Regulating Chemicals after the Transition Period

Health and Safety Executive

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Classification, Labelling and Packaging

GB CLP Regulation – After the UK Transition Period

- UK formally left the EU
- Transition Period has ended.
- UK Government made it clear it would maintain regulatory and legal autonomy
- Following the Withdrawal Agreement and Northern Ireland Protocol, UK Government put in place a **GB** regulatory framework for CLP.
- After the end of the transitional period, Northern Ireland remained within the EU Single Market and the EU Single Market regulatory area
- UK/EU Trade & Co-operation Agreement – chemicals annex

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GB CLP Regulation – After the UK Transition Period

Unchanged

- The main duties/obligations on manufacturers, importers, downstream users and distributors (“suppliers”) to classify, label and package the substances and mixtures placed on the market will remain, including self-classification and packaging requirements.
- Suppliers must comply with GB mandatory (formerly EU harmonised) classification and labelling requirements.
- GB now effectively adopts the United Nations Globally Harmonized System (UN GHS) in the same way as the EU - 6th and 7th editions.

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GB CLP Regulation – After the UK Transition Period

Main changes

- GB has its own independent GB CLP Regulation system.
- GB has a new mandatory classification and labelling (MCL) system and GB MCL List.
- GB notification arrangements for new and changes to already notified substances - sent to HSE (GB CLP Agency) not ECHA.
- New requirements on GB-based distributors supplied by the EU/EEA they became importers after the end of the transition period, *if* these supply arrangements continued.
- Changes to GB CLP Regulation to implement the NI Protocol and Unfettered Access.

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GB CLP Regulation – After the UK Transition Period

There are no transitional arrangements under GB CLP

Actions businesses wanting to access GB market can take

- Understand your role in the supply chain & your obligations under the GB CLP Regulation & your role in the supply chain – need a GB/NI based company to place product on GB market.
- Decide whether you may need help with the duties and obligations of an importer i.e. classification, labelling and packaging of substances and mixtures, and take action
- Work with the actors in your supply chain – they may be willing to help you by providing information and data on classification, to help you meet your classification/labelling obligations
- Can be two sets of contact details on labels – GB importer details/EU exporter details
- Think about existing stock on the shelves and whether any action is needed
- Sign-up to HSE's GB CLP e-Bulletin (you are encouraged to sign-up if you have not already done so for updates/ changes to the GB CLP Regulation)

What GB mandatory classification and labelling list looks like…

URL for the GB mandatory classification and labelling list (GB MCL list) is: https://www.hse.gov.uk/chemical-classification/assets/docs/mcl-list.xlsx

Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs (*) (*) ATEs for oral	Notes	Date of Secretary of State's Decision (new/revise	Date of entry into legal effect of new/revised UK mandatory classification and	Final compliance date
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)					
001-001-00-9	hydrogen	215-605-7	1333-74-0	Flam. Gas 1 Press. Gas	H220	GHS02 GHS04 Dgr	H220			U			
001-002-00-4	aluminium lithium hydride	240-877-9	16853-85-3	Water-react. 1 Skin Corr. 1A	H260 H314	GHS02 GHS05 Dgr	H260 H314						
001-003-00-X	sodium hydride	231-587-3	7646-69-7	Water-react. 1	H260	GHS02 Dgr	H260						
001-004-00-5	calcium hydride	232-189-2	7789-78-8	Water-react. 1	H260	GHS02 Dgr	H260						
003-001-00-4	lithium	231-102-5	7439-93-2	Water-react 1 Skin Corr. 1B	H260 H314	GHS02 GHS05 Dgr	H260 H314	EUH014					
003-002-00-X	n-hexyllithium	404-950-0	21369-64-2	Water-react. 1 Pyr. Sol. 1 Skin Corr. 1A	H260 H250 H314	GHS02 GHS05 Dgr	H260 H250 H314	EUH014					

Notifying under the GB CLP Regulation?

The following information will be required in a GB CLP notification

- identity of the notifier: Name, address and contact details,
- identity of substance: Chemical name (including IUPAC or other international chemical name), EC/CAS number and name, molecular/structural formula, composition (purity/impurities/additives);
- classification: Hazard class and category codes and hazard statements;
- justification for absence of hazard classification (if applicable);
- specific concentration limits, M-factors and/or acute toxicity estimates (ATE) – if applicable;
- labelling: Signal word, hazard pictogram(s), hazard statements, supplementary hazard statements (if applicable).

