply chains resulting in sustaining nearly [500,000 jobs](#) around the UK.
2. 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. Following EU Exit, these direct acting EU regulations became incorporated into UK law under section 3 of the European Union (Withdrawal) Act 2018.
3. The management of chemicals is complex and currently requires shared responsibility across government departments – including HSE, the Department for Business and Trade (DBT), and the Department for Environment, Food and Rural Affairs (Defra) – and devolved governments. HSE is the GB chemicals regulator but certain functions are also disaggregated across departments in accordance with existing portfolios and expertise along with application and class of chemical. The UK Chemicals Governance Group (UKCGG) provides strategic oversight of the various regulatory regimes within the UK. The UKCGG is informed by a number of groups, including the Chemicals Delivery Board (CDB), Pesticides Delivery Board (PDB), and Biocides Delivery Board (BDB).
4. Regulation must be balanced against removing unnecessary barriers to growth in the chemicals sector and set a clear path to regulation which supports the Government's Industrial Strategy set out in its green paper [Invest 2035: the UK's modern industrial strategy](#).
5. The [Regulatory Action Plan](#) (RAP) published by Government in March 2025 clearly sets out the ambition for regulatory reform. Reforms must support growth, be targeted and proportionate, transparent and predictable and adaptive to keep pace with innovation.
6. The aims described above can be achieved by changing how HSE approaches regulating chemicals. HSE will make changes to reduce burdens whilst maintaining existing levels of health and environmental protection.
7. The changes must continue to champion HSE's strategic goal to increase and maintain trust to ensure people feel safe where they live, where they work, and

in their environment, capitalising on HSE's expertise regulating across the chemicals and health and safety landscape.

8. This consultation document provides an outline of the key reforms HSE considers necessary or desirable to make changes to the chemicals regimes on which it leads. It seeks to do this by proposing changes to assimilated EU-derived legislation¹. Depending on the nature and extent of the proposed change, this suite of changes are likely to need a mixture of primary and secondary legislation. A summary of the proposals is below, with more detailed information set out in the background and regime-specific sections.

GB Biocidal Products Regulation (GB BPR)

- Introduce a system which allows the recognition of approvals and, where appropriate, authorisations given in foreign jurisdictions with similar standards. This proposal delivers on the Government's commitment that HSE 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, which was made as part of the Action Plan to ensure regulators and regulation support growth.
- Replace the 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.
- 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.
- 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 the regime in future in a more agile way.

Classification, Labelling and Packaging of Chemicals Substances and Mixtures (GB CLP)

- Consolidate Article 37 and Article 37A of the assimilated [Regulation \(EC\) No 1272/2008](#) 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).
- Revoke the GB CLP 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.
- Relocate explanatory notes relating to entries in the GB Mandatory Classification and Labelling (GB MCL) List from Annex VI to the Regulation to HSE's website. This proposal would enable the Agency to make future

¹ Assimilated law refers to the UK domestic law that was previously known as "retained EU law" (REUL) and which was created by the European Union (Withdrawal) Act 2018. The Retained EU Law (Revocation and Reform) Act 2023 changed the terminology to "assimilated law" on January 1, 2024.

revisions to notes pertaining to GB MCL entries in an administrative capacity, rather than through a Statutory Instrument.

- Introduce powers to make future amendments to GB CLP and its supporting regulations to implement general updates and international obligations. This will ensure the timely reflection of wider political, technological and scientific developments and will establish continuous means by which the UK can meet new or revised international commitments.

Prior Informed Consent for the Export and Import of Certain Hazardous Chemicals (GB PIC)

- 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.
- 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.
- Introduce powers to make future amendments and updates to GB PIC and its supporting regulations to implement general updates and international obligations. This will ensure that the UK can continue to implement its international obligations within the required timescales and to better tailor procedures to GB requirements.

9. This consultation is relevant to manufacturers, downstream users (e.g. formulators), distributors (e.g. retailers), importers and exporters of hazardous chemicals and the general public. It is also relevant to authorisation holders of biocidal active substances and suppliers of approved biocidal products.

About you

Note: The published comments will not contain any personal information

First Name

Please enter your first name

Francesca

Last / Family Name

Please enter your family name

Rapolla

Name of organisation	
Please add the organisation/institution name	Cosmetic, Toiletry and Perfumery Association
N/A	

Do you give permission for your company/institution name to be published on the HSE website?	
Yes	
No	
N/A (responding in individual capacity)	

Would you like your responses to remain confidential (so your name and/or business name will not be published on the HSE website)?	
Yes	
No	
If you answered yes, please give your reason:	

Would you be willing for HSE to contact you to discuss further your responses to this consultation?	
Please select a response and provide an email address in the next section if selected "Yes"	
Yes	
No	

Email address
Please enter your email address
frapolla@ctpa.org.uk

Demographic questions

Demographic Question 1:

Please indicate which chemical regime's changes you are responding to.

Please tick ALL that apply.

Biocides (GB BPR) – Section 3	
Classification, Labelling and Packaging (GB CLP) – Section 4	X
Prior Informed Consent (GB PIC) – Section 5	

Demographic Question 2:

Who are you responding as?

Please select only ONE.

As a member of the public	
As an employee	
As a business – contractor	
As a business – paid advisory services (e.g. consultancy; external health and safety advice)	
As a business (not covered in any of the other categories)	
As a Trade Union	
As a business representative body, trade association	X
National NGO	
International NGO	
As a consumer group	
As a government organisation or body (including local authorities, arms-length bodies and/or central government departments)	
Other (please specify)	

Demographic Question 3:

Excluding yourself, how many people does your business and/or organisation employ?

Please select only ONE. *[Only 'member of the public' to be excluded]*

0 (self-employed)	
1-4	
5-9	
10-19	X
20-49	
50-99	
100-249	
250+	
Don't know/unsure	

Demographic Question 4:

Please indicate your PRIMARY area of business.

Please select only ONE.

Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms (this group includes the manufacture of basic chemical products, fertilisers and associated nitrogen compounds, as well as plastics and synthetic rubber in primary forms)	
Manufacture of pesticides and other agrochemical products	
Manufacture of paints, varnishes and similar coatings, printing ink and mastics	
Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	
Manufacture of other chemical products (this group includes the manufacture of explosives and pyrotechnic products, glues, essential oils and chemical products not elsewhere)	

classified (n.e.c.), e.g. photographic chemical material [including film and sensitised paper, composite diagnostic preparations etc.]	
Manufacture of man-made fibres	
Manufacture of basic pharmaceutical products	
Manufacture of pharmaceutical preparations	
Any other type of manufacturer (e.g. crop and animal production, hunting & related service; manufacture of textiles; manufacture of rubber and plastic products; manufacture of leather and related products)	
Agents involved in the sale of fuels, ores, metals and industrial chemicals	
Wholesale of chemical products	
Retailers (e.g. retail sale of hardware, paints and glass in specialised stores; retail sale in non-specialised stores with food, beverages or tobacco predominating; other retail sale in non-specialised stores)	
Wholesale of perfume and cosmetics	
Wholesale of agricultural machinery, equipment and supplies	
Wholesale of chemical products	
Retail sale of hardware, paints and glass in specialised stores	
Retail sale of cosmetic and toilet articles in specialised stores	
Retail sale in non-specialised stores with food, beverages or tobacco predominating	
Retail sale via mail order houses or via Internet	
Other (please specify)	Trade association representing the cosmetics and personal care industry

Demographic Question 5:

Where does your organisation sit in the respective supply chain?

Please tick ALL that apply.

	Biocides		CLP	PIC
	Active substances	Biocidal products		
Manufacturer				
Importer				
Downstream user (incl. formulators)				
Distributor				
Exporter				
Research facility				
Not applicable (N/A)	X	X		X
Other (please specify)			X – trade association but our members are manufacturers, importers, DUs, distributors etc	

Demographic Question 6:

Please indicate where you are based.

Please select only ONE option.

England	X
---------	---

Northern Ireland (NI)	
Scotland	
Wales	
Other <i>Please write your country in the text box</i>	
Not applicable (N/A)	
Don't know/unsure	

Demographic Question 7:

Please indicate which markets you operate in (i.e. which market[s] you are selling into).

Please tick ALL that apply.

Great Britain (GB)	
Northern Ireland (NI)	
European Union (EU)	
Rest of World	
Not Applicable (N/A)	X – CTPA does not sell products and it represents members operating in the UK and globally

2. Background

2.1 HSE became the independent regulator for chemicals regulation in GB following EU Exit. To facilitate the transition, the chemicals regulatory framework was replicated onto the UK statute books using powers in the [European Union \(Withdrawal\) Act 2018](#). The retained law largely mirrored the EU regulations at the point of EU Exit to ensure legal certainty and continuity at the end of the EU Exit transition period.

2.2 This gave rise to the current regulatory framework for England, Scotland and Wales.

- [Biocidal Products Regulation \(GB BPR\)](#) – GB BPR provides a framework for the authorisation and approval of biocidal active substances and the products containing them. Biocides are a specific range of chemicals aimed at controlling harmful organisms and pests such as micro-organisms or rodents.
- [Classification, Labelling and Packaging of Substances and Mixtures Regulation \(GB CLP\)](#) – GB CLP provides a framework for the classification of hazardous chemicals (carcinogenic, toxic for reproduction, mutagenic) and the labelling and packaging of those chemicals. It adopts a UN agreement in this area called the Global Harmonised System (GHS).
- [The Export and Import of Hazardous Chemicals Regulation \(GB PIC\)](#) – GB PIC requires companies to notify exports of listed hazardous chemicals to countries outside Great Britain, and in some cases seek their consent to export chemicals. It implements the international Rotterdam Convention, to which the UK is a party.

2.3 When leaving the EU, these regulations were incorporated under section 3 of the European Union (Withdrawal) Act 2018. The regulations were amended in [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) and [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2020](#).

2.4 In order to facilitate its dual access to both the UK Internal Market and EU Single Market, Northern Ireland continues to apply certain rules relating to chemicals under the terms of the Windsor Framework. The territorial scope of the measures described in this consultation is GB. However, the Government intends to avoid any regulatory barriers between Northern Ireland and the rest of the UK, in line with the manifesto commitment to protect the UK Internal Market.

2.5 The proposals set out in this consultation document will give HSE greater flexibility and scope to make necessary – including urgent – or appropriate regulatory decisions in GB at pace with international partners, including the EU and the rest of the world where appropriate, easing potential trade frictions arising as a result of delayed regulatory decision-making.

2.6 The changes will assist HSE to become increasingly adaptive and ambitious in how it regulates chemicals in keeping with the Government's new approach to regulation and growth set out in the RAP. Removing duplication, streamlining processes and taking a more risk-based approach will ensure HSE remains an effective GB regulator and it will be better situated to pass efficiencies on to business.

Purpose of this consultation

2.7 HSE, with the agreement of Department for Work and Pensions (DWP) Ministers, is consulting on proposed changes to the GB BPR, GB CLP and GB PIC regimes. This document sets out the proposed changes to these regimes and seeks views.

2.8 In particular, HSE wish to consult on the commitment made in the RAP on ***how international approvals can be recognised to reduce the time and cost to bring chemicals products, including biocides, to the GB market***. The HSE proposed changes are framed with this in mind.

2.9 Any changes will be subject to ministerial approval and will need to be agreed by Parliament if primary legislation is required.

