

TOYS and BREXIT – Specific Guidance for Chemicals

REACH and CLP

Record of Amendments			
Version	Date	Amendment	Section/page affected
1	November 2020	First publication. Note previously published as part of the BTHA's Brexit Guidance.	
2	13 th Jan 2021	Changes throughout to reflect the fact that we have a deal. Clarification on the transfer of chemicals from Northern Ireland. Annex XVII information about UK/EU cooperation on chemical matters but without obligation. CLP updates to HSE planning advice	Various 2.3 3.2 5

LEGAL NOTICE

This document contains guidance only.

It is intended to explain obligations and how to fulfil them. However, readers are reminded that the text of the original regulation, directive or standard is the only authentic legal reference and that the information in this document does not constitute legal advice.

The British Toy and Hobby Association does not accept any liability with regard to the contents of this document.

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1 Introduction

The following guide is intended to help BTHA members prepare for Britain exiting the EU with regards to the REACH Directive and the CLP Regulation.

The following guide is intended to help BTHA members with the changes arising as a result of Great Britain exiting the EU. It has been put together to assist BTHA members in the dynamic circumstances surrounding Brexit, to give best available advice based on what the BTHA currently knows, as of 13th January 2021. As a reminder, as always with such guidance, the document is the best endeavoured advice to assist members to plan and does not constitute legal advice.

EU legislation ceased to apply in Great Britain (GB) and UK legislation is in force as of **1st January 2021**. However, in some cases the UK will allow transition times for GB companies for certain aspects. It can be assumed that UK Enforcement Authorities are very likely to be pragmatic in their approach to non-conformities arising from BREXIT changes to UK legislation. The same cannot be confirmed for trade with the EU where compliance may be enforced immediately. It is worth noting that the EU legislation is NOT CHANGING, it is only GB's status under EU law that will be different.

Negotiations for a Free Trade Agreement (FTA) have taken place and a deal has been agreed. The content of this document has been updated in line with the deal negotiated with the EU.

The content of this guidance is based on Government documents and discussions to date but cannot be fully confirmed therefore it would be prudent for companies taking significant steps to comply to be aware of the advice and to take account of any changes that have occurred since this document was drafted. It may also be advisable to seek further third-party help and companies should themselves refer to the government and EU white papers and advice.

2 Scope

Chemicals are probably the most complex and difficult area to move between the EU and UK. This chemicals guidance covers REACH and CLP. The scope of chemicals regulation includes articles, substances and mixtures. The following sections will apply depending on the product type you supply:

2.1 ARTICLES

An article is defined as “an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition”. Articles include plastic mouldings, cardboard jigsaw pieces, and textile coverings of plush toys for example.

Relevant sections

REACH Annex XVII	5.1.2 REACH Annex XVII Restrictions
REACH SVHC	5.1.3 REACH Substances of Very High Concern (SVHC's)
Waste Framework Directive	5.1.3 REACH Substances of Very High Concern (SVHC's)

2.2 SUBSTANCES AND MIXTURES

A substance is a single chemical. A mixture is several chemical substances combined in a product without a chemical reaction taking place. An example of a substances would be copper sulfate in an experimental set. Examples of products that are mixtures include wax crayons, ink in a felt tip, paints, modelling clay, and craft glues.

Relevant sections

REACH Annex XVII	5.1.2 REACH Annex XVII Restrictions
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Reach registration	5.1.1 REACH Registration
Safety data sheets	5.1.4 Safety Data Sheets
CLP	5.2 CLP

2.3 NORTHERN IRELAND

Transfers of chemicals from Great Britain to Northern Ireland are considered as imports into the EU, and the relevant obligations for importers under REACH, CLP, BPR, PIC and POPs apply.

3 REACH

The ECHA will publish a communications package to help all companies placing chemical substances on the EU market to prepare for the UK's withdrawal from the EU. The package will include new Q&As and step-by-step instructions for using the 'Brexit window' for UK-based companies to transfer their REACH registrations. In the meantime, some points for UK compliance are listed below.

The guide has been written in conjunction with REACHReady

REACHReady has recently developed dedicated no deal Brexit page  companies understand what their future obligations may look like, log in to our website today to find out more:

<https://www.cia.org.uk/reachready/Brexit/>.