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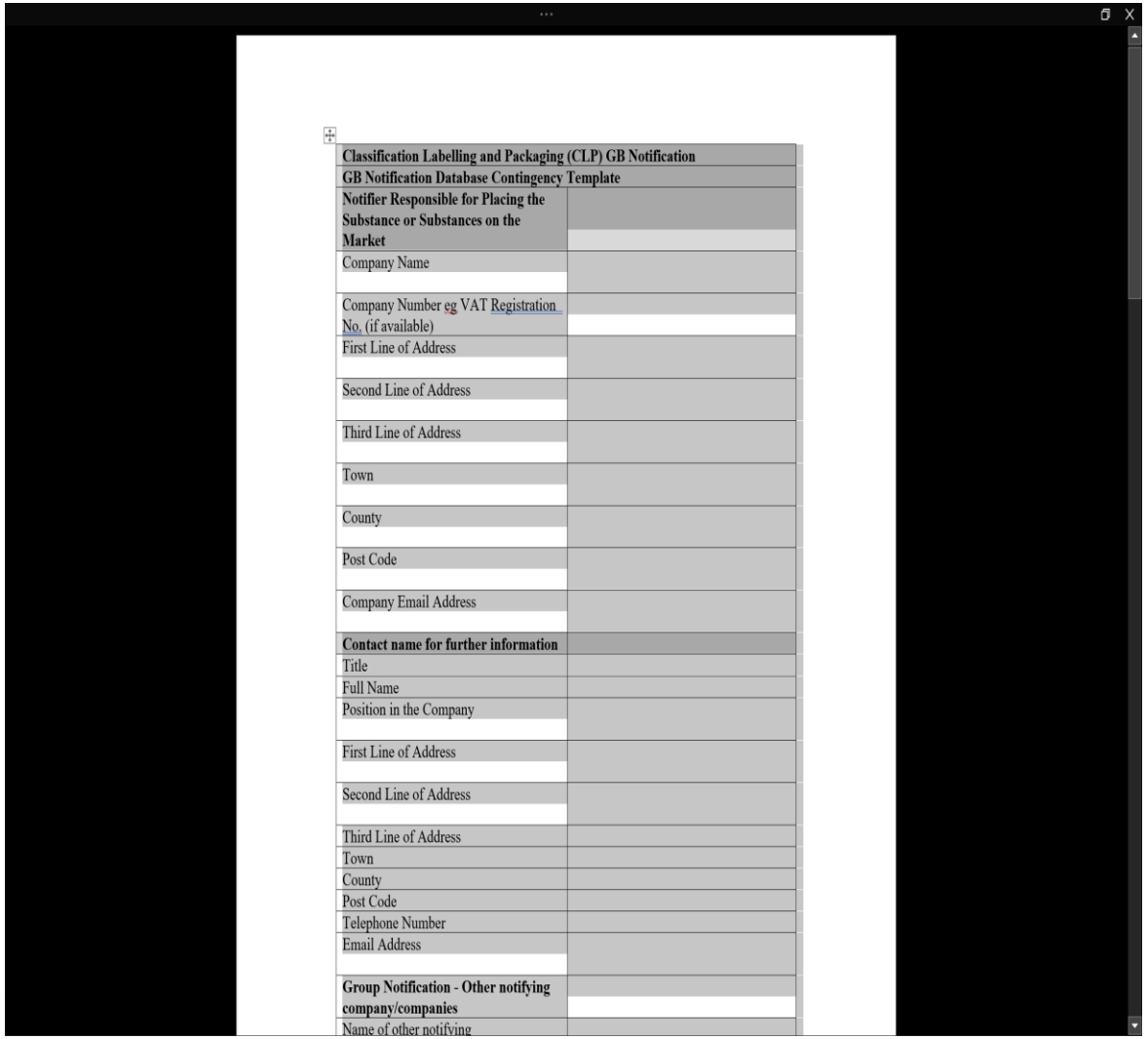