3. Biocidal Products

3.1 Background – Biocidal Products and GB BPR

- 3.1.1 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. They are regulated in GB under assimilated Regulation (EU) No 528/2012 on making available on the market and use of biocidal products (GB BPR).
- 3.1.2 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.
- 3.1.3 At the first step, active substances (the active ingredients which give biocides their controlling effect) are subject to a thorough scientific risk assessment to ensure that their risk profile is acceptable and that they have the intended biocidal effect against the target organism. Following this, at the second step businesses may apply for authorisation for products containing, consisting of, or generating approved active substances. At this point a further risk and efficacy assessment is carried out on the product, considering its specific formulation and intended uses. HSE acts as the competent authority in GB on behalf of ministers and undertakes the necessary evaluations at both steps.

3.2 Transition from EU BPR to GB BPR

- 3.2.1 The regulatory regime set out in GB BPR was first established when the UK was a Member State of the EU, under the EU Biocidal Products Directive ([Directive 98/8/EC](#)). This was later replaced by the EU Biocidal Products Regulation (Regulation EU No 528/2012) on making available on the market and use of biocidal products (EU BPR).
- 3.2.2 Under the EU regulatory regime, work on evaluating active substances was shared between EU Member States and centrally co-ordinated by the European Chemicals Agency (ECHA). Biocidal products were authorised by Member States but with mutual recognition arrangements and a facility to authorise certain products across the EU.
- 3.2.3 When the UK left the EU, EU BPR was retained in GB under [Section 3 of the European Union \(Withdrawal\) Act 2018](#). To coincide with EU Exit, amendments were made to GB BPR using powers in the EU Withdrawal Act. These amendments focused on adapting decision-making and institutional arrangements so that they were appropriate for the UK outside the EU. They did not permit wider policy changes. Therefore, in other aspects GB BPR remains identical to the EU BPR.

3.3 BPR Active Substance Review Programme

- 3.3.1 HSE inherited the EU's review programme of existing active substances (defined as those in biocidal products on the EU market on 14 May 2000). At the time of Exit, 243 active substance/product type combinations had been approved. Following transitional arrangements put in place after Exit, approximately 330 active substance/product type combinations were resubmitted, representing about 72% of the EU total at that time. HSE, acting as the competent authority for biocides, is now responsible for evaluating the approximately 330 remaining active substances on a GB-only basis. This forms the GB Active Substance Review Programme (GB ASRP).
- 3.3.2 Alongside the active substances still waiting to be reviewed, those which were approved while the UK was in the EU are starting to expire. Normally first approvals of active substances last 10 years. Between the end of 2020 and the end of 2026, 111 active substance/product type approvals will have expired, though over time this will increase as the full set of approvals issued to date reach their expiry.
- 3.3.3 When active substance approvals expire, GB BPR requires an application to be made to renew the approval, which HSE must then evaluate. To prioritise its work in the early years after the UK left the EU, HSE gained agreement from ministers to postpone all expiry dates that fell between the end of the transition period (31 December 2020) and the end of 2026 until 31 January 2027, subject to a renewal application being received. However, the provisions that allow postponements to be issued are tightly defined and extensions will not be possible indefinitely. Therefore, they cannot provide a long-term solution.
- 3.3.4 Resourcing the active substance workload, both the GB ASRP and renewals, is a major challenge for HSE. Even based on optimistic estimates of the regulatory resources HSE will have available over the coming years, it is anticipated that the GB ASRP will take at least several decades to complete. Also, if the increasing number of renewals cannot continue to be postponed, HSE's resources will need to be devoted increasingly towards renewing existing approvals rather than addressing the large backlog of first approvals. This will further slow progress on the GB ASRP.
- 3.3.5 These delays severely compromise HSE's ability to regulate biocides efficiently and effectively which risks undermining the purpose of the biocides regime to protect people and the environment, in line with [HSE's strategy](#). Reforms are urgently needed to put the GB biocides regime on a sustainable footing.

Implications for the UK internal market and Northern Ireland (NI)

- 3.3.6 As outlined, the territorial scope of these proposals is GB. The Government is committed to protecting the whole UK internal market, including mitigating any regulatory barriers between NI and the rest of the UK. HSE's general approach to mitigating regulatory barriers that may arise under GB BPR is to closely monitor EU regulatory decisions that apply in NI, to communicate these in a timely fashion to stakeholders so that they can plan and act where required. Where decisions introduce any regulatory differences between NI and GB, HSE

works with stakeholders and the NI authorities to identify any potential impacts and any regulatory actions that may be needed to mitigate these.

3.3.7 This general approach will not change following the proposed reforms. However, by introducing additional flexibility into the GB regulatory framework, it will be easier for HSE to manage the flow of regulatory decisions in GB in such a way as to minimise any differences with NI where this is appropriate. Therefore, the reforms will support the Government's commitment to protecting the UK internal market and minimising any barriers to trade in biocides between NI and the rest of the UK. This is explained further below for individual proposals where relevant.

3.3.8 To address these issues, HSE is exploring reforms in four areas, which collectively would significantly streamline and improve the flexibility of the regime, enabling it to function much more effectively in GB. These are:

3.3.8.1 Changes to support the recognition of international biocides approvals, and where appropriate, authorisations

3.3.8.2 Removal of active substance approval dates and calling in active substances for review

3.3.8.3 Expanded essential use provisions

3.3.8.4 Legislative powers to amend GB BPR

3.4 Changes to GB BPR to support the recognition of international biocides approvals

3.4.1 In line with the RAP, HSE is exploring introducing new provisions that would allow recognition of biocide approvals in foreign jurisdictions, where there is assurance that the foreign jurisdiction has similar standards for evaluation. This could apply to both active substances and biocidal products, though the case is more straightforward for active substances for reasons explained below.

3.4.2 Under the current provisions, HSE will always evaluate an application dossier before making a recommendation to the Secretary of State to approve an active substance, or before authorising a biocidal product. The proposal to recognise foreign approvals means removing this domestic evaluation and instead relying on the fact that approvals in trusted foreign jurisdictions have already been evaluated under similar standards. This would save the time and cost of undertaking evaluations for both applicants and HSE and has the potential to create substantial savings for applicants per application. Depending on how it is implemented, HSE estimates that it could save up to 97% of the application fee (the current fee of the order of £160,000 could be replaced with a fee of around £5,000 per application – see 3.8.3), or it could operate without fees if recognition does not require an application to be made.

3.4.3 A list of countries, jurisdictions and other bodies would be deemed trusted jurisdictions where it can be established that regulatory standards for biocides are similar to and at least as high as those in Great Britain. Trusted jurisdictions

could be listed in legislation, for example in a Schedule to an Act or set out in a statutory instrument so that it can be amended and updated. Given the close similarity in the GB and EU regimes, it would be likely that the EU would be included in any list, though the potential for any other countries or jurisdictions to be included is still being explored. HSE welcomes feedback on the prospects for recognising approvals or authorisations from outside the EU in response to this consultation.

3.4.4 To support the principle of recognition, several new powers would be required. These could include:

- i. A power given to the Secretary of State (SoS) to approve biocidal active substances when they are approved in trusted jurisdictions. Another option is that approvals in listed jurisdictions are automatically approved (without a specific decision from the Secretary of State), while granting the Secretary of State powers to refuse an approval on specified grounds (see below, paragraph 3.4.5). Decisions would be subject to consent from ministers in Scotland and Wales, as at present.
- ii. A power given to the SoS to add further trusted jurisdictions to a list (for example in a Schedule to an Act or set out in a statutory instrument) where they meet suitable criteria – these are expected to include that standards and evaluation procedures are at least equivalent to those in GB.
- iii. A power to request information from any applicant as is necessary to advise the SoS on whether to recognise any active substance approval from a trusted jurisdiction. For example, it may be necessary to obtain more detailed information on the scientific evaluation or data underlying a foreign approval before it is recognised if there are specific issues of concern. HSE would likely seek regulation-making powers to set out any procedures for requesting information in more detail (see below, section 3.7). Data protection considerations may also require that an applicant submits data to HSE as a condition of recognising a foreign approval, but this is still being explored (see section 3.4.9).

3.4.5 A clause would also be required stating that the SoS or the competent authority (Scottish or Welsh Ministers for devolved matters) may refuse to approve an active substance approved in a trusted jurisdiction on specified grounds. While it is expected that most EU active substance approvals would be recognised, this is to ensure that there is flexibility not to do so where it would be harmful to GB interests. Grounds for refusal could include:

- i. Absence of the target organism in GB or evidence that a biocidal product or active substance would not be efficacious against the target organism in GB
- ii. Where the SoS or the competent authority considers that it has not been demonstrated by the trusted jurisdiction that the biocidal active

substance or biocidal product meets the criteria for approval/authorisation

- iii. Protection of the environment or public health in GB
- iv. Protection of cultural heritage in GB
- v. Reasons of public policy or public security

3.4.6 HSE is also considering the introduction of a separate power for it, as competent authority, to use any evaluation available to it, which it considers reliable, from any foreign jurisdiction to inform any evaluation of an active substance or biocidal product. This allows necessary further efficiency in processing applications, by enabling use of reliable information from jurisdictions where it may not be possible to fully recognise approvals due to differences in standards or methodologies. This proposal would rely on any evaluation being legally available to HSE to use.

3.4.7 The principle of recognising foreign approvals or authorisations could be extended to biocidal products. Like recognition of active substance approvals, this would require a power for the competent authority to authorise biocidal products authorised in trusted jurisdictions and also a power to refuse authorisations on specified grounds (similar to those listed in 3.4.5). However, recognising biocidal product authorisations from other jurisdictions may be less straightforward than recognising active substance approvals. Biocidal product evaluations are more likely to differ between countries, due to factors such as differences in product uses, climatic conditions, target species, resistance status, etc. Nevertheless, there would still be substantial efficiencies where this approach can be applied.

3.4.8 Recognising foreign approvals or authorisations also raises the question of how any subsequent decisions in the foreign jurisdiction would be handled, such as renewal, restriction or non-approval of an active substance. One option is for these decisions also to be recognised, similar to initial approvals. Another option would be for restrictions or bans to trigger a review in GB (similar to the call-in proposals described below, see 3.5.3). An intermediate option would be that a ban or restriction in a foreign jurisdiction would normally be recognised, but with an opportunity for applicants to submit a data package and pay for re-evaluation in GB in case of any concerns. However, for candidates for substitution² or products containing them, some further evaluation is likely to be needed in GB even if another jurisdiction renews, because regulatory decision making depends on whether there are suitable alternatives on the market and this may differ between countries.

3.4.9 HSE is aware that recognising foreign approvals or authorisations raises questions of data protection and data ownership. For example, if a company provided a data package to support an active substance approval in another

² Candidates for substitution are active substances with specific intrinsic hazardous properties which are considered to be of higher concern. They are defined in [Article 10 of GB BPR](#).

country and GB recognises that approval, it would need to be determined whether, and how, that data could be protected if other companies then benefit from that approval in GB. As indicated above, one option could be to require an applicant to submit the underlying data package when a foreign approval or authorisation is recognised to support data protection in GB. HSE is considering these issues and would welcome feedback on matters to consider if the recognition approach is pursued.

Biocides Question 1:

To what extent do you agree or disagree with the principle of enabling approvals of **biocidal active substances** granted in foreign jurisdictions to be recognised in Great Britain?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know

Biocides Question 1a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

[Free Text]

Biocides Question 2:

To what extent do you agree or disagree with the principle of enabling authorisations of **biocidal products** granted in foreign jurisdictions to be recognised in Great Britain?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know

Biocides Question 2a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

[Free Text]

Biocides Question 3:

Are you aware of any practical difficulties that might affect an approach to recognise active substance approvals granted outside GB?

Tick the relevant answer.

Yes	No	Don't know/Unsure

Biocides Question 3a:

If 'yes', please briefly explain what these practical difficulties might be.