All gold subscribers can email in their specific Brexit questions to our helpdesk at enquiries@reachready.co.uk

The EU REACH Regulation has been brought into UK law by the European Union (Withdrawal) Act 2018. This effectively replicates the existing provisions of REACH with modifications to make it UK specific. The EU has published a Technical note https://ec.europa.eu/info/sites/info/files/chemicals-regulation-under-reach_en.pdf

3.1 REACH Registration

This will affect companies that supply substances (either on their own or in mixtures) over 1 tonne per annum into the UK or the EU and those companies that currently rely on EU suppliers REACH registration as they will become new UK importers which will most likely have obligations under UK REACH. Those UK companies that currently have EU REACH registrations will be able to grandfather them into the UK REACH system once the UK has left the EU. This process will involve a notification to be submitted to the HSE within 120 days of the UK leaving the EU via the new UK REACH IT system, followed by the submission of the full registration dossier within 2 years of the UK leaving the EU. The registration dossier should be the same as what had been submitted to ECHA for EU REACH. This means that companies may have to request access to the data within the dossier for use under UK REACH. The new UK importers will also have a short transitional period in which to supply information on the substances they are importing to the HSE. A notification will need to be submitted via the new UK REACH IT system within 180 days of the UK leaving the EU, followed by a full registration dossier within 2 years of the UK leaving the EU. See Appendix B for more details if you are affected by REACH registration.

3.2 REACH Annex XVII Restrictions

The existing EU REACH Annex XVII restrictions will be carried across to UK REACH, therefore the immediate impact is low. The UK however has indicated that after the UK has left the EU it will be free to add its own restrictions. There is no mechanism by which future EU Annex XVII restrictions will be automatically implemented in the UK. The Trade and Cooperation Agreement provides for cooperation in chemicals matters with consultation on both sides. However, the Agreement does not obligate either party to automatically adopt each other's decisions. The potential therefore exists for divergence in the future with the obvious implication that toy manufacturers will have to comply with the restrictions in both UK REACH and EU REACH if the product is likely to be supplied to both markets.

3.3 REACH Substances of Very High Concern (SVHCs)

The UK will adopt the existing substances included in the Candidate List but will be free to add additional substances after the UK has left the EU. These substances could be different than those in Europe and vice versa.

The immediate impact is low, however, as the candidate list is updated every 6 months there is possibility for divergence between the UK and EU versions of this list.

Separate notification in the EU will be required if SVHCs are present in articles and intended to be released. This situation is however unlikely to affect toy manufacturers.

The EU database to capture information from companies producing, importing or supplying articles containing SVHCs (SCIP) is going ahead under the Waste Framework Directive.

UK: SCIP is not being implemented in the UK. There is no data reporting requirement for goods placed on the UK market.

EU: The SCIP obligations do not apply to UK companies as the UK is outside of the EU. However, EU customers will have the obligation as importers and will probably request information on the presence of SVHCs in article from UK suppliers. Toy manufacturers supplying to the EU should expect to see more requests from EU retailers for SVHC in preparation for the deadline.

Northern Ireland: The relevant parts of the Waste Framework Directive have not been implemented in the Northern Ireland Protocol, therefore SCIP does not apply.

3.4 Safety Data Sheets

The format, content and conditions under which Safety Data Sheets are required, as specified in the EU REACH Regulation and the subsequent amendments, will remain the same. This means that Safety Data Sheets created under EU REACH will be valid under UK REACH.

4 Key legal timelines

- **120 days after IP end day:** Notifications for grandfathering currently held EU registrations should be submitted
- **180 days after IP end day :** Downstream user notifications for new UK importers should be submitted
- **2 years after IP end day:** Full registration dossier for those that completed grandfathering and downstream user notifications to be submitted

For new registrations an inquiry dossier must be submitted to HSE followed by full registration dossier before the substance can be placed on UK market above 1 tonne per year.

4.1 Actions to take now

Review substance supply chains and determine which cases are likely to apply.

Prioritise registrations in Europe

4.2 Other obligations but not included above

A no deal scenario also applies to substance authorisations. It is unlikely that a toy manufacturer will be subject to substance authorisation. It also applies to substances in articles where these are intended to be released in amounts greater than one tonne per annum. This is unlikely to apply to the majority of toy materials.

4.3 Toy specific examples

4.3.1 Example 1

A UK toy company currently imports wax crayons from China. The crayons contain paraffin wax and more than one tonne is placed on the market.

The toy company has a current registration under EU REACH. In the last calendar year, they imported 15 tonnes of paraffin wax in the crayons. Out of this, 8 tonnes were placed on the EU market and 7 tonnes on the UK market.