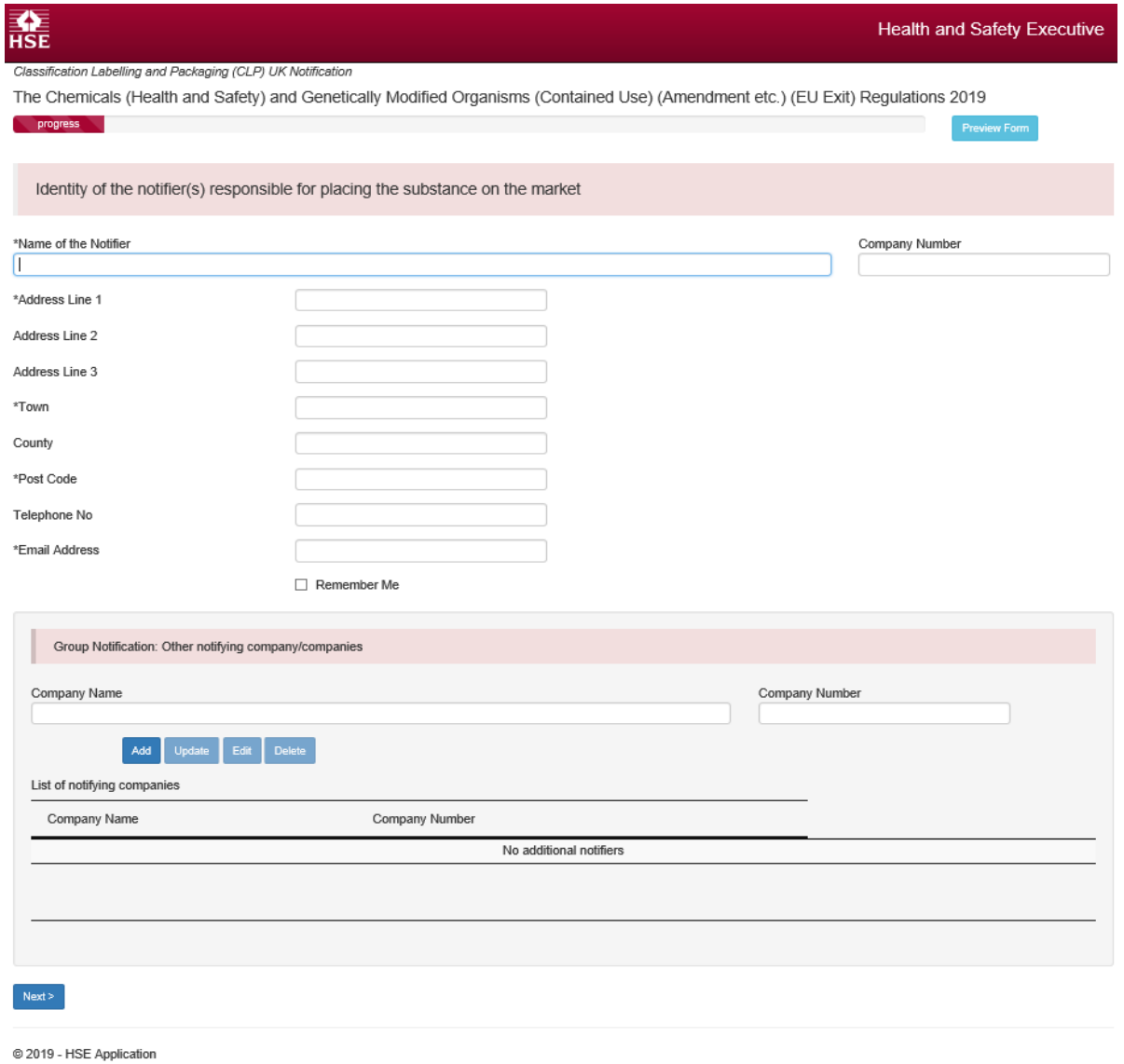
GB CLP Notification...