[Free Text]

Biocides Question 4:

Are you aware of any practical difficulties that might affect an approach to recognise biocidal product authorisations granted outside GB?

Tick the relevant answer.

Yes	No	Don't know/Unsure

Biocides Question 4a:

If 'yes', please briefly explain what these practical difficulties might be.

[Free Text]

Biocides Question 5:

Are there any unintended consequences which you think may result from an approach to recognise active substance approvals granted outside GB?

Tick the relevant answer.

Yes	No	Don't know/Unsure

Biocides Question 5a:

If 'yes', please briefly explain what these unintended consequences might be.

[Free Text]

Biocides Question 6:

Are there any unintended consequences which you think may result from an approach to recognise biocidal product authorisations granted outside GB?

Tick the relevant answer.

Yes	No	Don't know/Unsure

Biocides Question 6a:

If 'yes', please briefly explain what these unintended consequences might be.

[Free Text]

Biocides Question 7:

To expand on HSE's knowledge base, do you have any additional information about whether it would be appropriate to recognise active substance approvals granted outside the EU?

Tick the relevant answer.

Yes	No	Don't know/Unsure

Biocides Question 7a:

If 'yes', please provide any relevant and useful information here:

[Free Text]

Biocides Question 8:

To expand on HSE's knowledge base, do you have any additional information about whether it would be appropriate to recognise biocidal product authorisations granted outside the EU?

Tick the relevant answer.

Yes	No	Don't know/Unsure

Biocides Question 8a:

If 'yes', please provide any relevant and useful information here:

[Free Text]

Biocides Question 9:

There are currently three proposed approaches to how subsequent decisions in recognised foreign jurisdictions - such as renewal, restriction or non-renewal of an active substance - should be handled in GB BPR. Please rank these approaches – so '1' is your preferred approach, '2' is your second preferred approach, etc.

(Note: candidates for substitution, or products containing them, would need further evaluation in GB irrespective of whether they are renewed in another jurisdiction).

Rank	Proposed approach
	Subsequent decisions in recognised foreign jurisdictions (renewals, non-renewals and restrictions) are recognised in GB (similar to initial approvals).
	Renewals are recognised in GB but restrictions or bans in recognised foreign jurisdictions trigger a separate review in GB.
	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.

Biocides Question 9a:

Please briefly explain the reason(s) for your preferred approach (the approach you ranked number 1).

[Free Text]

3.5 Removal of active substance approval dates and calling in active substances for review

- 3.5.1 In addition to recognising foreign approvals, HSE is exploring the removal of all active substance approval expiry dates. Instead, approvals would be issued on the condition that the Secretary of State or the competent authority may ‘call-in’ active substances at any time for review, using a risk-based approach. This would remove the current pressures to prioritise resources towards renewing existing approvals, and instead introduce flexibility for HSE to prioritise its evaluation work where it would have the greatest impact on reducing risks.
- 3.5.2 This would apply to active substances where the recognition approach above had not been taken, and therefore where there would otherwise still be a need for full evaluation and renewal by HSE. HSE is considering whether renewals should also be removed where a foreign approval has been recognised; this is closely linked to how renewals in the foreign jurisdiction are handled (see 3.4.8).
- 3.5.3 An active substance could be ‘called in’ for a full re-evaluation in light of new evidence (similar to a renewal under the current system) or could be focused on specific parts which are of particular interest. Examples of such new evidence could include new studies indicating a previously unforeseen risk, a new mandatory classification and labelling decision, or adverse data from use of biocidal products containing the active substance. In some cases, this could be planned in advance (for example if a range of active substances are to be re-evaluated in light of new guidance). Alternatively, if there is an urgent concern there would also remain the possibility to carry out unplanned reviews.
- 3.5.4 HSE is still considering the detailed operation of this proposal, such as the methodology of the risk-based approach to trigger a ‘call-in’ and the sequencing and requirements for applicants. It is likely that secondary legislation would be needed to set out details.
- 3.5.5 Operating a ‘call-in’ system may require industry to track new information on an active substance and make it available to HSE, to help inform whether active substances should be called in for review. This would be an alternative to the current renewal system, where a full renewal dossier must be submitted at defined intervals. There are several ways this could operate, for example, industry providing a periodic return to HSE on any new evidence likely to trigger the need for re-evaluation or making information available to HSE if requested. The impacts would need to be considered during development of secondary legislation. However, such a proposal would be implemented in such a way as

not to increase burdens on HSE or industry, particularly considering that many applicants already monitor the performance of biocides on the market and collect adverse data.

Removal of expiry dates from biocidal products

- 3.5.6 HSE is also considering whether the same principles should be applied to biocidal products. This would mean that expiry dates are removed from all biocidal product authorisations meaning they would continue indefinitely unless 'called in' for review. HSE, acting as competent authority, would selectively 'call-in' authorised products for re-evaluation if there is emerging evidence of risk or based on other relevant considerations, for example if it is appropriate to re-evaluate authorised products based on changed risk criteria or guidance changes.
- 3.5.7 Another possible model would be to retain the current system for products, so that expiry dates remain in place and authorisation holders must apply for a biocidal product authorisation to be renewed before it expires if they wish to keep the product on the market. This could be done while removing expiry dates and operating call-in arrangements to active substances.
- 3.5.8 There are advantages and disadvantages to either approach. Removing expiry dates from products would be consistent with the approach being considered for active substances. It would allow HSE to better time product re-evaluations to follow shortly after active substance re-evaluations, allowing the conclusions to be considered. This may achieve greater efficiency and consistency than an approach where active substance and product re-evaluations could happen at different times.
- 3.5.9 Alternatively, continuing with the current renewal system for products ensures that product evaluations are updated to consider new evidence, guidance and evaluation criteria at more predictable intervals than if expiry dates were removed in favour of call-in arrangements.
- 3.5.10 HSE would welcome the views of respondents on whether the proposals outlined for active substances (removal of expiry dates with the possibility to 'call-in' for review) should also apply to biocidal products.

Biocides Question 10:

To what extent do you agree or disagree with HSE's proposal to remove biocidal active substance expiry dates, and replace the process of periodic renewals with a process where active substances are called in for review based on new information?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know

Biocides Question 10a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

[Free Text]

Biocides Question 11:

To what extent do you agree or disagree that there should be arrangements to require industry to provide information so that HSE can make evidence-based decisions on call in of active substances for review? Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know

Biocides Question 11a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

[Free Text]

Biocides Question 12:

HSE is considering different possibilities for how requirements to obtain new information could operate. Do you have any suggestions as to how we could best implement this approach? Tick the relevant answer.

Yes	No	Don't know/Unsure

Biocides Question 12a:

If you have responded yes, please provide further information:

[Free Text]

Biocides Question 13:

To what extent do you agree or disagree that **biocidal product** expiry dates should be removed, and the process of periodic renewals replaced with a system where biocidal products are 'called-in' for review based on new information?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know

Biocides Question 13a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

[Free Text]

3.6 Expanded essential use provisions

3.6.1 Where the Secretary of State decides not to approve an active substance in the GB ASRP, they can issue (with consent from ministers in Scotland and Wales) an 'essential use derogation' if the active substance is considered essential to society according to criteria set out in the legislation. This allows products containing the active substance to remain legally on the market and in use for a temporary period, while an application is prepared to approve the active substance. Current essential use provisions are set out in [Article 22 of assimilated 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 referred to in Regulation \(EU\) No 528/2012 of the European Parliament and of the Council \('the Review Regulation'\)](#).

3.6.2 To count as essential, an active substance must meet the criteria set out in Article 5(2) of GB BPR, namely:

- 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

- 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.
- 3.6.3 The essential use criteria are stringent so as not to provide a route to bypass the normal regulatory requirements. However, there have been cases where specific active substances have fallen within the criteria. Examples have included active substances that are critical for water treatment, preservation of wood in essential infrastructure, to avoid bacterial contamination in food and drink manufacture, and in transportation applications.
- 3.6.4 Currently active substances outside the GB ASRP cannot receive essential use derogations. Nevertheless, these active substances could also meet the criteria for being essential to society.
- 3.6.5 Loss of an important active substance or product has the potential for major adverse social and economic consequences. Although the purpose of the biocides regime, to protect people and the environment, must not be undermined, essential active substances or biocidal products will sometimes fall out of compliance with the GB BPR requirements for reasons unrelated to their risk profile. For example, this could happen because businesses who were previously supporting an active substance decide no longer to do so for purely commercial reasons.
- 3.6.6 HSE believes that to avoid the risk of such disruption, which could be significant and affect everyday life in the country and GB's competitiveness, it should be possible for temporary derogations to be issued from the normal authorisation requirements for biocidal product whenever they are societally essential. Currently the provisions enabling this to happen are too inconsistent and leave the risk that HSE has no way of permitting essential products even when there are severe consequences if they must cease to be used.
- 3.6.7 HSE proposes that this could be remedied by granting a power to the Secretary of State to issue an essential use derogation at any time, and to any active substance that meets the criteria for being essential. It would then be possible for products containing that active substance to be authorised for the period of any derogation. To avoid potential abuse, it would be appropriate to include similar safeguards to those in place now, namely:
- there must be a public consultation on any proposed derogation
 - any derogation must only apply as long as the conditions for being essential apply
 - appropriate risk mitigation measures must be applied to minimise any exposure to people, animals and the environment and
 - it must be ensured that alternatives are being sought or an active substance application is being prepared during the period of the derogation
- 3.6.8 HSE will always consider UK internal market implications when deciding which substances should be considered essential. Where active substances are

considered essential in GB, HSE will also work with NI authorities to consider whether action is required in NI to facilitate the same outcomes.

Biocides Question 14:

To what extent do you agree or disagree that the Secretary of State should have the power to issue an essential use derogation for any active substance at any time when it meets criteria for being societally essential, such as those defined in Article 5(2) of GB BPR?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know

Biocides Question 14a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

[Free Text]

Biocides Question 15:

Are there any unintended consequences which you think may result from '**expanded essential use provisions**' proposal?

Tick the relevant answer.

