Requirements for Toys in UK

Detailed insight into the legal situation from January 1st, 2021

November 2022

BREXIT

The United Kingdom (UK) left the European Union on January 31st, 2020 (Exit Day). After the end of the "UK/EU Implementation Period" (IP) at January 1st, 2021 (IP Completion Day), UK became a third country with its own independent legislation. For some aspects, UK regulators postponed the deadline to give companies time to comply (UK transition period). Although the United Kingdom as a whole has left the EU, there are different provisions in Great Britain ("GB") which comprises England, Scotland and Wales than in Northern Ireland ("NI").

To give further assistance, the UK government released a Collection Brexit guidance (published on March 28th, 2022) to find out how new Brexit rules apply to things like travel and doing business with Europe. The guidance Product safety for businesses: A to Z of industry guidance (last updated April 3rd, 2020) gives an overview of product specific regulations of the UK. Official guidance is available for Placing manufactured goods on the market in Great Britain from January 1st, 2021 (last updated November 14th, 2022) as well as Placing manufactured goods on the market in Northern Ireland (published December 31st, 2020). Additionally, the Department for Business, Energy & Industrial Strategy (BEIS) is presenting a series of webinars to give an overview of the new responsibilities and regulations for businesses regarding using the UKCA marking and placing goods on the market in Great Britain and Northern Ireland.

NORTHERN IRELAND

The Ireland/Northern Ireland protocol is a Brexit Withdrawal Agreement avoiding a hard border on the island of Ireland and protecting North-South cooperation. It governs the unique customs, trade of goods and immigration issues at the border between the United Kingdom of Great Britain and Northern Ireland and the European Union. For as long as it is in force, EU free movement of goods rules still apply in NI. Northern Ireland will align with relevant EU rules relating to the placing on the market of manufactured goods. A special feature is the conformity mark: Products that have been approved by a UK Notified Body must bear the CE mark and the UKNI mark (see below).

The UK government committed to providing unfettered access for "qualifying NI goods" (QNIG) to the rest of the UK market without the need for additional approval. Goods processed in Northern Ireland are qualifying Northern Ireland goods if they are in free circulation in Northern Ireland - that means not under a customs procedure or in an authorized temporary storage facility - before moved from Northern Ireland to Great Britain (see guidance Moving qualifying goods from Northern Ireland to the rest of the UK). Goods starting their journey in the EU will not qualify for unfettered access if they are moved through Northern Ireland into Great Britain for an avoidance purpose.

GENERAL MARKETABILITY OF GOODS

All stock that had been placed on the GB or EU market (manufactured, labelled and offered for sale) before the end of the UK/EU Implementation Period can continue to be circulated in the GB market and EU without changes. New deliveries placed on the market after December 31st, 2020 must comply with the appropriate new requirements.

Products as well as accompanying information (instructions, leaflet, and document accompanying the toy or packaging) have to be labelled with the market placer's details, including the company's name and a contact address. Now after Brexit, a UK Address is needed for circulation in the UK and an EU Address for circulation in the EU.

For marketing imported goods in the UK, companies have the following options:

a) Use of a UK based office address (e.g. of a subsidiary or a local representative) or

b) The Customer, previously considered a distributor, will become an Importer (his name and address must be added) or

c) Appointment of a UK based "Authorized Representative".

In November 2022, the UK government announced to give business 2 additional years to adjust product marking and that it will be allowed to include importer information for products from EEA countries on an accompanying document or label until December 31st, 2027. After that date, importer details must be affixed directly on the product.

TRANSFORMATION OF EUROPEAN LAWS AND STANDARDS INTO UK LEGISLATION

On January 1st, 2021, the UK Regulations were comprehensive and included all aspects of the corresponding EU laws. The EU Withdrawal Act 2018 preserved the UK Regulations and enabled them to be amended so as to continue to function effectively. All EU decisions legally in force on December 31st, 2020 (e.g. CLP harmonized classification and BPR active substance decisions) became UK law.

EU Regulations were replaced by specific EU Exit Regulations (e.g. the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 for the transposition of European REACH Regulation (EC) no. 1907/2006), which came into force on the exit day. UK Regulations implementing EU Directives were revised by Amendment Regulations (e.g. the Product Safety and Metrology etc. (EU Exit) Regulations 2019) to fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the UK market. Support was given by the UK government with the excel table relevant UK rather than EU legislation comparing EU legislation and UK legislation.