Classification Labelling and Packaging (CLP) GB Notification GB Notification Database Contingency Template	
Notifier Responsible for Placing the Substance or Substances on the Market	
Company Name	
Company Number eg VAT Registration No. (if available)	
First Line of Address	
Second Line of Address	
Third Line of Address	
Town	
County	
Post Code	
Company Email Address	
Contact name for further information	
Title	
Full Name	
Position in the Company	
First Line of Address	
Second Line of Address	
Third Line of Address	
Town	
County	
Post Code	
Telephone Number	
Email Address	
Group Notification - Other notifying company/companies	
Name of other notifying	



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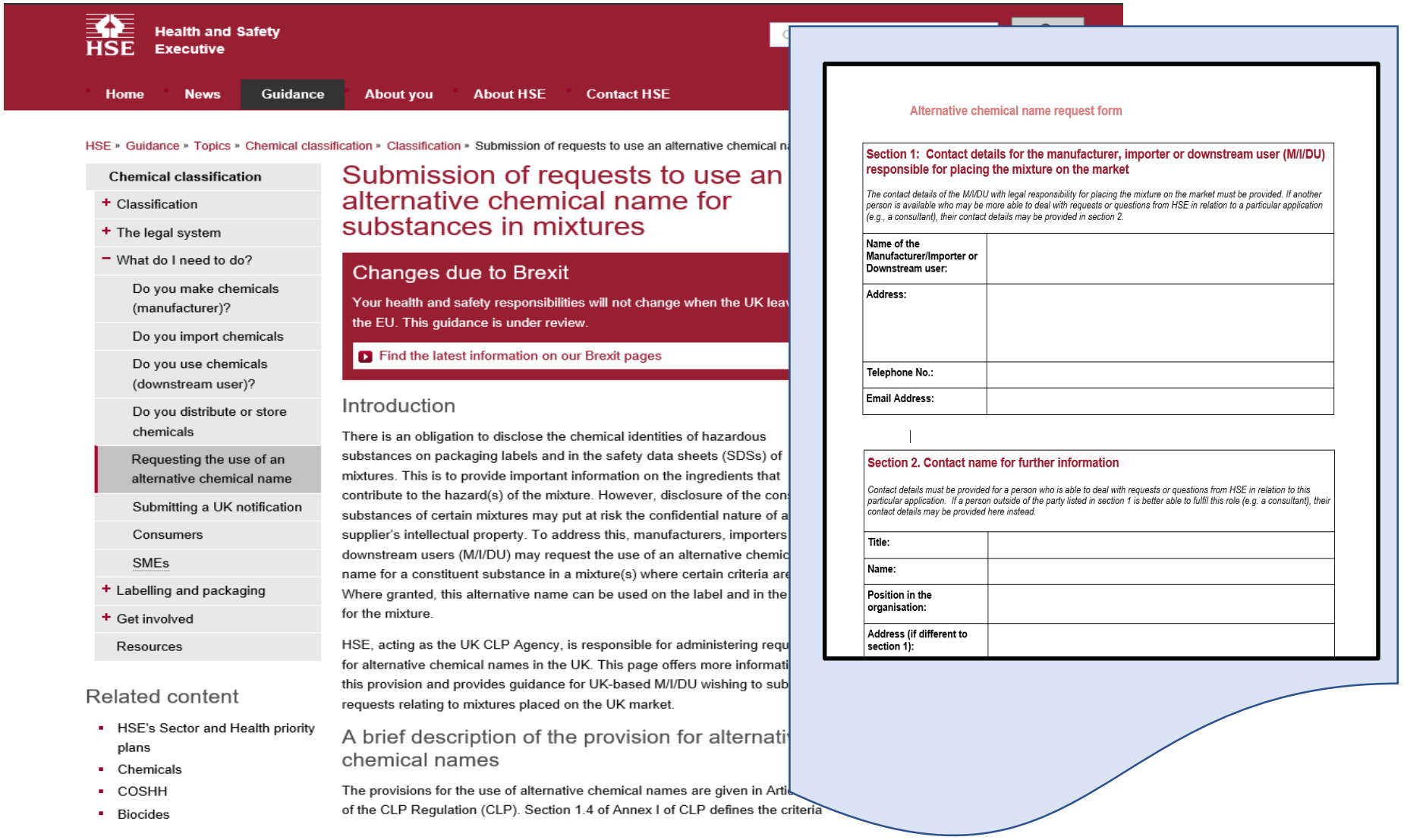
Requesting an alternative chemical name...



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HSE » Guidance » Topics » Chemical classification » Classification » Submission of requests to use an alternative chemical n

Chemical classification

- + Classification
- + The legal system
- − What do I need to do?
  - Do you make chemicals (manufacturer)?
  - Do you import chemicals
  - Do you use chemicals (downstream user)?
  - Do you distribute or store chemicals
  - Requesting the use of an alternative chemical name
  - Submitting a UK notification
  - Consumers
  - SMEs
- + Labelling and packaging
- + Get involved
- Resources

Related content

- HSE's Sector and Health priority plans
- Chemicals
- COSHH
- Biocides

Submission of requests to use an alternative chemical name for substances in mixtures

Changes due to Brexit

Your health and safety responsibilities will not change when the UK leav the EU. This guidance is under review.