Yes	No	Don't know/Unsure

Biocides Question 15a:

If 'yes', please briefly explain what these unintended consequences might be.
[Free Text]

3.7 Powers to amend GB BPR and its supporting regulations

- 3.7.1 GB BPR, like other chemicals legislation, is assimilated EU law. Although it was amended after the UK left the EU to be operable in GB, it is largely identical to the EU Biocidal Products Regulation.
- 3.7.2 Currently, there are no ongoing powers which allow GB BPR to be amended through secondary legislation. The Retained EU Law Act 2023 provides powers for assimilated law to be amended, subject to certain conditions. However, most of the powers expire in June 2026 and cannot be used if amendments are required beyond that date.
- 3.7.3 As assimilated EU law, GB BPR includes more prescriptive, operational and procedural detail than is typical in UK law. Currently this detail requires primary legislation to amend, making it very cumbersome to introduce changes to improve the operability and efficiency of the regime.
- 3.7.4 To remedy this, HSE proposes to seek appropriate powers to amend GB BPR through secondary legislation. The scope of these powers will need to be clearly defined. Any powers to amend GB BPR through secondary legislation would be subject to parliamentary scrutiny but HSE envisages that such powers would include powers to:
- i. Specify detailed arrangements for implementation of the international recognition
 - ii. Specify, amend or revoke detailed matters of operation in GB BPR and its supporting regulations, including procedures, timeframes and information requirements relating to any application or other procedure mandated in GB BPR
 - iii. Specify matters in relation to how GB BPR and its supporting regulations will be enforced
 - iv. Specify timeframes and information requirements in relation to any request for information as a condition for any active substance approval to continue
 - v. Address new risks to human health or the environment which may arise within the purposes of BPR
 - vi. Put in place transitional arrangements relating to any of the new provisions

- vii. A further provision allowing amendments which reduce burdens on business while not reducing standards of health or environmental protection

Biocides Question 16:

To what extent do you agree or disagree with HSE's proposal to introduce powers to amend GB BPR using secondary legislation in the areas outlined?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know

Biocides Question 16a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

[Free Text]

3.8 Biocides cost estimates

- 3.8.1 Estimated costs and savings of the proposals on biocides are based on previous impact assessments of the regulations, internal expert estimates and workplans for active substance and product assessments in GB and the EU. The figures are initial and reflect the early stage of policy development. They will be refined via further research, industry engagement and subsequent consultation on detailed proposals.
- 3.8.2 On **recognising international biocides approvals**, HSE estimates that for active substances, the vast majority (perhaps 97% to 99% based on an assessment of the number of active substances on the GB and EU Article 95 lists) would be eligible for recognition.
- 3.8.3 If EU and other international active substance approvals were recognised as they were issued (without the need for a GB applicant), then this would save the entirety of the assessment and fee that HSE would otherwise charge. This would be around £160,000. Alternatively, if HSE adopted a system whereby HSE would only recognise an EU or other international approval following an application and dossier submission in GB, this would be expected to incur a limited HSE review similar to a completeness check, charged at around £5,000.
- 3.8.4 HSE anticipates that choice of the recognition model would affect whether data protection could be claimed in GB, i.e. the ability for the company that owns

data underlying an approval to charge others for access to that data. Subject to further analysis, HSE anticipates that granting data protection would rely on the data owner submitting a data package to HSE when a foreign approval is recognised. If there is no application, and no data protection, alternative active substance suppliers (other than the person who owns the data underlying the foreign approval) could benefit from the GB approval and supply the active substance for use in biocides without compensating the data owner. This could have implications for competition and the attractiveness of the GB market to investment and innovation, though we have not attempted to model this further at this stage.

- 3.8.5 For products, HSE estimates that between around one-third and two-thirds could be eligible for GB recognition of international authorisations. This estimate is based at the top end (two-thirds) on an assessment of the proportion of products authorised in GB that are also authorised in the EU; and at the bottom end (one-third) on an expectation that differences in authorised products in other jurisdictions would require a more detailed review by HSE.
- 3.8.6 HSE estimates that those products eligible for recognition of international authorisations might incur an assessment fee of between £200 and £1,000. The remainder would continue to require a fuller assessment and fees of around £58,000.
- 3.8.7 For both active substances and products, the timing and sequencing of approvals and authorisation based on international recognition will depend on the flow of such decisions from suitable international regulators. We do not currently anticipate that GB applicants for international recognition would make any savings or incur any additional costs in terms of dossiers of evidence as we understand that they would send to HSE the same dossier they had sent to any international regulator.
- 3.8.8 On **removing active substance approval dates and calling in active substances for review**, HSE estimate that around 29% of active substances might be in scope of being 'called-in' for review (based on an estimate of the number that are candidates for substitution), but this is a rough initial estimate and the actual number called in each year will depend on HSE's assessment of risk for individual actives. In other cases, HSE might choose to recognise renewal decisions issued by the EU or other suitable international regulators.
- 3.8.9 For any active substances called in by HSE without an international decision to recognise, HSE estimate that assessment costs and fees might be between 25% and 100% of the current fee of around £220,000 – although such cases are expected to be very rare. Potential cost savings are due to HSE being able to focus the review just on the particular area of concern.
- 3.8.10 For any active substances called in by HSE with an international decision to recognise, initial estimates are that assessment costs and fees might be between around £25,000 and £30,000.

- 3.8.11 We do not anticipate that active substances going through the GB review process would incur any additional costs or make any savings in terms of dossiers of evidence as they would send to HSE what they had already shared with international regulators.
- 3.8.12 For products, again HSE estimates that perhaps 29% might be in scope of being called in, but actual numbers would depend on HSE decision-making based on intel on risk of individual products. For those products that would be called in, HSE estimate that assessment costs and fees might come to between around 75% and 100% of the current cost of around £5,700. As above, any savings are due to HSE being able to focus their review just on the particular area of concern.
- 3.8.13 For GB products that are not also on EU markets (around 32%), HSE estimate that they would save money on the compilation of a dossier of evidence where they are no longer subject to fixed renewal dates.

4. Classification, Labelling and Packaging

4.1 Background – The Great Britain Classification Labelling and Packaging (GB CLP) Regulation

- 4.1.1 Chemicals supplied to the Great Britain (GB) market can sometimes have properties with the potential to cause harm (hazardous properties). Such chemicals are regulated under the assimilated [Regulation \(EC\) No 1272/2008 on classification, labelling and packaging of substances and mixtures](#) (GB CLP) so that people using them, in industry or as consumers, can understand their hazardous effects. The purpose of GB CLP is to ensure a high level of protection of human health and the environment.
- 4.1.2 GB CLP adopts the [United Nations Globally Harmonized System](#) of classification and labelling of chemicals ('the UN GHS'); a voluntary internationally agreed system, upon which the classification and labelling provisions of GB CLP are based. The UN GHS facilitates trade by providing the basis for harmonising regulations on chemicals at national, regional, and worldwide levels.
- 4.1.3 GB CLP applies to manufacturers, importers, downstream users (e.g. formulators) and distributors (e.g. retailers) that supply chemicals to the GB market. Within scope are chemical substances, mixtures, explosive articles and pyrotechnic articles regardless of their volume or weight. Some specialised chemicals, such as cosmetics, food, and waste are regulated under alternative product- and sector-specific laws and are not in scope.
- 4.1.4 Before placing chemicals on the GB market, suppliers are required to:
- **Classify** their chemicals through mandatory classification or self-classification to identify and evaluate hazardous properties. Mandatory classification specifies the legally binding classifications and accompanying hazard labelling that must be used, which may cover some or all hazard classes. Where no mandatory classification exists, the supplier must gather and evaluate all the available information, then compare it to the classification criteria and decide on the classification (self-classification).
 - Communicate the hazards identified via **labelling**.
 - Ensure the safe and secure **packaging** of their chemicals prior to them being placed on the GB market.
- 4.1.5 GB CLP places additional requirements on certain suppliers of chemicals. For example, manufacturers and importers are required to notify HSE when supplying a new substance to the GB market and are responsible for updating their notifications following a change in classification.

4.2 Transition from EU CLP to GB CLP

- 4.2.1 Prior to the UK's exit from the European Union, the classification, labelling and packaging framework applicable to the UK was [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](#) ('EU CLP'). EU CLP was adopted by Member States on 16 December 2008 and was published in the Official Journal on 31 December 2008. It entered into force on 20 January 2009.

- 4.2.2 EU CLP was incorporated into GB law under [Section 3 of the European Union \(Withdrawal\) Act 2018](#). Amendments were made to the retained EU CLP Regulation to address deficiencies that would arise from the UK's withdrawal from the EU. For example, the responsibilities previously held by the European Chemicals Agency (ECHA) were transferred to HSE, such as evaluation of legally binding classifications and labelling. The modifications made were limited as the powers provided did not permit changes to policy.
- 4.2.3 The resulting CLP regime includes supplier requirements that are unnecessary and burdensome. It has also created disproportionate and inefficient processes to deliver scientific and technical updates, and a lack of legislative powers to introduce wider updates of a non-scientific or non-technical nature. In line with the Regulatory Action Plan (RAP), reform of GB CLP is required to address these problems to remove nonessential requirements on business and the ability to keep pace with the EU where appropriate. The changes would need to be delivered through a mix of primary and secondary legislation.
- 4.2.4 In order to facilitate its dual access to both the UK Internal Market and EU Single Market, Northern Ireland (NI) continues to apply EU CLP under the terms of the Windsor Framework. The Government recognises the potential for differences between GB CLP and EU CLP to become a source of trade friction between GB and NI and will seek to mitigate any regulatory barriers between NI and the rest of the UK, in line with the manifesto commitment to protect the UK Internal Market.
- 4.2.5 On 20 January 2025, the Secretary of State for NI set out the Government's commitment to take any future steps necessary to avoid new barriers that would affect supplies of such products into NI. They made this commitment in recognition of the deeply held and genuine concerns raised by Members of the Northern Ireland Assembly about the EU's recent reform to its own CLP regime. The UK Government recently [consulted on the operation of the UK Internal Market Act 2020](#) and is analysing the responses received to understand whether further actions are needed to safeguard the UK Internal Market.

4.3 Making GB CLP Evaluation More Agile and Predictable

- 4.3.1 HSE, as the GB CLP Agency, produces legally binding 'mandatory' classification and labelling requirements that chemical suppliers must use where applicable. These classifications and labelling elements are set out in the [GB Mandatory Classification and Labelling \(GB MCL\) List](#) which HSE has a statutory duty to maintain using the legal procedures set out in Articles 37 and 37A of GB CLP.

- 4.3.2 These procedures are administrative as they do not require the creation of new laws. Instead, changes to the GB MCL List are made with the Secretary of State's approval and the consent of Scottish and Welsh Government ministers. To inform decision making, both procedures include the consideration of scientific, impact and policy considerations, which are set out in the publicly available technical reports and Agency opinions produced by HSE.
- 4.3.3 Article 37 links GB MCL evaluation activity to that of the EU's analogous harmonised classification and labelling (EU CLH) system by creating a statutory obligation to consider all EU Committee for Risk Assessment (RAC) opinions on harmonised classification proposals made under Article 37(4) of EU CLP, even for those which consider substances or hazard classes not authorised for use in GB. In such cases, HSE is still legally required to prepare a technical report and an Agency opinion, the production of which can take up to 18 months.
- 4.3.4 The requirement to consider RAC opinions that are not relevant to GB adds additional burdens for the regulator. This issue is exacerbated by the recent revisions of EU CLP, under which the six new hazard classes introduced into EU CLP by Regulation (EC) 2023/707 have been prioritised for consideration under the EU CLH system. This will result in a greater proportion of RAC opinions featuring non-GB CLP hazard classes.
- 4.3.5 In addition, statutory timelines set out in Article 37 of the GB CLP Regulation, are currently triggered by the publication of a RAC opinion, requiring evaluations to be sequenced by the RAC opinion publication date determined for the EU. The current timelines restrict HSE's ability to prioritise its GB MCL evaluation work appropriately and to provide suppliers with regulatory clarity to a timescale dictated by relevance to the GB market.
- 4.3.6 Taking this into account, HSE believes that amendments to the Article 37 and 37A procedures are necessary to provide greater certainty for duty holders and to ensure that future GB MCL evaluation activity can be delivered predictably and sustainably.
- 4.3.7 HSE would seek to consolidate Articles 37 and 37A into one procedure under which proposals for mandatory classification and labelling would be evaluated, thereby simplifying the process for substance and mixture classification in GB. The consolidated procedure would include a fast-track evaluation pathway (depicted in Figure 1) for assessing classification proposals from territories that adopt the UN GHS and have a transparent classification process. Fast-track evaluation amends the time limit for publication of a technical report from 6 to 12 months whilst removing the requirement to publish an Agency opinion and its associated 12-month time limit. If compared to the existing Article 37 procedure, fast track evaluation would result in a 12-month reduction for delivery of changes to the GB MCL List following publication of the technical report. Figure 1 provides a possible way in which a fast-track procedure would work. Classification proposals from jurisdictions that do not adopt the UN GHS and do not have a transparent classification process would be evaluated under a full process, similar to that currently described in Article 37A.