In the context of the UK's EU Exit, the original set of UK Regulations had to be amended by separate versions for Great Britain and Northern Ireland, as different changes were required here. Great Britain wants to enact its own provisions whereas Northern Ireland is aligning with relevant EU rules relating to the placing on the market of manufactured goods while the Northern Ireland Protocol is in force. Various UK regulations (e.g. The Toys (Safety) Regulations 2011) needed to be amended by The Product Safety and Metrology etc. (Amendement etc.) (EU Exit) Regulations 2019 (S.I. 2019/696) to capture the UK specific issues. These 2019 Regulations were then further amended by regulations that apply in Great Britain respectively in Northern Ireland only. GB enforced The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/1676) whereas NI enacted The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112) to give effect to the Ireland/Northern Ireland protocol (e.g. "the United Kingdom" is substituted by "Northern Ireland" and "relevant state means Northern Ireland or any EEA state"). The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460)

regulates details of the UKNI marking and marketability of 'qualifying Northern Ireland goods' which have been correctly CE marked (or, where applicable, UK NI marked) in GB.

Further information is available in the guides on specific product safety and metrology for Great Britain (Product safety and metrology from January 1st, 2021: Great Britain) as well as Northern Ireland (Product safety and metrology from January 1st, 2021: Northern Ireland).

EU legislation	UK Statutory Instrument	UK Amendment for Brexit
DIR 2009/48/EC (TSD) on the Safety of Toys	The Toys (Safety) Regulations 2011	The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019
REG (EC) No. 1223/2009 on Cosmetics	The Cosmetic Products Enforcement Regulations 2013	
DIR 2014/35/EU (LVD) electrical equipment designed for use within certain voltage limits (recast)	The Electrical Equipment (Safety) Regulations 2016	
DIR 2014/53/EU (RED) on radio equipment	The Radio Equipment Regulations 2017	
DIR 2014/30/EU (EMC) on electromagnetic compatibility (recast)	The Electromagnetic Compatibility Regulations 2016	
REG (EC) No. 1935/2004 (FCM) on materials and articles intended to come into contact with food	The Materials and Articles in Contact with Food (England) Regulations 2012	The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019
REG (EC) no. 1272/2008 (CLP) on classification, labelling and packaging of substances and mixtures	The Classification, Labelling and Packaging of Chemicals(Amendments to Secondary Legislation) Regulations 2015	The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (CMGO Regs 2019)
REG (EU) No 528/2012 (BPR) concerning the making available on the market and use of biocidal products	The Biocidal Products Regulations 2001 (BPR)	
REG (EC) No. 1907/2006 (REACH) on Registration, evaluation, authorisation and restriction of chemicals	REACH (Enforcement) Regulations 2008	The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019
REG (EU) 2019/1021 (POP) on persistent organic pollutants (recast)	Persistent Organic Pollutants (POPs) Regulations 2007	The Persistent Organic Pollutants (Amendement) (EU Exit) Regulations 2019 (S.I. 2019/1340)
DIR 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment	Restriction of Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012	The Waste (Miscellaneous Amendments) (EU Exit) (No. 2) Regulations 2019
DIR 2006/66/EC on batteries and accumulators and waste batteries and accumulators	The Batteries and Accumulators (Placing on the Market) Regulations 2008	
DIR 94/62/EU on packaging and packaging waste	The Producer Responsibility Obligations (Packaging Waste) (Amendment) Regulations 2010	

Table 1: Examples of legislation relevant for toys.

Since January 1st, 2021, the GB regulations and the corresponding EU regulations and standards operate independently from each other. Thus, the GB Regulations are not amended automatically when changes in EU legislations occur and UK will have a separate discussion on whether and to what extent GB should adopt these changes. Accordingly, there may be differences between the EU and the GB and companies need to ensure that the relevant duties are met under both pieces of legislation. Due to the timing of Brexit, GB regulations are lacking behind in implementation of amendments and further legal updates like harmonization of new versions of standards. As the additional UK legislation process always requires a certain period of time, currently the changes of the EU law come into force in GB with a delay of several months.

On September 22nd, 2022, Prime Minister Liz Truss's new government introduced the Brexit Freedoms Bill to parliament, announcing that all retained EU laws will sunset on December 31st, 2023, giving ministers new secondary powers to amend, replace or repeal them. All EU legislation will be amended, repealed, or replaced, which will end the special legal status of all retained EU law by 2023, and give the UK the opportunity to develop new laws that best fit the needs of the country and grow the economy.

European standards (EN) are still valid and were not changed. As before, they use the prefix 'BS' to indicate that they are standards adopted by the UK's national standards body British Standards Institution (BSI). BSI currently remains a full member of CEN and CENELEC, enabled by the fact that their General Assemblies have created a new type of full member. In practical terms, this means that the rights of BSI experts to contribute to European technical work continues as does the right of BSI to propose new work items, apply to hold secretariats and to nominate committee chairs.