Find the latest information on our Brexit pages

Introduction

There is an obligation to disclose the chemical identities of hazardous substances on packaging labels and in the safety data sheets (SDSs) of mixtures. This is to provide important information on the ingredients that contribute to the hazard(s) of the mixture. However, disclosure of the cons substances of certain mixtures may put at risk the confidential nature of a supplier's intellectual property. To address this, manufacturers, importers downstream users (M/I/DU) may request the use of an alternative chemic name for a constituent substance in a mixture(s) where certain criteria are Where granted, this alternative name can be used on the label and in the for the mixture.

HSE, acting as the UK CLP Agency, is responsible for administering requ for alternative chemical names in the UK. This page offers more informati this provision and provides guidance for UK-based M/I/DU wishing to sub requests relating to mixtures placed on the UK market.

A brief description of the provision for alternati chemical names

The provisions for the use of alternative chemical names are given in Arti of the CLP Regulation (CLP). Section 1.4 of Annex I of CLP defines the criteria

Alternative chemical name request form

Section 1: Contact details for the manufacturer, importer or downstream user (M/I/DU) responsible for placing the mixture on the market

The contact details of the M/I/DU with legal responsibility for placing the mixture on the market must be provided. If another person is available who may be more able to deal with requests or questions from HSE in relation to a particular application (e.g., a consultant), their contact details may be provided in section 2.

Name of the Manufacturer/Importer or Downstream user:	
Address:	
Telephone No.:	
Email Address:	

Section 2. Contact name for further information

Contact details must be provided for a person who is able to deal with requests or questions from HSE in relation to this particular application. If a person outside of the party listed in section 1 is better able to fulfil this role (e.g. a consultant), their contact details may be provided here instead.

Title:	
Name:	
Position in the organisation:	
Address (if different to section 1):	

Labelling chemicals under the GB CLP Regulation…

Labelling requirements

- GB CLP hazard labels are there to help identify hazardous chemicals and explain what the hazards are and how to avoid them.
- Under the GB CLP Regulation, there are no significant changes to the existing labelling elements and requirements.
- Hazard labelling for substances and mixture placed on the GB market must be in English although other languages may also appear in addition to English.
- Supplemental information on the label –
  - EUH statements and GB REACH statements
  - Other ‘chemicals’ labelling requirements including those from Biocides, Pesticides and Detergents Regulations.

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Northern Ireland Protocol and CLP

- As a result of the Withdrawal Agreement and the Northern Ireland Protocol, the EU CLP Regulation (Regulation (EC) No. 1272/2008) continues to apply in Northern Ireland including published and upcoming ATPs (harmonised classifications) and Annex VIII which will apply.
- Northern Ireland-based businesses must:
  - notify ECHA of new/revised hazard classification and labelling of their substances to the ECHA Classification and Labelling Inventory.
  - follow scientific and technical developments in relation to the substances and mixtures and update classification and labelling accordingly,
  - submit specific information on their products to the NPIS and include a UFI on the label or, in some cases, the packaging of the products that contain a hazardous mixture

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Northern Ireland Protocol and CLP

- UK Government is committed to unfettered access for NI goods moving to the rest of the UK market.

‘Qualifying NI goods

Only ‘Qualifying NI goods’ will benefit from mutual recognition - enabling goods to continue to be placed on the whole UK internal market - and no checks and controls as goods move from Northern Ireland to the rest of the UK

Qualifying NI goods are:

- any goods present in Northern Ireland (and not subject to any customs supervision, restriction or control which does not arise from the goods being taken out of the territory of Northern Ireland or the European Union)
- any goods that have undergone processing operations in Northern Ireland incorporating either domestic goods or goods not under customs supervision, restriction or control at the time of processing

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Northern Ireland Protocol and CLP

Classification

- Northern Ireland-based manufacturers can supply goods (substances and mixtures) directly to GB (England, Scotland and Wales) if they are supplying qualifying NI goods. These goods must be classified according to the GB CLP Regulation.
- Northern Ireland-based importers must comply with the EU CLP Regulation first. If next they supply directly to the GB market, they effectively become a downstream user or distributor and must ensure the hazard classification and labelling are correct and in accordance with GB CLP Regulation requirements.
- Northern Ireland-based downstream users and distributors who supply directly to the GB market will **not** be able to rely on classification and labelling from others in the Northern Ireland supply chain. They will have to classify the substances and mixtures according to GB CLP Regulation against the CLP application criteria as if they were an importer