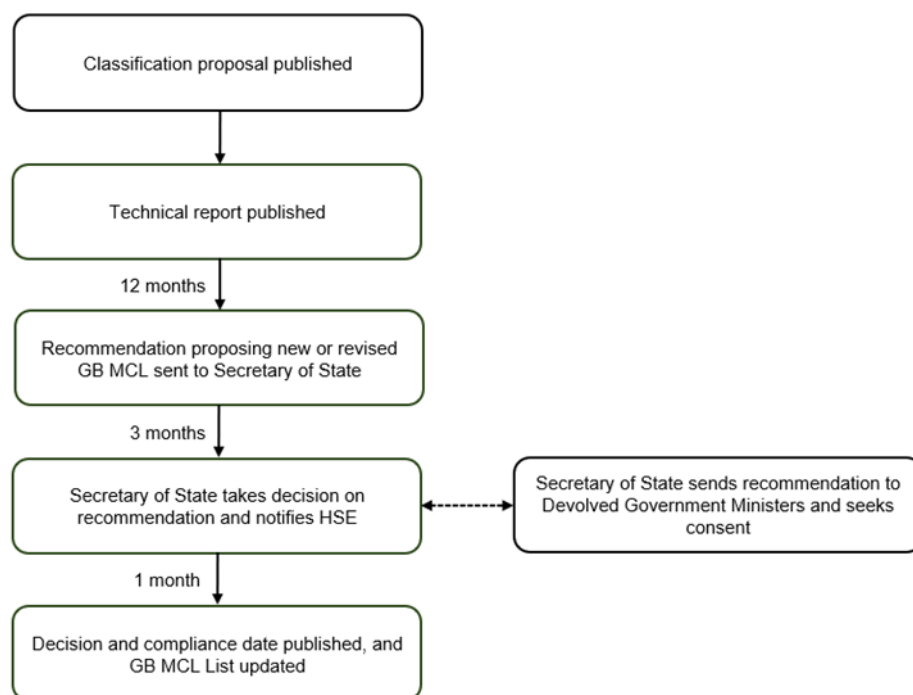


Figure 1:

Possible route to fast-track evaluation for assessing classification proposals from UN GHS adopting territories that have a transparent classification process.

- 4.3.8 The mechanism by which consent is obtained for updates to the GB MCL List also presents burdens as its current design is duplicative. The current mechanism includes a copy of HSE's ministerial recommendation being sent to devolved government (DG) ministers twice. Under the Article 37 and 37A procedures, HSE is required to send a copy of its recommendation to DG ministers. A copy of the recommendation is also sent to DG ministers when the UK Government minister seeks DG consent to satisfy the requirements of Article 53B of GB CLP.
- 4.3.9 HSE is seeking to omit from the consolidated procedure the legal requirement for HSE to send a copy of its ministerial recommendation to DG ministers. This would reduce the administrative burdens arising from this aspect of delivery of the GB MCL system and ensure that resource is used proportionately.
- 4.3.10 The consolidated procedure retains the ability to consider EU RAC opinions whilst providing the option for faster consideration of classification proposals from other jurisdictions also adopting the UN GHS. The consolidated procedure would be complemented by a GB MCL workplan setting out the classification proposals to be considered in future. As well as providing transparency for stakeholders, the workplan would enable early stakeholder input.
- 4.3.11 The proposed changes would not impact the obligation under Article 36(1) of GB CLP to subject substances with the most significant hazards to mandatory classification and labelling requirements. HSE remains committed to the

evaluation of classification proposals that focus on carcinogenic, mutagenic, reproductive toxic and respiratory sensitising hazards. These proposals would be prioritised for fast-track evaluation where they originate from EU. The amendment of Article 37 would not affect HSE's ability under Article 36(3) of GB CLP to evaluate RAC opinions featuring the new EU CLP hazard classes on a case-by-case basis where sufficient justification is provided. Nor would it prevent the adoption and prioritisation of these hazard classes in future, should the UK Government's position on the inclusion of these hazard classes in GB CLP change.

CLP Question 1:

To what extent do you agree or disagree that HSE's proposal for fast-track process will improve the existing GB MCL evaluation procedures described in Articles 37 and 37A?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know
		X			

CLP Question 1a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

CTPA identifies both benefits and disadvantages to the HSE's proposal for a fast-track process to improve the existing GB MCL evaluation procedures. A benefit is the reduction in administrative burden for the Agency and reduction in regulatory timeline. CTPA also supports the proposal to issue a GB MCL workplan, setting out the classification proposals to be considered in future. This would offer greater predictability for businesses regarding classification decisions, which is crucial for product development and supply chain management. However, there are several important implications to consider, including the removal of the specific step to assess socio-economic impacts (Agency Opinion) and potential knock-on effects of fast-tracking EU CMR hazards on the downstream UK Cosmetics Regulation.

According to Figure 1, the fast-track process does not include the Agency Opinion. The purpose of the Agency Opinion is to consider the potential policy and socio-economic impacts (costs and benefits) of the proposed GB MCL. For example, the new or revised classification might trigger additional controls under other chemical regulations. If the impacts are significant, the HSE might recommend to Ministers that the GB MCL is implemented in a way that will reduce or mitigate these

impacts, while maintaining the level of protection for people and the environment. It is important that such considerations are still made within a fast-track framework. There are harmonised classification proposals coming from the EU process, for which the socio-economic impact assessment, as part of the final opinion, is vital; examples of these are ethanol and sodium fluoride. The fast-track process also does not include a public consultation step, which is extremely important to allow industry and external stakeholders to provide their perspective on the proposed mandatory classification. It is vital that regulatory management processes under GB CLP are transparent and provide an opportunity for industry and stakeholders to submit any relevant information.

Paragraph 4.3.11 states that CMR and respiratory sensitising hazards would be prioritised for fast-track evaluation where they originate from the EU. It is important to consider the impact of fast-tracked timelines on other legislation which is dependent on GB CLP; in particular, Article 15 of the [UK Cosmetics Regulation](#) (UKCR) mandates that cosmetic ingredients which have received a mandatory CMR classification under GB CLP must undergo a specific exemption process under the UKCR, to allow their continued use in cosmetic products. Timings of the OPSS CMR [process](#) are integrated into the timings of the GB MCL process, and if the lead time for adoption of CMR hazards originating from the EU in GB is reduced to 16 months, the OPSS CMR process will need to be revised to ensure that there is sufficient time for the industry to apply for the required exemption.

In addition, there may be some EU CMR proposals upon which GB does not take the same view, either for technical or socio-economic reasons. It is important to ensure the GB CLP framework allows for full scrutiny of these proposals, rather than sending them directly into a fast-track process.

CLP Question 2:

To what extent do you agree or disagree with HSE's proposal that the criteria for fast-track evaluation should be based on a jurisdiction's adoption of GHS, rather than publication of an ECHA RAC opinion?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know
			X		

CLP Question 2a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

Whilst other jurisdictions may follow the UN GHS for classification of substances, their chemicals legislation may not be compatible with GB CLP – in particular in regard to the classification of substances. For example, countries who adopt GHS do not necessarily implement all hazard classes, or not all categories for a specific hazard class. Even if a country may adopt GHS for a certain hazard class/category, they may not do so for all substances. If a substance's hazard class/category is not implemented in domestic legislation from GHS, then the classification criteria may not be harmonised. Therefore, it is important to ensure that, when looking at a substance classification from a third country, the hazard class/category of interest specifically follows the GHS classification criteria and it is not a class/category not aligned with GHS. For example, Canada does not implement the following GHS classes and categories: the Explosives hazard class, the Desensitized Explosives hazard class, all Environmental hazard classes, Acute Toxicity Category 5, Skin Corrosion/Irritation Category 3 and Aspiration Hazard Category 2. Therefore, Canada would not be an appropriate jurisdiction to consider these hazard classes.

In principle, reviewing the documentation related to classification of substances from other jurisdictions allows to make a classification proposal based on all available evidence. However, if the HSE intends to assess classification and labelling of chemicals from other countries that adopt UN GHS, this should be done after carefully identifying and assessing how UN GHS is implemented in those countries. Furthermore, having the public consultation step within the process becomes even more vital when considering classification proposals from non-EU jurisdictions.

CMR substances are of particular importance for the cosmetics industry because Article 15 of the UKCR states that the cosmetics industry must apply for an exemption, to continue safely using substances with a mandatory CMR classification as cosmetic ingredients. Currently, the industry tracks the progress of CMR substances undergoing EU classification and begins preparing the lengthy exemption dossier at ECHA Registry of Intentions stage. If CMR substances from other jurisdictions are fast-tracked through the GB MCL process, it is essential that the cosmetics industry has enough time to prepare the exemption dossier. Therefore, the cosmetics industry would need a notification of HSE's intention to adopt such a classification from a non-EU jurisdiction at the earliest possible stage. On this point, members flagged concerns around divergence in mandatory classification vs the EU, in particular for CMRs which directly impact the use of cosmetic ingredients in finished products. The main concerns are around the instances where GB adds more mandatory classifications vs the EU; or if the EU is overclassified vs GB. In cases where the EU imposes more, or a higher level of,

classifications than GB, it would be very helpful to businesses if the HSE could also accept the labelling of raw materials and their SDS for the GB market, making the documentation compliant for the EU as well as the GB markets. This will reduce costs for businesses as it will avoid having different documentation for the two markets, which adds administrative and financial burden to companies. These instances would not only apply to cosmetic ingredients, but also bulk of cosmetic products which are not yet in the finished state (ready for sale to the consumer) and the bulk must be labelled as per the CLP requirements.

CLP Question 3:

Are there any unintended consequences which you think may result from changing the Article 37 and 37A procedures in GB CLP?

Tick the relevant answer.

Yes	No	Don't know/Unsure
X		

CLP Question 3a:

If 'yes', please briefly explain what these unintended consequences might be.

There are both advantages and disadvantages to the proposed changes for merging the processes of Articles 37 and 37A.

Advantages

By combining Article 37 and 37A, the HSE will no longer need to produce reports for classifications which are not relevant to GB. This would therefore allow the HSE to prioritise classification and assessment of chemicals that are more relevant to the GB market.

The UK Cosmetics Regulation (UKCR) has a direct link to GB CLP, by which substances that receive a mandatory classification as a CMR are automatically banned for use in cosmetics. This is unless industry applies for an exemption for continued use in cosmetics, as per the requirements of Article 15 of the UKCR. However, it is very difficult for industry to meet the exemption criteria for a CMR1 substance, therefore leading to an automatic ban solely based on hazard and not taking a risk-based approach. In the EU, there has been an increasing number of ingredients with a harmonised classification as CMR1, in particular natural and fragrance ingredients; as well as proposals for ingredients which are vital for public health, such as ethanol and sodium fluoride. Decisions on these harmonised

classifications would benefit from a robust and holistic scientific evidence and wider policy considerations, in addition to appropriate hazard assessment. The HSE is currently legally bound to review chemicals originating from the EU CLP processes according to a specific timeframe, meaning that GB-specific prioritisation of chemicals cannot take place. Therefore, it would be beneficial to de-link GB CLP from EU CLP to ensure that the HSE can determine which chemicals from the EU CLP process are relevant to review for GB, and in which order.

Furthermore, GB may choose to take a different scientific approach from the EU for certain hazard identification. For example, the Committee on Carcinogenicity (COC) [Guidance Statement G11](#) indicates that in future, GB may wish to develop a better approach to assessing risk of cancer caused by chemicals, and this could also be the case for other hazards.