UK also kept the principle of standards assigned to a directive. After December 31st, 2020, EU harmonized standards became "Designated standards" in the UK. As soon as a standard is referenced in the corresponding UK list of designated standards (recognized by government in part or in full by publishing its reference on GOV.UK in a formal notice of publication) it is considered to be mandatory for "presumption of conformity" with the corresponding regulations. The designation process is lead and coordinated by the Office for Product Safety and Standards (OPSS). In December 2020, OPPS published an initial lists of designated standards. General information and links to designated standards for various regulations can be found on the website Guidance Designated Standards (last updated January 10th, 2022). In case of amendments, BSI submits propose updates to the list of standards OPSS. Guidance and latest proposals are shown on the official website Designated standards: new or amended notices of publication (last updated September 27th, 2022).

UK TOYS SAFETY REGULATIONS (S.I. 2011/1881)

The Toys (Safety) Regulations 2011 (S.I. 2011/1881) implemented the requirements of the European Directive on the Safety of 2009/48/EC (TSD). To deal with aspects related to the EU exit, the regulations were amended by schedule 15 of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696). For handling further amendments, the Office for Product Safety and Standards (OPSS) mandates the Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS) to provide an opinion. OPSS will then review the opinions from SAG-CS and draft an amending UK Statutory Instrument.

The initial version of the Toys (Safety) Regulations 2011 on January 1st, 2021 reflected the state of the European TSD in 2018 last updated with amendment of Annex II Appendix C as regards addition of phenol and lowered limit for bisphenol A as well as adaptation of point 13 of part III of Annex II as regards lowered limits for chromium VI and lead. On June 16th, 2022, The Toys and Cosmetic Products (Restriction of Chemical Substances) Regulations 2022 (S.I. 2022/659) was published which amended the Toys Regulations as well as the Cosmetics Regulations. The

limits for aluminum, formaldehyde and aniline entered into force on October 15th, 2022 whereas the requirements for prohibited allergenic fragrances will apply from December 15th, 2022. This amendment aligned the UK with EU requirements that were not yet transposed following Brexit, except for the extended list of fragrance allergens that require labelling on toys. The latter is expected towards the end of the year 2022.

However, SAG-CS plans stricter rules in future to achieve even better protection. Within their Opinion on Formaldehyde in Toy Materials, they regard the new limits are indeed a good first step, but based on the indoor air quality guidelines from Public Health England (now UK Health Security Agency), but further reductions in exposure may be justified. Additionally, requirements for formaldehyde in toy materials aimed at children older than 36 months, or not intended for mouthing/chewing should be considered. Concerning aniline, the scientific advisory group concluded that the limit values adopted by the EU are likely to be adequately protective and should be implemented as an interim measure until health-based limit values can be derived. Further work could be undertaken to ascertain whether these levels should be further lowered.

Commission Implementing Decision (EU) 2021/1992 of November 15th, 2021	Consolidated list of designated standards on toy safety Version 2, September 1st, 2022
EN 71-1:2014+A1:2018	EN 71-1:2014+A1:2018
EN 71-2:2020 *EN 71-2:2011+A1:2014 will be withdrawn by May 15th, 2022*	EN 71-2:2020
EN 71-3:2019+A1:2021 *EN 71-3:2019 will be withdrawn by May 15th, 2022*	EN 71-3:2019+A1:2021 *Notice: The interpretation of clause 7 of the standard should be taken to require that test portions should not be made up of combined materials prior to the migration and analysis stages of the test.*
EN 71-4:2020 *EN 71-4:2013 will be withdrawn by May 15th, 2022*	EN 71-4:2020
EN 71-5:2015	EN 71-5:2015
EN 71-7:2014+A3:2020 *EN 71-7:2014+A2:2018 was withdrawn on November 28th, 2021*	EN 71-7:2014+A3:2020
EN 71-8:2018	EN 71-8:2018
EN 71-12:2016 *Instead of the limit values from point (a) of Table 2 of clause 4.2 of EN 71-12:2016, compliance with the limit values set in point 8 of part III of Annex II to Directive 2009/48/EC is required.* *EN 71-12:2013 was withdrawn on November 28th, 2021*	EN 71-12:2016 *Notice: The limit values in point a) of Table 2 of clause 4.2 of standard 'EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances' are lower than the limit values to be complied with set in point 8 of part III of Annex II to S.I. 2011/1881.*
EN 71-13:2021 *EN 71-13:2014 will be withdrawn by May 15th, 2022*	EN 71-13:2021
EN 71-14:2018	EN 71-14:2018
EN IEC 62115:2020 EN IEC 62115:2020/A11:2020 *EN 62115:2005 and its amendments were withdrawn on November 28th, 2021*	EN 62115:2005 EN 62115:2005/A2:2011 EN 62115:2005/A11:2012 EN 62115:2005/A12:2015 EN 62115:2005/A2:2011/AC:2011 EN 62115:2005/A11:2012/AC:201