Labelling and packaging

- Under the GB CLP Regulation, the existing general requirements on the labelling elements (from GHS), the packaging requirements and exemptions continue to apply
- The substances and mixtures must be labelled in accordance with the hazard classification and any GB mandatory classification and labelling

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Further Guidance

- **HSE webpages**
- For information on GB CLP – see Chemical classification – HSE. Sign-up to HSE's GB CLP e-Bulletin
- For information on GB CLP and Northern Ireland – see Duties of NI-based businesses directly supplying chemicals to Great Britain - Chemical classification (hse.gov.uk)
- HSE still has some information and podcasts on the HSE 'Brexit' webpage - http://www.hse.gov.uk/Brexit/
- Retained Regulation (EC) No. 1272/2008 in GB law - 'GB' CLP Regulation – awaiting changes/amendments from EU Exit to be made
- The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019
- The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020
- If you require further assistance or guidance, please contact EU-Exitchemicals@hse.gov.uk
- **Department of Health and Social Care/ Department of Health**
- Guidance on Submitting chemicals information to the National Poisons Information Service on GOV.UK - If you have any queries, please contact environmental.hazards@dhsc.gov.uk
- **Latest information from the EU on the impact of the withdrawal and the NI Protocol**
- https://echa.europa.eu/uk-withdrawal-from-the-eu
- https://echa.europa.eu/uk-company-based-in-northern-ireland
- https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1701
- **Information from HSENI and the Department for the Economy**
- HSENI - CLP (Classification, Labelling and Packaging)
- HSENI - CLP after the transition period - The North

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Questions

Thank you for listening

REACH and CLP*:
REACH.CLP@HSE.gov.uk

Biocidal Products Regulation (BPR)

Current Regulatory Position

- UK formally left the EU
- Transition Period ended
- Under the NI Protocol, NI continues to follow EU BPR
- GB has a new, independent, regulatory framework.
- Active substance approvals & product authorisations already in place remain valid in GB & NI - (subject to establishment requirements)

Biocidal Products Regulation in GB (GB BPR)

- EU BPR has been ‘lifted & shifted’ into GB BPR
- The new GB regime reflects the EU framework, but they operate independently
- Companies have to be established in UK (GB or NI) for Art 95 listing and product authorisation
- Many GB BPR functions remain the same (no policy changes)
- Some EU functions have been removed as they no longer operate in a GB-only context (‘inoperables’)
- HSE acts as the competent authority for GB
- Live applications have to be resubmitted to HSE with supporting data

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Process Summary – Active Substances & Products What's changed

Main changes
-Application forms
-Templates
-HSE's Upload Link

Main changes
-Communication via email

Main changes
-OMS not involved
-OGDs / DAs

Main changes
-SoS makes decision
-HSE publishes PAR, SPC, public lists

GB BPR
What's not changed

- HSE
- Active Substance Dates of Approval
- Active substance* & Product dates of renewal
- Data requirements
- Evaluation methodology & technical guidance
- Timelines
- Fees (new initial estimates)

GB BPR

- EU active substance (a.s.) Review programme transferred to GB programme where dossiers resubmitted
- GB review programme (priorities/timings) tbc
- Will be set up once a.s. dossiers resubmitted
- Products can remain on market under UK transitional arrangements until a.s. review completed

GB BPR
Transitional Arrangements

Applications not finished before the end of the transition period

- Active substance and product applications to be resubmitted to HSE by :
  - 31 March 2021, where UK=lead
  - 29 June 2021, where UK≠lead
- Use HSE new application form
- Full original data package and any later submissions
- Note and justify any data gaps

GB BPR Transitional Arrangements: Article 95 listing

- EU Article 95 list of suppliers of active substances was transferred to a GB Article 95 list at the end of the Transition Period
- To remain on the GB Article 95 list:
  - businesses must submit a supporting dossier or letter of access, as submitted to ECHA
  - be established in the UK
- Within 2 years of the end of the Transition Period

- HSE will publish which companies have fulfilled the requirements (list updated regularly up to deadline).