Disadvantages

The EU and UK markets are closely integrated and UK exports to the EU were worth over £2.6 billion in 2024. UK-EU imports and exports are well balanced, with EU exports of cosmetics and personal care products to the UK worth over €3.5 billion in 2024. 64% of all UK exports are destined for the EU, while 67% of all UK imports are from EU countries, meaning that the EU is the UK's most significant trading partner^[1] in our sector. Therefore, it is important to maintain regulatory compatibility between the two markets to allow shared documentation, labelling and packaging where possible and to facilitate the movement of goods in the most cost-effective way. It is important to highlight that this aspect would only affect cosmetic ingredients, or cosmetic bulk (a cosmetic mixture not ready for sale to consumers), and not to finished cosmetic products.

Furthermore for cosmetic products, mandatory CMR classifications which only apply in GB where there is no CMR classification in the EU would pose a major problem because companies may not invest in the necessary expensive defense work for the GB market only, therefore raising the need for different formulations (not ideal for an integrated supply chain) and less consumer choice between the two markets. This would also put GB at a competitive disadvantage.

Due consideration must be given to the interaction for companies operating across the whole of the UK, including Northern Ireland and the need to ensure that companies are able to benefit from as much compatibility as possible. Generally, when different regulations apply in the UK and EU markets, efforts are made to ensure mutual compatibility. It is acceptable for the regulations to differ, provided they do not create barriers preventing products from being available in both markets.

4.4 Changes to GB CLP substance notification

- 4.4.1 Article 40 of GB CLP requires the following suppliers to provide HSE with classification and labelling information on new chemical substances they place on the GB market: GB-based manufacturers and importers; and NI-based manufacturers, downstream users and distributors directly supplying the GB market. Further notifications must be made by suppliers when the classification of these substances change.
- 4.4.2 The notifications received by HSE populate a GB CLP notification spreadsheet. HSE, as the GB CLP Agency, has an inherited duty under Article 42 of GB CLP to set up and maintain a publicly facing database for such notifications. However, this type of database is not in existence due to resource constraints on establishing it around the time of EU Exit. HSE has subsequently come to the view that such a database is not essential for how it regulates chemicals.
- 4.4.3 The GB CLP notification requirements replicate the supplier obligations of EU CLP, which was necessary to align with the policy constraints imposed during the UK's EU Exit. However, the GB CLP notification requirements are viewed as disproportionately burdensome due to their onerous resource implications for notifiers and the non-value added nature of the requirements themselves.
- 4.4.4 The European Commission's 2017 review of EU CLP and other EU chemicals legislation estimated that the time taken to submit a notification to the analogous Classification and Labelling Inventory is 11 minutes. Informal stakeholder engagement with GB CLP-regulated businesses conducted by HSE in 2024 indicated that submission of a notification to the GB CLP notification database takes on average approximately three times longer (36 minutes) which suggests that GB CLP notifiers currently face increased burdens to comply.
- 4.4.5 The notification requirements aim to provide oversight of chemicals placed on the GB market which are excluded from the provisions of the assimilated Regulation (EC) No 1907/2006 on the registration, evaluation, authorisation and restriction of chemicals (UK REACH) or the Biocidal Products Regulation (BPR); and to encourage industry cooperation to agree self-classifications. However, experience shows that the outcomes of such self-classifications are variable and the only way HSE could assure the robustness of any self-classifications would be to validate the entries itself, thereby undermining the rationale for self-classification.
- 4.4.6 HSE achieves oversight through alternative means set out in legislation. Under Article 49 of GB CLP, suppliers are required to maintain information used to classify and label chemicals they place on the GB market, and to make it available on request to HSE and enforcement authorities. Part 1.1.0 of Annex I to GB CLP encourages suppliers to cooperate to meet classification and labelling requirements. Where data and expertise are shared for these purposes, suppliers are expected to document the basis for classification

decisions and to make it available on request to HSE and enforcement authorities. As such, the information received via notification is not used by HSE for GB CLP enforcement or delivery purposes.

- 4.4.7 A publicly available notification database risks containing inaccurate information and diverging classifications for the same substances, as HSE does not verify submissions and there is no duty to notify HSE if the supply of a previously notified substance to the GB market ceases. Additionally, the identity of notifiers is not made publicly available which prevents communication between notifiers of the same substance and acts as a barrier to industry cooperation.
- 4.4.8 To ease burdens on businesses, HSE is seeking to remove the GB CLP requirements relating to notification, namely the Article 40 supplier obligations to notify the GB CLP Agency and the Article 42 duties to establish and maintain the notification database. Such actions would reduce the time and cost of regulatory compliance for business and support the government commitment in the RAP to cut administrative costs for business by 25% by the end of the Parliament. It would also remove an unnecessary regulatory statutory requirement and prevent the significant financial expense to establish and maintain a Government Digital Service-compliant database.
- 4.4.9 Revoking the notification database obligations would not change the general requirements for suppliers to classify, label and package their chemicals under Article 4 of GB CLP. These are separate obligations applying to a wider range of suppliers and chemicals than those in scope of notification and allow for the regulation of hazard communication. Existing provisions in other chemicals regulations provide oversight of chemicals supplied to the GB market, such as UK REACH. Under UK REACH, manufacturers and importers of chemical substances supplied in quantities of 1 tonne or more per year must submit a registration to HSE for those substances. Therefore, HSE is confident that the revocation of the notification database will not inhibit its ability to regulate hazard communication in the supply and use of chemicals in GB.

CLP Question 4:

To what extent do you agree or disagree that removal of the Article 40 requirement to notify the GB CLP Agency would save businesses time?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know
X					

CLP Question 4a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

Removing the Article 40 notification requirement of GB CLP will certainly save businesses time, as they would have one less obligation under this regulation. CTPA agrees with the rationale set out in 4.4 explaining that removing this requirement will have no negative impact on safety.

CLP Question 5:

Are there any unintended consequences which you think may result from removing Article 40?

Tick the relevant answer.

Yes	No	Don't know/Unsure
	X	

CLP Question 5a:

If 'yes', please briefly explain what these unintended consequences might be.

The purpose of submitting an Article 40 notification is to allow the HSE to have visibility of which substances are placed on the GB market. Indeed, this can also be done under UK REACH; but this framework only applies to substances above 1 tonne/year. This document states that the HSE can oversee which chemicals are placed on the GB market via the Article 49 of GB CLP, by carrying out enforcement activities. Another route to monitor chemicals placed on the GB market can be the list of Downstream User Import Notifications (DUINs) from the UK REACH framework, which was implemented as a transitional requirement. Therefore, removing the Article 40 notification will not lose important information as this information is not necessary for the HSE currently; but the HSE may wish to consider alternative methods for ensuring it has a complete picture of chemicals, especially low-tonnage non-biocidal chemicals, placed on the GB market.

If a third party wished to access the notification information, it is available on the EU C&L. It is important to note that the EU C&L would not take into account any divergence in classification between the UK and the EU, leading to the risk of obtaining incorrect information.

However, divergence in mandatory classification can be checked in the GB MCL, which is the legally binding and official source for mandatory classifications, rather than a notification database which would need to be kept up to date regularly.

4.5 Relocation of technical provisions

- 4.5.1 Suppliers of hazardous chemicals to the GB market must apply the relevant mandatory classifications and accompanying labelling elements set out in the GB Mandatory Classification and Labelling (MCL) List. Some entries on the GB MCL List have explanatory notes assigned to them which suppliers must take into account when applying mandatory classification and labelling.
- 4.5.2 The GB MCL List is an administrative list, hosted on the HSE website, whereas the notes accompanying GB MCL entries are described in Part 1 of Annex VI to the GB CLP legislation. The difference in location of GB MCL information arises from the relocation of the **mandatory classification and labelling list** from Annex VI to HSE's website to enable post-EU Exit updates of the GB MCL List to be made through simpler, non-legislative procedures. HSE understands that the resulting difference in location of GB MCL information makes it difficult for suppliers to find the necessary information and extends the time taken to classify.
- 4.5.3 HSE is seeking to move the notes assigned to GB MCL entries from Part 1, Annex VI to HSE's website. The notes assigned to GB MCL entries would be located on the same spreadsheet as the GB MCL List or in an accompanying document hosted in the same location.
- 4.5.4 This change would simplify the process duty holders have to follow to identify a mandatory classification and the accompanying notes, which in practice would reduce the time taken to carry out classification. Additionally, this would align the process of adding, amending or removing notes pertaining to GB MCL entries with that of the GB MCL procedure, ensuring more efficient updates through an administrative, rather than legislative, process.

CLP Question 6:

To what extent do you agree or disagree that changing the location of the GB MCL notes would make it easier to access GB MCL information?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know
	X				

CLP Question 6a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

In principle, CTPA agrees that relocating the GB MCL notes into the GB MCL spreadsheet or related location would simplify gaining access to this information as well as updating it. Consolidating explanatory notes directly with the GB MCL List on the HSE website would create a single, easily accessible, and comprehensive source of information. This significantly improves clarity and ease of use for duty holders. Another advantage of this proposal is that it would eliminate the need to cross-reference multiple documents or navigate complex legislative texts, saving time and reducing the risk of errors.

It is important that the location of this information is made very clear within the GB CLP regulation and the GB CLP website. The change of location also has to be widely communicated, so that all stakeholders (including those based overseas) know where to find the correct information. Most companies and stakeholders may expect for this information to be in Annex VI of the GB CLP, as it has been so far and as they might be familiar with the EU CLP format.

Furthermore, should there be changes in the information which would impact businesses' compliance and ways of working, then industry should be properly consulted on with reasonable transition timelines.

CLP Question 7:

Are there any unintended consequences which you think may result from the relocation of technical provisions?

Tick the relevant answer.

Yes	No	Don't know/Unsure
	X	

CLP Question 7a:

If 'yes', please briefly explain what these unintended consequences might be.

It is important that the GB CLP Regulation clearly refers to the new location of the information, so it remains legally binding. This would avoid any misunderstanding that the technical provisions are no longer legally binding because they are no longer included in the legal text.

As mentioned in the previous question, it is key that the change of location is widely communicated, so that all stakeholders (including those based overseas) know where to find the correct information.

4.6 Power to make general updates

- 4.6.1 Article 53 of GB CLP provides an ongoing power to update the Regulation but its use is limited to the implementation of scientific and technical developments arising from the UN GHS. It is necessary to consider issues that are beyond the scope of the UN GHS or at a faster pace than is possible at the UN GHS to provide regulatory clarity or respond to international changes in areas such as UK free trade agreements with other countries in a timely manner. However, a continuing power does not exist through which such issues can be addressed in the GB CLP regime.
- 4.6.2 HSE is seeking the creation of an ongoing power, exercisable by statutory instrument under which GB CLP and its supporting legislation can be amended to:
- Implement UN GHS provisions in a fundamentally different way to reduce regulatory burden while maintaining existing levels of protection.
 - Make non-scientific and non-technical changes to improve compliance with or address ambiguities in the legislation for duty holders, Devolved Governments and other regulators.
 - Incorporate suitable classification, labelling and packaging requirements that are in force in NI to harmonise requirements across the UK, ease trade friction for GB businesses supplying NI or international markets and to ensure that the UK maintains parity with other countries on health and environmental protections.
 - Implement scientific and technical aspects of international agreements beyond UN GHS, such as international treaties or UK Free Trade Agreements, which may enable the UK to meet its international commitments without imposing new regulatory regimes on businesses.
- 4.6.3 The proposed power is necessary to create agility in the CLP regime, allowing it to adapt quickly and support growth in light of wider political, technological and scientific developments; and to ensure that HSE has a vehicle to implement international obligations on an ongoing basis.

CLP Question 8:

Are there any unintended consequences which you think may result from the creation of an ongoing power under which GB CLP and its supporting legislation can be amended?