Table 2: Harmonized standards for Directive 2009/48/EC (TSD) versus designated standards for The Toys (Safety) Regulations 2011

On December 9th, 2020, OPSS and BEIS published the first version of consolidated list of designated standards on toy safety (version 1, January 1st, 2021). This reflected the list published in the EU's Official Journal (OJEU) with Commission Implementing Decision (EU) 2019/1728. Meanwhile, the EU had two updates of the standards listed in OJEU (latest update was Commission Implementing Decision (EU) 2021/1992 of November 15th, 2021). In September 2022, UK updated its list (Designated standards: toy safety – notice of publication, September 1st, 2022). The only remaining difference is now in the standards for electrical safety (EN 62115). In practice, this means that currently some toys with electrical function have to be tested and assessed separately for each of the two sales markets, as certain technical changes in the standards can lead to different results.

The Office for Product Safety & Standards (OPSS) released on the website Statutory guidance Toys (Safety) Regulations 2011 (last updated November 17th, 2022) further guidance for businesses on the regulations as they apply to toys being supplied in or into Great Britain respectively Northern Ireland.

UKCA MARKING

The new UKCA (UK Conformity Assessed) marking is a new UK product marking applicable for goods being placed on the market in Great Britain that required the CE marking previously. Conditions for attachment and appearance of the UKCA marking are regulated by Schedule 5 Article 30 of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019. Harmonized goods can carry both the CE and UKCA marking.

The UKCA marking is applicable from January 1st, 2021. However, to allow businesses time to adjust to the new requirements, CE marked goods can continue to be placed on the GB market until December 31st, 2024 (in October 2022, extension of another 2 years to the transitional period was granted) as long as the rules in EU and UK remain the same (no deviations between EU and UK legislations arose). In any case, UKCA marking will be required from January 1st, 2021 if products require generally mandatory third party conformity assessment not applicable for toys but e.g. for medical devices) or have had conformity assessment by a UK Approved body (e.g. type examination of a cuddly toy with double-function as a warming pad, in which the filling is heated in the microwave oven).

Rules for using the UKCA image:

- fixed proportion for the letters forming the UKCA marking
- height at least 5mm (unless different specification in relevant legislation)
- easily visible, legible
- different colors (solid or transparent) are possible
- can be affixed alongside other markings, such as CE marking

Details are described in the official guidance Using the UKCA marking (last updated November 14th, 2022) issued by the Department for Business, Energy & Industrial Strategy (BEIS) and also in their document UKCA Implementation Guidance (last updated in June 2022). In June 2022, BEIS further published a short UKCA guidance for businesses as well as a UKCA Step-by-Step Guide.

Product specific regulations define where to place the UKCA marking. The Toys (Safety) Regulations 2011 demand that the UKCA label must be affixed to either the toy or a label affixed to the toy or the toy's packaging unless the toy is small or consists of small parts (reflecting Directive 2009/48/EC). Until December 31th, 2027, the UKCA may alternatively be placed on a label which is not affixed to the product or a leaflet which accompanies the product (UK government extended the deadline to reduce labelling costs). However, this must stay with the good until it reaches its end user.

For Northern Ireland, CE marking or and UKNI marking together with CE marking is to be used. Products which are marked on the basis of a self-assessment or have been checked by an EU Notified Body bear the CE mark. Products that have been approved by a UK Notified Body must bear the CE mark and the UKNI mark.
The UKNI indication is introduced by Schedule 1 of The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020. Products specific requirements are regulated within schedule 2 (e.g. Part 5 to amend The Toys (Safety) Regulations 2011). Further information can be found on the official website Using the UKNI marking from January 1st, 2021 (last updated February 1st, 2022).

Rules for using the UKNI image:

- fixed proportion for the letters forming the UKNI marking
- height at least 5mm (unless different specification in relevant legislation)
- easily visible, legible
- different colors (solid or not) are possible
- must accompany the CE Marking

DECLARATION OF CONFORMITY (DOC)

Like the EC declaration of conformity for the CE-marking, most products lawfully bearing a UKCA marking must be accompanied by a UK declaration of conformity. The UK DoC is identical in format and appearance to the EU DoC but in the content some UK adaptations are to be done:

- relevant UK regulations rather than EU legislation
- UK designated standards rather than standards cited in the Official Journal of the European Union

The declaration must match the attached conformity mark. As long as CE-marking is used, the EU declaration of conformity must be supplied. As soon as the product bears a UK marking, it must be accompanied by a UK declaration of conformity. Although both conformity marks may be affixed to the same product, EU and UK DoC should be separate documents and not merged into one.