(Re)Submission of Applications & dossiers to GB

- Download the relevant Application form from HSE's website
  - Complete form
- Submit application form to HSE via email
- HSE will send an Upload link (secure)
  - Upload your files
  - Link remains valid for 5 working days
  - Only upload files specific to that application

Northern Ireland Protocol (NIP)

- Biocidal Products for NI market

- Biocidal products supplied in NI are subject to EU BPR
- HSE will act as the competent authority on behalf of HSENI
- Applications for NI authorisations and related processes (renewals, changes, etc) to be made to HSE
- Companies have to be established in EU or NI for Art 95 listing and product authorisation

NIP - Unfettered Access from NI to GB

- UK Government committed to ‘unfettered access’ for NI goods moving to the rest of the UK
  - NB. Biocides = ‘Highly Regulated Goods’
- BPR notification procedure:
  - Eligibility: GB a.s. approval, GB Article 95, UK establishment
  - Notify to HSE same information as provided for EU/NI authorisation & authorisation certificate
  - Biocidal product may be made available after 90 days provided no objections raised
  - No charge

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Active substance review programme in NI

- EU active substance (a.s.) review programme still applies in NI
- Products can remain on NI market under transitional arrangements until EU a.s. review completed
- Participants in EU's programme are transferred to GB review programme, if dossiers resubmitted to GB
- Products can remain on market until GB a.s. review completed
- GB and EU review programmes will operate independently – if you supply to NI and GB, keep an eye on both

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Establishment rules

- If necessary companies will need to apply to HSE to change Authorisation Holder (AH)
  - ‘Admin change’ application
  - Use HSE new application form
  - Fee applies
- If both GB & NI markets required : 2 sets of certificates issued, both companies/addresses can go on the product label

Establishment rules

- An authorisation holder of an NI or EU (inc EEA, CH) product must be established in **EU or NI**.
- GB BPR : authorisation holder to be established in **UK (inc NI)**

For an authorisation in…	Authorisation Holder must be established in….	By…
EU/EEA	Northern Ireland or EU/EEA/Switzerland	1 Jan 2021
Northern Ireland	Northern Ireland or EU/EEA/ Switzerland	1 Jan 2021
Great Britain	UK (Great Britain or Northern Ireland)	See below*

*For products already authorised in GB market: 1 year transition period
For resubmissions in GB: by the time HSE authorises
For new applications for GB: on application

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Northern Ireland Protocol (NIP) - Routes to NI market

Apply for a….	To…	Note that…
National authorisation	HSE	Can do joint GB/NI application, HSE will evaluate together provided guidance/requirements the same
Union authorisation	ECHA	UK/ HSE has no involvement. When granted, applies in NI.
Mutual recognition	ECHA, then HSE	Process still in development, likely to be only MR in sequence. An EU reference Member State will authorise. Then you apply to HSE to have it recognised in NI
Simplified authorisation	ECHA, then HSE	Another Member State will issue a simplified authorisation. Then notify to HSE before placing on the NI market.

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Northern Ireland Protocol (NIP)

- Routes to GB market from NI

Apply to	For	Note that…
HSE	National authorisation	Can be done jointly with an NI national authorisation application, assuming guidance/requirements the same. Can apply for simplified authorisations
HSE	Unfettered Access notification	Applies when you already have an authorisation or other permission in NI – then wish to supply that product to GB

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Enforcement of Biocides

The Enforcement Regs remain the same

- Via The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (SI 2013/1506) and NI equivalent

REGISTRATION / AUTHORISATION RELATED DUTIES

- HSE in Great Britain and HSENI in Northern Ireland

SUPPLY-CHAIN RELATED DUTIES

- HSE/HSENI until retail sale (then Trading Standards)
- Advertisement – Local Authorities

USE RELATED DUTIES

- existing GB enforcement regime and enforcing authorities for health, safety and environmental legislation

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Enforcement of Biocides

What stays the same

- The HSE Enforcement Policy
- This is driven by / consistent with the Principles of the Regulatory Reform Act
- The priority and strategy
- Consideration of the activities that pose the greatest risk.
- Duty holders that cause us the greatest concern.