Tick the relevant answer.

Yes	No	Don't know/Unsure
X		
CLP Question 8a: If you answered 'don't know/unsure', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.		
<i>CTPA supports more agile amendments to existing regulations, in order to reduce Ministerial times and processes. However, it is important that any relevant changes are still subject to scrutiny including public consultation and industry feedback, to ensure they may be fit for purpose. This is both to ensure that future policy proposals are compatible with legislation from relevant trade partners; and to ensure that industry has enough notice of upcoming policy changes for preparedness.</i> <i>It may be advantageous to make regulatory changes in a more agile way, as this can allow regulations to keep up with scientific and technical advancements. For example, testing requirements for classification can be updated to include additional non-animal approaches; or the classification criteria can be amended to also meet the latest advancements in animal-free science.</i> <i>However, it is fundamentally important for businesses that regulations in GB are compatible with those internationally. If implementing GHS provisions in a different way leads to classification criteria in GB which are more onerous or incompatible with international regulatory regimes and markets, this will lead to significant barriers to trade, increased costs and burdens for businesses and reduce the competitiveness of the GB market.</i> <i>In regard to Free Trade Agreements or international treaties, again, it is important that these are implemented into GB regulations in a way which is compatible with international trade.</i>		

4.7 CLP cost summary

- 4.7.1 The majority of the changes to CLP relate to the streamlined running of the regime and HSE's ability to focus on the substances of greatest concern. The proposal with direct impacts on business would be the revocation of the GB CLP notification database, which will save dutyholders time and the associated cost of notification. The total savings from this are expected to be around 36 minutes per notification across around 2,400 notification per annum which equates to an estimated saving of £34,000 per annum for business. We will develop this analysis further through consultation on detailed proposals.

4.8 Protecting Northern Ireland's Place in the UK Internal Market

- 4.8.1 The revision of the EU CLP Regulation (Regulation (EC) No. 1272/2008) by two pieces of amending legislation, Commission Delegated Regulation (EU) 2023/707 and Regulation (EU) 2024/2865, introduced differences between the EU CLP and GB CLP regimes.
- 4.8.2 The Government recognises that the operation of distinct CLP regimes in Northern Ireland and Great Britain has the potential to impact on the operation of the UK internal market. As set out in the letter from the Secretary of State for Northern Ireland to the Speaker of the Northern Ireland Assembly on 20 January 2025, the Government's assessment is that the majority of those trading relevant products between Great Britain and Northern Ireland are likely to trade with the EU as well as within the UK, and therefore will have incentives to comply with EU arrangements. As such, the Government's assessment is that the impact of distinct arrangements is unlikely to have a significant adverse impact on the UK internal market.
- 4.8.3 Nonetheless, the Government has also been clear that it will take any necessary steps to protect the UK's internal market and avoid the development of disincentives for traders to move goods from Great Britain to Northern Ireland.
- 4.8.4 For that reason, the Government is considering the incorporation of these measures into the domestic CLP regime on a UK-wide basis, where this is relevant for Great Britain, and with the intention of supporting the smooth operation of the UK internal market and reducing barriers to trade with the EU.
- 4.8.5 Commission Delegated Regulation (EU) 2023/707 introduced six new hazard classes into EU CLP:
- endocrine disruption (ED) for human health and the environment (separate hazard classes);
 - persistent, bioaccumulative, toxic (PBT);
 - very persistent, very bioaccumulative (vPvB);
 - persistent, mobile, toxic (PMT); and
 - very persistent, very mobile (vPvM).
- 4.8.6 The new hazard classes are now the focus of United Nations Globally Harmonized System for the Classification and Labelling of Chemicals (UN GHS) discussions and the UK Government is engaging in these international discussions on whether and how to include the potential hazard issues in the UN GHS.
- 4.8.7 Regulation (EU) 2024/2865 further amended the EU CLP Regulation to improve how chemical hazards are classified, provide clearer safety warnings and improve compliance and user safety. These new measures are aimed at optimising labelling provisions concerning hazard communication, introducing labelling rules such as minimum font size, line spacing and colouring, whilst also permitting for broader use of fold-out labels.

- 4.8.8 The EU CLP Regulation, as amended, already applies in Northern Ireland under the Windsor Framework and includes the following measures:

Changes to hazard identification

- **Application of the six new hazard classes to classification and labelling**

Suppliers are required to self-classify and label their chemical substances and mixtures in accordance with the hazard classes specified in paragraph 5. Chemical substances with these hazard classes will be prioritised for EU Harmonised Classification and Labelling. Suppliers are required to apply harmonised classification and labelling elements where available for the chemicals they intend to supply.

- **Clarified rules for the evaluation and classification of complex substances containing more than one constituent**

Where data on individual constituents are available, such substances should be classified using the same classification rules as mixtures unless otherwise specified in Annex I to EU CLP. Relevant data on the multi-constituent substance should be taken into account but where an absence of certain properties or less severe properties is indicated, data on the substance should not override the information available on the individual constituents.

Changes to hazard communication

- **Additional label formatting rules**

Suppliers must label their chemicals in accordance with new rules which specify the minimum font size, background colour and line spacing to be used.

- **Broader use of fold out labels**

The general use of fold out labels is permitted. Previously under EU CLP, use of fold out labels was limited to chemicals in small or unsuitably shaped packaging. Rules governing the location of information in fold out labels are also introduced.

- **Rules on voluntary use of digital labelling**

Non-obligatory information can be provided in a digital only format. When using digital labelling, suppliers have to fulfil new requirements which include being searchable and accessible to all users in the EU free of charge, being available in less than two clicks and not tracking any user data.

- **New deadline for updating labels**

Suppliers must update their labels within six months following a change in the classification and labelling of their chemical(s) which results in an additional hazard class, a more severe hazard class or category or new supplemental labelling elements.

- **Refill station labelling**
Where chemicals are supplied via refill for example detergents, a visible label must be firmly affixed to the refill station.
- **Additional hazard communication requirements for advertisements**
More hazard information is required in advertisements for hazardous substances and mixtures. In addition to the hazard class, advertisements should contain the hazard pictogram, the signal word and the hazard statements. The types of advertisements regulated under EU CLP are widened to include distance sales offers also.
- **Labelling Exemptions**
Derogations to the labelling requirements of EU CLP are introduced for chemicals supplied without packaging (such as fuel at filling stations), chemicals contained in very small packaging with contents below 10ml, and ammunition.

Adaptation to new methods of supply

- **Risk management at refill stations**
New rules focusing on risk management are introduced for suppliers of chemicals by refill. Suppliers must ensure that clean and suitable packaging is used, the refill station's operating buttons are kept out of reach of children. Appropriate training of the supplier's staff must be undertaken and the supplier must be available to provide immediate assistance at the moment of refill. The sale via refill of chemicals with certain hazardous properties is prohibited. These properties are acute toxicity, specific target organ toxicity, carcinogenicity, germ cell mutagenicity, reproductive toxicity, respiratory sensitisation, skin corrosion/irritation, aspiration hazard, flammability, ED, PBT, vPvB, PMT and vPvM.

4.8.9 In line with the Government's commitment to protecting 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. This call for views is distinct from but complements that commitment.

4.8.10 HSE is interested in your views on these recent revisions to EU CLP, their potential impact on the UK's internal market and the merits of applying a consistent regime across the UK, taking into account the current requirements of GB CLP. The information you provide below will be used by the UK Government to understand how best to address the impact, if any, of the associated changes in classification and labelling on trade between Great Britain and Northern Ireland, as well as to help inform any future impact assessments.

CLP Question 9:

Do you agree or disagree that a consistent CLP regime between Great Britain and Northern Ireland is beneficial to safeguard the UK Internal Market?					
Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know
X					

Question 9a:

If you answered 'Agree' or 'Strongly Agree', what would you see as the main benefits of a consistent CLP regime between Great Britain and Northern Ireland?

Finished cosmetic products are exempt from the requirements of the CLP Regulation; they instead follow the UK Cosmetics Regulation (for GB) and the EU Cosmetic Products Regulation (for the EU and NI). Therefore, having a consistent CLP regime between GB and NI does not impact finished cosmetic products.

However, GB CLP impacts cosmetic ingredients as raw materials and cosmetic bulk (a cosmetic mixture not in the finished state ready for sale to the consumer). One way CLP impacts finished cosmetics indirectly, but very importantly, is through classification of substances as CMR. This triggers a ban under the UK Cosmetic Regulation unless the ingredients are defended, by way of an extensive safety dossier to permit their continued safe use. Due to the very high expense and resource requirement, only a small number of CMR-classified cosmetic ingredients are defended. Classifications which occur in GB and not in the EU are much more likely to lead to a loss of that ingredient in GB, because of the challenge of investing in defence work for the smaller market. This will result in loss of competitiveness of GB compared with the EU market.

Therefore, compatibility between the GB and NI regimes is important for our members to support an efficient supply chain. Members reported that selling to Northern Ireland becomes extremely challenging, unless GB and NI follow the same rules. It is easier to maintain smooth trade and keep manufacturing cost-efficient when there are compatible regulations. Consequences of incompatible regulations can range from different product labels, different warehousing locations, different management of supply chains, different quality control requirements. It is important to keep in mind that the current Government agenda is to reduce costs to businesses to increase competitiveness and growth in GB. The ability to share the same CLP documentation for raw materials across GB, NI and EU as much as possible is vital to reduce costs to businesses.

CLP Question 10:

Do you agree or disagree that the *current* CLP regime between Great Britain and Northern Ireland is working?

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know
		X			

Question 10a:

If you answered 'Do not agree or disagree' or 'Don't know', please move to the next question.

Otherwise, please briefly describe in what ways the current CLP regime between GB and NI is either working or not working.

As mentioned in the previous questions, finished cosmetic products are exempt from the requirements of the CLP Regulation. As mentioned in Q9, it is challenging for members to sell into NI without having a compatible regulatory framework. It is easier to maintain smooth trade and keep manufacturing cost-efficient when there are compatible regulations. With increasing divergence between the EU and GB, members shared their concerns in regard to the feasibility of the current regime between GB and NI. Currently, our members are working towards complying with the EU requirements as the "most stringent" framework, which allows to sell products in the EU, NI and GB (some adjustments to ingredients labels and documentation are needed to sell in GB, but not for finished cosmetic products). Should the GB framework become more stringent or significantly incompatible with the EU one, members will find it very difficult to comply with all different requirements and will have to re-arrange their whole supply chain with increase in costs.

CLP Question 11:

Do you think the Government should apply any of the EU CLP Regulation measures detailed in paragraph 4.8.8 in Great Britain?

Yes	No	Don't know
		X

Question 11a:

If you answered 'Yes', please briefly describe which measure(s) should be applied to GB, and the reasons why.

Please indicate what the practicalities of applying the measure(s) would be, and whether the measure(s) would promote and/or boost trade between Great Britain and Northern Ireland.

Also, can you please provide further details of the approximate time and/or costs or savings incurred in the event of applying these measures.

There are some aspects of the EU CLP revised legislation that are worth considering for implementation in GB CLP; as well as aspects that CTPA does not support for implementation into GB CLP, as they would pose significant challenges to the cosmetics industry. This is why 'I don't know' has been selected as the answer to this question. As previously mentioned, finished cosmetic products are exempt from the requirements of GB CLP; however, there is a direct link between the UK Cosmetics Regulation and GB CLP that can affect the use of CMR-classified ingredients in finished cosmetic products. Cosmetic ingredients are fully in scope of GB CLP.