CONFORMITY ASSESSMENT

After Brexit, UK-based Notified Bodies turned into UK approved bodies. The UK Market Conformity Assessment Bodies (UKMCAB) database serves as the UK's database of Conformity Assessment Bodies (CABs) and replaces the EU's New Approach Notified and Designated Organizations (NANDO) database. The United Kingdom Accreditation Service (UKAS) will continue as national accreditation body.
UK approved bodies must be established in the UK (as it is the other way round for the EU). Currently there is no system of mutual recognition and CE conformity assessment must be done by an EU Notified Body whereas UK conformity assessment must be done by a UK approved body. On September 14th, 2022, UK government announced to allow conformity assessment activities for CE marking undertaken by December 31st, 2024 to be used by manufacturers as the basis for the UKCA marking, until December 31st, 2027.

For Northern Ireland, either an EU recognized Notified Body (obligation to use CE-marking) or a UK approved body (in this case the labelling with CE marking accompanied by the UKNI marking is required) can be commissioned.

Further details can be found in the guidance Conformity assessment and accreditation (last updated January 1st, 2021) issued by OPSS.

LEGISLATION CONCERNING CHEMICALS

The Health and Safety Executive (HSE) is Britain's national regulator for workplace health and safety. Its work covers a varied range of activities from shaping and reviewing regulations, producing research and statistics and enforcing the law. HSE's Chemicals Regulation Division (CRD) is responsible for the regulation of biocides, detergents, chemicals covered by REACH, and for compliance with the CLP-Regulation (Classification, Labelling and Packaging). The Department for Environment Food & Rural Affairs (Defra) has the lead responsibility for professional plant protection products (PPPs), submission and managing chemical registrations and notifications under REACH, fluorinated gas (F gas) as well as persistent organic pollutants (POPs).

UK REACH: REACH (Enforcement) Regulations 2008 (S.I. 2008/2852)

EU REACH Regulation was brought into UK law as REACH (Enforcement) Regulations 2008 (S.I. 2008/2852). REACH, and related legislation, was replicated in the UK with the necessary changes and the key principles of the EU REACH Regulation will be retained. The functions and powers of the Agency under the REACH legislation (ECHA) have been taken over by the HSE. Official guidance can be found on the HSE Website UK registration, evaluation, authorization and restriction of chemicals (REACH).

EU and UK registrations are not recognized vice versa and for each market supplied, an independent registration must have been made prior to placing the substance on the market. EU/EEA based companies who import chemicals into the UK under UK REACH can register the substance under UK REACH through a UK-based Only Representative (OR) or an affiliate UK importer.

1. Transfer of UK-based existing EU-Registrations ('Grandfathering')
   Immediately after Brexit, UK based registrations could shift existing EU-registration directly into UK REACH by data validating. UK-based holders had 120 days (by April 30th, 2021) to provide HSE with some initial information and may continue the 'grandfathering' process by providing basic information within 300 days plus either 2, 4 or 6 years (see table 3). If the EU registration was transferred to UK before January 1st, 2021, the registration could be treated as held by GB entity.
   Defra has published a "grandfathered registration notified substances list" on GOV.UK which includes the names and CAS/EC numbers for substances taken from notifications made under Article 127B(4)(a) of UK REACH.

2. Downstream User Import Notification (DUIN)
   GB-based legal entities that were a downstream user or distributor under EU REACH or were regarded as a downstream user by virtue of an Only Representative (OR) agreement in the 2 years prior to January 1st, 2021 (as defined in Article 127E), benefit from the deferred registration deadline by submitting a DUIN to HSE before October 27th, 2021 (300 days from January 2021) for 2, 4 or 6 years (see table 3). A DUIN is not an obligation to register.
   DUIN could also submitted by manufacturers, formulators and article producers based outside of Great Britain that appointed a GB-based OR to notify on behalf of their GB-based customers.

3. New registrants under UK REACH
   A new registration is required if grandfathering or DUIN is not possible (e.g. for formulators based outside of GB intending to appoint a GB-based OR).
   The first step of any new registration is to submit an Article 26 Inquiry. The applicant's contact details will be shared with existing registrants, grandfathered registrants and other successful inquirers regarding that

substance. This will enable stakeholders to engage in the data sharing process. If there is more than one registrant for a substance, co-registrants should agree between themselves who the "lead registrant" will be. Once a potential registrant has received his inquiry number, he will be able to submit his registration dossier.