Further Information

- Website info for GB
  https://www.hse.gov.uk/biocides/index.htm
- GB Fact sheets for active substances and products
  https://www.hse.gov.uk/biocides/biocides-fact-sheet.pdf
- Application forms
  https://www.hse.gov.uk/biocides/information.htm
- Method for submitting applications & supporting data to HSE
- Products - https://www.hse.gov.uk/biocides/eu-bpr/product-authorisation-overview.htm
  (provides links to type of application e.g. National, Simplified, Changes etc.
- Actives - https://www.hse.gov.uk/biocides/how-to-apply.htm
- Article 95 - https://www.hse.gov.uk/biocides/uk-article-95-how-to-apply.htm

- Biocides e-bulletin:
  Sign up for free from our website (links above)

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Questions

Thank you for listening

- Applicant questions - GB.Biocides@hse.gov.uk
- NI only questions - NI.Biocides@hse.gov.uk
- Scope/general advice - biocidesenquiries@hse.gov.uk
- Enforcement- CRDEnforcement@hse.gov.uk

Prior Informed Consent

Prior Informed Consent (PIC) – After the UK Transition Period

Unchanged

- HSE continues to act as the GB PIC Designated National Authority (DNA) & HSENI for NI – EU PIC continues to apply in NI.

Main Changes

- Companies exporting PIC-listed chemicals from Great Britain can no longer use ePIC and now need to notify HSE of exports of listed chemicals using the new notification procedures.
- The GB PIC regime applies to listed chemicals that are exported from Great Britain, including to EU countries and to NI. Companies that currently only move listed chemicals within the EU single market and do not export them outside the EU or NI have to notify these to HSE.

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Prior Informed Consent (PIC) – After the UK Transition Period

Main Changes (continued)

- Where explicit consent has been given by an importing country to another EU country under the previous EU PIC arrangements, it is necessary to seek the consent of that country for GB exports of the chemical. HSE will seek consent on the exporter's behalf.

- Exporters and importers will need to include in the information they submit to HSE in the first quarter of each year, details of the quantities of listed chemicals exported to or imported from EU countries and NI, as well as other countries.

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Prior Informed Consent (PIC) – After the UK Transition Period

HSE Health and Safety Executive

Form for export notification of a PIC chemical/mixture/article

Note for the importing country:

This export notification for a chemical that is banned or severely restricted in the United Kingdom (UK) is sent by the PIC Designated National Authority (UKDNA) in accordance with Article 8 of Regulation (EU) No 649/2012, as it forms part of domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018.

The UKDNA will only notify the first yearly export from the UK to your country of the chemical, mixture or article identified below. You are kindly requested to acknowledge receipt of this export notification within 30 days of the date of the email, preferably by completing the form for acknowledging receipt, attached to the email.

Reference number:

Exporting country:

Importing country:

HSE

Guidance on UK PIC: Your roles and duties

Contents

Preface

This guidance has been prepared by HSE as the PIC Designated National Authority (UK DNA). The aim of this document is to describe the new processes in place for the export and import of banned or severely restricted chemicals under UK PIC (following the UK's withdrawal from the European Union). Some parts of ECHA's current Guidance on the EU PIC Regulation (649/2012) are still relevant and can be found within the PIC guidance document publicly available on the ECHA website.

Introduction

The PIC UK DNA has created this short guidance to assist UK exporters of PIC-listed chemicals to comply with the requirements of the UK PIC system for notifying exports of certain hazardous chemicals. This document covers the changes to the EU PIC Regulation made by virtue of Section 3 of the EU Withdrawal Act 2019 to enable it to operate in the UK after EU

UK PIC List

(referred to in Article 7 of the PIC Regulation)

Part 1

Chemicals subject to export notification procedure

(referred to in Article 8 of the PIC Regulation)

Where chemicals listed in this part of the UK PIC List are subject to the PIC procedure, the export notification obligations set out in Article 8(2), (3) and (4) will not apply provided that the conditions laid down in points (b) and (c) of the first subparagraph of Article 8(6) have been fulfilled. Such chemicals, which are identified by the symbol '#' in the list below, are listed again in Part 3 of the UK PIC List for ease of reference. Where the chemicals listed in this part of the UK PIC List qualify for PIC notification, those chemicals are also listed in Part 2 of the UK PIC List. Such chemicals are identified by the symbol '+' in the list below.

Chemical	CAS Number	Einecs No	Commodity code (**	Subcategory (*)	Subcategory (*)	Countries for which no notification is required

Further Guidance

Guidance for NI businesses on EU Exit and the NIP for PIC can be found at https://www.hse.gov.uk/brexit/pic-ni.htm
Information on 'GB' PIC is available on the HSE webpages - The Prior Informed Consent (PIC) Regulation - HSE
Information is also available on ECHA's website at https://echa.europa.eu/advice-to-companies-q-as/general and https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1711
HSENI has published further information and resources on PIC on its website - PIC – Prior informed consent | Health and Safety Executive Northern Ireland (hseni.gov.uk)