A very important aspect that is introduced by the revised EU CLP Regulation 2024/2865, and which was not taken into account in paragraph 4.8.8 of this consultation, is the introduction of data obtained from New Approach Methodologies (NAMs) for hazard classification of substances and mixtures. This is a priority aspect that must be taken into account for GB CLP as well, especially considering the amount of work going into transitioning towards reducing and replacing animal testing for chemicals. CTPA and the UK cosmetics industry support the inclusion of these provisions into GB CLP. To further support the inclusion of NAMs for hazard classification of substances, is the COC [Guidance Statement G11](#) which indicates that in future, GB may wish to develop a better approach to assessing risk of cancer caused by chemicals, and this could also be the case for other hazards.

CTPA and the UK cosmetics industry do not support the inclusion of the EU CLP's new hazard classes until they are adopted under UN GHS. CTPA considers it important that new hazard classes are adopted under UN GHS before implementation into national legislation, to promote global harmonisation and regulatory compatibility.

CTPA does not support implementing the provision into GB CLP of the overall classification of complex substances containing more than one using the same classification rules as mixtures. This aspect has a significant impact on cosmetic ingredients and finished cosmetic products, in particular in regard to natural and botanical ingredients which are widely used in cosmetic products and fragrances. Naturals and botanical ingredients are complex substances, as they are composed of more than one constituent. Specific constituents considered in an isolated way can have hazard properties that might not be expressed in the complex mixture as a whole. However, under the updated provisions of EU CLP, the hazard classification of a single substance in a complex mixture supersedes

the classification of a mixture as a whole. Substances which receive a mandatory classification as a CMR under the GB CLP Regulation are banned for use in cosmetics, unless industry applies for an exemption as per specific safety criteria under Article 15 of the UK Cosmetics Regulation. With the new EU CLP provisions, if a constituent of a natural or botanical blend received a CMR classification, then the whole blend is also classed as a CMR, causing its automatic ban in cosmetic products. This is currently causing significant challenges to the cosmetics and fragrance industries in the EU, either losing a significant number of ingredient mixtures solely based on the hazard classification of one components (without taking into account the exposure when used in a cosmetic product), or having to invest significant amounts of administrative and financial resources to defend continued use of the component and its presence in ingredient mixtures. Examples: **p-cymene and carvone**. We expand in more detail the example of p-cymene. P-cymene received a CMR 1B (reprotox) classification under EU CLP; this substance is present in around 350 natural complex substances at different concentrations used in fragrance and cosmetics. Therefore, a ban of this constituent would potentially render a very large number of cosmetic products on the market today non-compliant with the EU Cosmetic Products Regulation (approximately 40% of cosmetic products on the EU market contain p-cymene within natural complex substances). The reformulation costs of a single ingredient are typically 75K€ per formulation; therefore, the total cost of reformulating all products affected by the automatic ban of p-cymene would be around 15BN€. This would imply the complete business loss of a number of iconic fine fragrances, which cannot be reformulated without losing their olfactory identity. The EU cosmetics industry is working to defend continued use of p-cymene, investing significantly in this defence action.

CTPA and the UK cosmetics industry support the implementation of the updated “labelling, voluntary use of digital labelling, refill station labelling” requirements from the updated EU CLP into GB CLP. Finished cosmetic products are exempt from the provision of the CLP regulation; therefore, these requirements do not impact finished cosmetic products. However, cosmetic ingredients as raw materials and cosmetic bulk (mixture not ready for sale to the consumer) are within the scope of CLP. It is important to keep in mind that the requirements for label formatting rules and the additional hazard communication for adverts are going to be repealed from EU CLP as part of the [simplification omnibus](#) and the related WTO [notified](#) regulation. These two aspects should therefore not be implemented into GB CLP.

Should the HSE decide to consider implementing any elements of the EU CLP revision into GB CLP, there should be a full and detailed public consultation to ensure that each proposal is carefully considered for its potential impact on businesses, how it may apply to GB specifically and whether it truly supports the objectives of the regulation.

CLP Question 12:

Do you have any further thoughts or views about the application of EU CLP Regulation measures in GB (e.g. the potential impact on UK-EU trade; impact on UK industry)?		
Yes	No	Don't know
	X	
Question 12a: If you answered 'Yes', please briefly detail these further thoughts about the application of EU CLP Regulation measures in GB.		
.		

5. Prior Informed Consent

5.1 Background – The export and import of certain hazardous chemicals under GB PIC

- 5.1.1 Assimilated [Regulation EU No. 649/2012 on the Export and Import of Certain Hazardous Chemicals](#) (known as 'GB Prior Informed Consent' or 'GB PIC') implements the UK's obligations under the international [Rotterdam Convention](#) on international trade in certain hazardous chemicals. The main objectives are to promote shared responsibility and cooperation in the international trade of hazardous chemicals, and to protect human health and the environment by providing importing countries with information on how to store, transport, use and dispose of hazardous chemicals safely.
- 5.1.2 GB PIC goes significantly beyond the Rotterdam Convention by extending the requirements to chemicals that meet the criteria to be considered as being 'banned' or 'severely restricted' in Great Britain (GB), not just those that have been agreed for listing under the Convention. GB PIC requirements also apply irrespective of the intended use of the chemical in the importing country and to exports to all countries, not just those that are parties to the Convention.
- 5.1.3 GB PIC requires companies to notify the first export in any year of any hazardous chemical that is in the [GB PIC list](#) to any importing country (including the EU and movement to NI) at least 35 days before the intended date of export. Some chemicals, those in Parts 2 and 3 of the GB PIC list, additionally require the consent of the importing country before export can take place.
- 5.1.4 When the UK left the European Union, the EU PIC Regulation was retained in GB under [section 3 of the European Union \(Withdrawal\) Act 2018](#). The proposed changes aim to remedy issues in the assimilated Regulation that have

been identified through experience of operating GB PIC, so they are more appropriate for the UK.

- 5.1.5 Since the establishment of the GB PIC regime, the number of annual export notifications administered by HSE, the GB PIC Designated National Authority (DNA) has increased as the regulatory requirements now apply to export of listed chemicals from GB to the EU and to movement from GB to NI under the Windsor Framework arrangements. Although the transition to GB PIC has not presented any significant challenges to the operation of the regime, there are some limited and technical changes that HSE propose to make to ensure that the legislation is proportionate to the needs of GB. The intended result would be that the UK can continue to implement its international obligations within the required timescales.

5.2 Removal of the Special Reference Identification Numbers procedure

- 5.2.1 GB PIC does not apply to small quantities of listed chemicals (not exceeding 10kg in any year from each exporter to any importing country) being exported for the purposes of research and analysis that are unlikely to affect human health or the environment. However, exporters of these chemicals must obtain from the DNA, a Special Reference Identification Number ('Special RIN' or 'SRIN') and include it in their export declaration. A Special RIN is also required where the export of a chemical relates to an emergency situation.
- 5.2.2 The Special RIN is not a requirement of the Rotterdam Convention, and it does not implement any provision of that Convention. No further use is made of the Special RIN by HSE or UK customs authorities, nor is it a requirement of importing countries. The Special RIN procedure was introduced into the EU PIC Regulation when the ePIC system for electronic submission of export notifications was established. The GB PIC DNA no longer uses ePIC and the Special RIN serves no useful purpose in the operation of the GB PIC Regulation. Chemicals exported under the Special RIN procedure are excluded from GB PIC annual requirement to report the quantities of listed chemicals that have been exported or imported during the previous year. HSE therefore proposes the removal of the Special RIN procedure.

PIC Question 1:

To what extent do you agree or disagree with the proposal to remove the Special Reference Identification Number (SRIN) procedure?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know

PIC Question 1a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

[Free Text]

PIC Question 2:

Approximately how many SRINs does your organisation apply for in a typical year?

Please enter a WHOLE NUMBER or indicate 'DK' if you don't know or are unsure.

[Input field]

PIC Question 3:

Are there any unintended consequences which you think may result from removal of the 'Special Reference Identification Numbers' procedure?

Tick the relevant answer.

Yes	No	Don't know/Unsure

PIC Question 3a:

If 'yes', please briefly explain what these unintended consequences might be.

[Free Text]

5.3 Amendment of the waiver from requirement for explicit consent to import provision

5.3.1 The GB PIC Regulation makes provision for the DNA to grant a one-year waiver from the explicit consent requirement at the request of the exporter and on a case-by-case basis where no response has been received from the authorities in the importing country to repeated requests for consent. Certain conditions must be met before a waiver can be granted such as evidence that the chemical is authorised or used in that country.

5.3.2 The current waiver provision applies certain hazard criteria to the use of the waiver for those chemicals that are listed under the Rotterdam Convention such as classification as carcinogenic or meeting the criteria to be considered persistent, bio-accumulative and toxic, going significantly beyond what the

Convention requires. This can create a barrier to the export of a chemical that falls within these criteria when the importing country fails to respond to a consent request. HSE considers that removing the hazard criteria that attach to chemicals listed under the Rotterdam Convention and streamlining the waiver conditions so that the same requirements apply to all chemicals that require the explicit consent of the importing country would facilitate decision making by the DNA and provide greater regulatory clarity.

- 5.3.3 Where there has been no response from the importing country to repeated requests for explicit consent, this proposal would allow the DNA to grant a one year 'waiver' for any Rotterdam Convention-listed chemical where the intended use of the chemical is not in a category for which it is listed in Part 3 of the GB PIC list and there is evidence from official sources that the chemical has been used in or imported into the importing country in the last five years.

PIC Question 4:

To what extent do you agree or disagree 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?

Tick the relevant answer.

Strongly Agree	Agree	Do not agree or disagree	Disagree	Strongly Disagree	Don't know

PIC Question 4a:

If you answered 'don't know', please go to the next question. Otherwise, please briefly explain the reason(s) for your response.

[Free Text]

PIC Question 5:

Approximately how many waivers does your organisation apply for in a typical year?

Please enter a WHOLE NUMBER or indicate 'DK' if you don't know or are unsure.

[Input field]

PIC Question 6:

Are there any unintended consequences which you think may result from 'Waiver from requirement for explicit consent to import' proposal?

Tick the relevant answer.

Yes	No	Don't know/Unsure

PIC Question 6a:

If 'yes', please briefly explain what these unintended consequences might be.

[Free Text]

PIC Question 7:

Please provide any additional comments you have on any of the PIC proposals.

[Free Text]

5.4 Power to make general updates

5.4.1 Article 23 of the GB PIC Regulation provides an ongoing power to update the Regulation, but this power is limited to technical changes to the annexes of the Regulation. HSE is seeking the creation of an ongoing power under which GB PIC and its supporting legislation can be amended to:

- Implement any future changes to the Rotterdam Convention to ensure that the UK can continue to meet its international obligations as a Party to the Convention and make non-scientific and non-technical changes to improve compliance with or clarity of the legislation for duty holders, Devolved Governments and other regulators.
- Implement scientific and technical aspects of international agreements beyond the Rotterdam Convention such as international treaties or UK Free Trade Agreements, which may enable the UK to meet its international commitments without imposing new regulatory regimes on businesses.

PIC Question 8:

Are there any unintended consequences which you think may result from the creation of an ongoing power under which GB PIC and its supporting legislation can be amended?

Tick the relevant answer.		
Yes	No	Don't know/Unsure
PIC Question 8a: Please briefly explain the reason(s) for your response if you answered "Yes" in the previous question. Otherwise, this is the end of the survey.		
[Free Text]		

5.5 PIC cost summary

- 5.5.1 The proposals likely to yield savings to businesses would be those related to the reform of the waiver process and the removal of the Special Reference Identification Number procedure. Any savings are not yet estimated, but given the low volumes of business activity in these areas, savings are expected to be minimal. We will develop this analysis further through consultation on detailed proposals.