The registration deadline depends on tonnage and/or hazard profile of substance.

Deadline (last date for dossier submission)	Tonnage per year	Hazard properties
October 27th,2023	≥ 1000	• Carcinogenic, mutagenic or toxic for reproduction (CMR) - 1 tonne or more per year • Very toxic to aquatic organisms (acute or chronic) - 100 tonnes or more per year • Candidate list substances = SVHC (as at December 31st, 2020)
October 27th, 2025	≥ 100	Candidate list substances = SVHC (as at October 27th, 2023)
October 27th, 2027	≥ 1	[nothing special]

Table 3: Deadlines for Registration under UK-Reach after notification

An extension of the registration deadlines is currently being considered. The UK's Department for Environment, Food and Rural Affairs (Defra) was seeking views on extending the current UK REACH submission deadlines for REACH registration. This consultation ran from July 5th, 2022 to September 1st, 2022. Under option one, Defra would extend all current submission deadlines for each tonnage band by three years to October 2026, October 2028 and October 2030. Option two would extend the first deadline to October 2026, the second deadline to October 2027 and the third deadline to October 2028. Option three was to do nothing.

The database "Comply with UK REACH" is an IT-tool for businesses to submit information to HSE. This functions for article 26 inquiries as well as submission and management of chemical registrations and notifications. Defra gives further guidance on the website Comply with UK REACH: submit and manage chemical registrations and notifications (last updated June 22nd, 2022).

UK REACH restriction process for Annex XVII is similar to that in the EU. A restriction for a substance, mixture treated article will be introduced if evidence shows an unacceptable risk to human health and the environment. After request from the Defra Secretary of State, with agreement from the Scottish and Welsh Governments, HSE will prepare an Annex 15 dossier. Article 69(6) of UK REACH requires HSE to publish proposals for restrictions on its website. This will open a 60-day call for evidence allowing interested parties to express their views and concerns. The feedback gathered will be taken into account when forming an opinion within the creation of the restriction dossier. This stage of "opinion development" can last several months until the prepared dossier is finally submitted. When the dossier has been published, within 6 months a public consultation takes place where all interested parties are invited to consider the questions posed. HSE will further engage with independent experts on the REACH Independent Scientific Expert Pool (RISEP), who will form a Challenge Panel to provide knowledge, scrutiny and challenge. Afterwards HSE, with support from the Environment Agency (EA), will conduct the scientific review of the evidence as well as Risk Management Option Analysis (RMOA) and consider how best to manage any identified risks. Ultimate decision will be done by the Secretary of State. On HSE's website links to the List of restrictions as well as to the Registry of restriction intentions (including links to public consultations) can be found.

Regarding Substances of Very High Concern (SVHC), all substances that were on the EU REACH candidate list were carried over onto the UK REACH Candidate List of substances of very high concern (SVHCs) for Authorization when UK REACH came into force (version of June 25th, 2020). The UK REACH work programme for 2021/22 states that HSE will assess all the substances that have been submitted for identification as Substances of Very High Concern (SVHCs) in EU REACH at the time the work programme was published (if they are not already on the UK REACH Candidate List) and consider if they are appropriate for SVHC identification in UK REACH. Recently, HSE has assessed 11 substances and substance groups as potential UK SVHC that were submitted for identification as SVHC in EU REACH in 2021. For details about UK REACH approach to including substances of very high concern on the candidate list see the policy paper (published on December 9th, 2021). The Defra Secretary of State, Welsh ministers, Scottish ministers and HSE can put a substance forward for inclusion on the candidate list. HSE, with the Environment Agency will then prepare a dossier in accordance with Annex 15 of UK REACH to formally identify how a substance meets the SVHC criteria.
Periodically, HSE will recommend priority substances for inclusion in the Authorization List and publishes the UK REACH Authorization List (Annex 14). The database on authorization decisions gives information on granted authorizations and applications in progress.
Public consultations about identification as Substances of Very High Concern (SVHCs), inclusion of substances in Annex 14 of UK REACH, applications for authorization, restriction proposals and further topics are published on the HSE Consultations Hub and interested parties will be invited to comment within a set timeframe.
Currently, there is no UK legislation implementing Article 9(1)(i) of the Waste Framework Directive (WFD) 2009/48/EC that provides submit information on SVHC in articles to the SCIP (Substances of Concern In articles as such or in complex objects (Products)) database.

Differences will also occur in the substances scheduled for other regulatory control. The current UK rolling action plan (RAP) recently listed two substances which are not listed in the EU's Community rolling action plan (CoRAP). In contrast to this, the EU's CoRAP lists 58 assessment which have either not been started or are under development.

The Safety Data Sheets (SDS) will contain the information necessary to allow employers to do a risk assessment as required by the Control of Substances Hazardous to Health Regulations (COSHH). The format, content and conditions under which SDS remained the same as specified in the EU REACH Regulation.

POPs: The Persistent Organic Pollutants Regulations 2007 (S.I. 2007/3106)

The Persistent Organic Pollutants Regulations 2007 (S.I. 2007/3106) originally implemented Regulation (EC) No. 850/2004. The Persistent Organic Pollutants (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1405) was released to fix regulatory aspects concerning Brexit. After the EU set up Regulation (EU) 2019/1021 on persistent organic pollutants (recast), The Persistent Organic Pollutants (Various Amendments) Regulations 2019 (S.I. 2019/1099) transposed the references from the old EU Regulation to the new EU Regulation. Further formal corrections were done with The Persistent Organic Pollutants (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1340) and The Persistent Organic Pollutants (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1358). The current UK POPs Regulations refer to EU POPs Regulation (EU) 2019/1021 in its original version. Substances currently classified as POPs in UK have been published by the Environment Agency within the guidance Using persistent organic pollutants (POPs) (last updated September 21st, 2021).
UK is a signatory the Stockholm Convention on Persistent Organic Pollutants, a treaty negotiated under the auspices of the United Nations Environment Programme (UNEP). The UK is still a member in the UN Economic Commission

for Europe (UNECE). Thus, future updates will reflect Stockholm Convention decisions but not necessarily changes to the EU POPs Regulation if it diverges.

GB CLP: The Classification, Labelling and Packaging of Chemicals (Amendments to Secondary Legislation) Regulations 2015 (S.I. 2015/21)

The EU CLP Regulation as amended, is retained in GB law. In order to operate fully and effectively in Great Britain, The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720) was enacted and later amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2019/1567). The requirements and labelling requirements were not significantly changed and existing European harmonized classification were transferred. In the future, Great Britain will continue to adopt the United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS) in a similar way to the EU CLP Regulation. However, new classifications may differ from EU assessment. Great Britain mandatory classification and labelling (GB MCL) replaces the EU harmonized classification and labelling system. Information on the single substances can be found in the GB mandatory classification and labelling list (GB MCL list). It is amended annually to keep the entries up to date with scientific and technical developments. Updating the GB MCL List is similar to how EU harmonized classification is updated. Introducing new or revising existing GB MCL comprises the following stages:

1) GB MCL proposal for new or revised GB MCL
   Proposals may be submitted either by GB-based manufacturers, importers and downstream users of substances or GB CLP competent authorities (the Secretary of State, and Scottish and Welsh ministers) or HSE (as the GB CLP Agency).
2) Public consultation on GB MCL proposals (8 weeks)
   The aim is to gather information on the scientific and technical aspects of proposed classifications as well as the policy and socio-economic aspects of such a proposal. A summary of responses to the public consultation is published on the HSE website.
3) GB CLP Agency (HSE) GB MCL Technical Report
   Specialists in HSE and the Environment Agency will carry out a detailed scientific analysis of the available data, including information submitted during the public consultation, and decide on the substance's intrinsic hazardous properties. A GB MCL Technical Report will be created and published on the HSE GB CLP publication table.
4) GB CLP Agency (HSE) GB MCL Opinion
   The GB MCL Technical Report is combined with an assessment of possible socio-economic costs and benefits and policy impacts of the proposal to produce the GB MCL Agency Opinion which is also published on the HSE website. It forms the basis of the recommendation made to ministers for new or revised GB MCL.
5) GB MCL Recommendation and Decision amending the GB MCL List
   Where HSE considers it appropriate to introduce or revise a GB MCL, it must, within 12 months of the publication of the GB MCL Agency Opinion, make a recommendation to the Secretary of State (ministers) to give effect to the Opinion. Usually this happens once a year. The final Decision on the new or revised GB MCL is made by the Secretary of State, with the consent of the Scottish and Welsh Governments.

Further details can be found on the HSE Website GB classification and labelling.

Analogously to the EU's C&L-inventory database, a system called GB CLP substance notification was established. The GB CLP notification database is maintained by the HSE and contains new GB notifications received after December 31st, 2020. 'Notification' means submission of information to HSE about the chemicals supplied. The type of substances which must be notified have not changed. Substances requiring notification are:

- substances subject to REACH registration
- hazardous substances placed on the market on their own
- hazardous substances placed on the market in a mixture, resulting in that mixture being classified as hazardous

Notification is necessary within one month of placing new substances on the GB market for GB-based manufacturers or importers placing chemicals on the GB market as well as NI-based manufacturers, downstream users or distributors supplying qualifying NI goods directly to the GB market. A notification should contain information about the classification and labelling of the substance. Notifications already made to ECHA that have been included in the C&L-inventory on December 31st, 2020, do not need to be re-notified.

There is no requirement to generate a Unique Formula Identifier (UFI) code in the UK.

Also GB-CLP includes the duty to submit information on health emergency response and preventive measures for hazardous mixtures to the UK National Poisons Information Service (NPIS). GB-based importers and downstream users, as well as NI-based downstream users supplying the GB market, have to send a Safety Data Sheet (SDS) to sds.npis@nhs.net. Actually the plan was to implement a voluntary scheme for poison center notifications instead of the mandatory provisions under Annex VIII to the EU CLP. The government agencies in charge of CLP are now working to rectify what it calls an error. However, the timeline for this is unclear and all in all, the process may well take up to a year, if not slightly longer.

GB BPR: The Biocidal Products Regulations 2001 (S.I. 2001/880)

The EU BPR Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products was officially copied across to GB law with the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (S.I. 2013/1506) which amended the The Biocidal Products Regulations 2001 (S.I. 2001/880) to the new EU legislation. The UK laws amending the retained EU biocide legislation and ensure that it can operate effectively in GB are The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720) and The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567). Toys remain exempt from BPD requirements in GB as well (see Article 2 point k of GB and EU BPR). Several other EU regulations applying to biocides were also transcribed and enacted on January 1st, 2021. General information on the use of biocides in the UK, as well as further guidance on similarities and differences between EU BPR and GB BPR, can be found on the HSE website under the topic "Biocides regulation, supply and use". The BPR active substance lists for GB and NI shows all the biocidal active substances under the relevant BPR (GB or EU) that either have been approved or are/were being evaluated or have a non-approval decision or are simplified active substance. Comparable to the EU BPR, the GB Article 95 List gives details of the suppliers for active substance / product type combinations that can be used in biocidal products in GB. Suppliers included on the EU Article 95 List on December 31st, 2020 were automatically added to the corresponding GB List. If they want to remain there after December 31st, 2022, they must resubmit their data or letter of access to HSE and confirm to HSE that

they (or their representative) are established in the UK (Great Britain or Northern Ireland). HSE publishes the UK Authorized Biocidal Products List for GB and NI market and also a fact sheet with detailed information for companies wishing to gain or retain access to the GB market after December 31st, 2020.

UK ROHS: RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT REGULATIONS 2012 (SI 2012/3032)

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (SI 2012/3032) entered into force on January 2nd, 2013, transposing the requirements of Directive 2011/65/EU. Brexit issues were fixed with The Waste and Environmental Permitting Etc. (Legislative Functions and Amendment Etc.) (EU Exit) Regulations 2020 (S.I. 2020/1540) and The Hazardous Substances and Packaging (Legislative Functions and Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1647).

OPSS has been appointed by Defra to enforce the regulations in Great Britain and Northern Ireland. Detailed information is available on the official website Guidance Regulations: restriction of hazardous substances (RoHS) (last updated April 8th, 2022) which also includes on special guidance documents regarding on the regulations as they apply to equipment being supplied in or into Great Britain as well as in Northern Ireland.

Since its EU Exit, UK has already adopted some of the amendments made to the EU RoHS Directive. Subsequent to The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations 2021 (S.I. 2021/422) and The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) (No. 2) Regulations 2021 (S.I. 2021/1395). On June 9th, 2022, the secretary of state published the latest amendment The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations 2022 (S.I. 2022/622) which entered into force on July 1st, 2022. It reflects the amendments to the EU RoHS implemented by Delegated Directives 2021/1980/EU, 2021/1979/EU and 2021/1978/EU (new specific and time-limited exemptions for phthalates in certain components as well as in spare parts for the repair or refurbishment of medical devices). Meanwhile, EU RoHS was amended further by Commission Delegated Directives published on February 24th, 2022.

MARKET SURVEILLANCE & DATABASE OF UNSAFE PRODUCTS

Market surveillance authorities will notify unsafe and noncompliant products to the Office for Product Safety and Standards (OPSS) on the Product Safety Database which is comparable to the EU's Safety Gate (RAPEX). Unsafe products posing a risk to the health and safety of consumers may be recalled. Public information can be found in the List of Product Safety Alerts, Reports and Recalls. On the official website Guidance Product Recalls and Alerts (last updated November 3rd, 2022) the OPSS posts weekly reports and further information.

Further information on current legal changes can also be found on our homepage at www.tuv.com or www.tuv.com/regulations-and-standards/en/.

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