To continue importing into the UK and supplying the UK market the company would need to grandfather their EU REACH registration into the UK system. To do this they must open an account in UK REACH IT and submit a notification within 120 days of UK leaving the EU. Following on from this they would need to submit the full registration dossier to the HSE within 2 years of the UK leaving the EU (the dossier should contain all information that was submitted to ECHA so the company will need to ensure that they are able to access the data for use in the UK REACH system)

To continue supplying EU customers, the manufacturer can appoint an Only Representative in the EU or ensure that the EU customer has a valid EU REACH registration for importing that substance.

4.3.2 Example 2

A UK toy company that is a subsidiary of an EU company currently imports modelling clay from China. The clay contains microcrystalline wax and more than one tonne is placed on the market.

The toy company has a current registration under EU REACH. In the last calendar year, they imported 15 tonnes of microcrystalline wax in the clay. Out of this, 8 tonnes were placed on the EU market and 7 tonnes on the UK market.

To continue importing into the UK and supplying the UK market the company would need to grandfather their EU REACH registration into the UK system. To do this they must open an account in UK REACH IT and submit a notification within 120 days of UK leaving the EU. Following on from this they would need to submit the full registration dossier to the HSE within 2 years of the UK leaving the EU (the dossier should contain all information that was submitted to ECHA so the company will need to ensure that they are able to access the data for use in the UK REACH system)

To continue supplying EU customers, the company can transfer the importing operations related to the registered substance to a legal entity within the EU, in this case the EU parent company. The EU parent company is responsible for the substances covered by the registration and this means that the responsible staff and paperwork must be present at the address of the registrant. ECHA have stated that setting up a company on paper only in the EU-27 or EEA is not sufficient.

4.3.3 Example 3

A UK toy company imports play sets containing dough into the UK from China. The dough contains calcium chloride and after reviewing the bill of substances and the number of sets brought into the UK, the importer calculates that 1.4 tonnes of calcium chloride is imported each year.

The play sets are only sold to UK retailers and not supplied to the EU. The importer has not previously registered the substance.

Note: There is no example that refers to a UK toy company that purchases materials from the EU who will become new UK importers once the UK has left the EU

5 CLP

The existing CLP Regulation (EC) No 1272/2008 is the legal implementation of the voluntary Globally Harmonised System (GHS). The current position is that the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (EU Exit) (Amendment etc.) Regulations 2019 will make the necessary changes to CLP. The Health and Safety Executive have however indicated that a standalone GB CLP will be applied from January 2021. The UK would effectively adopt the GHS in the same way as the EU and the classification and labelling criteria would be based on the existing EU Regulation

- The existing harmonised classifications will be transferred to the UK mandatory classification and labelling list (MCL)
- All current CLP labelling requirements will apply.
- Distributors (such as retailers) placing a substance or mixture on the market supplied from the EU will become importers under UK CLP. Classifications for substances and mixtures will require to be determined by the UK company. Existing EU classifications will not automatically be valid.
- There will be a separate voluntary obligation to submit information on hazardous substances and mixtures that are placed on the market to the National Poisons Information Service rather than the mandatory EU requirement for notification through the ECHA Poisons Centre Notification system. The UFI number required in the EU does not appear to apply in the UK based on current understanding.
- After 1st January 2021, the UK will no longer automatically accept classification proposals from the ECHA Risk Assessment Committee. Classification decisions will be determined in the UK after review of the scientific evidence and the economic impact.
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The HSE have published scenario planning guidance: <https://www.hse.gov.uk/brexit/clp-scenario-table.pdf>

UK: Practically no change however a UK address and contact details are required on the CLP label.

EU: For generation of UFI numbers the ECHA site still accepts GB VAT numbers. Therefore, it will be still be possible to add EU UFI numbers of the labels of hazardous mixtures. It is understood that UK companies will be able to submit Poison Centre Notifications for hazardous mixtures sold in the EU. CLP labels must contain the name and contact details of an EU entity. The UK address is no longer acceptable. The Trade And Cooperation Agreement allows for a supplier to use a sticker with the EU supplier's details to cover those of the non-EU supplier (Article TBT.8)

Appendix A Chemical Directives and Legislation related to Toys

The following table shows the chemical legislation that may affect toys or toy companies. It shows the legislation in place now – before Brexit and the corresponding UK legislation. It shows also how the legislation will change post Brexit, e.g. if it will remain the same or if there are to be new statutory Instruments or amended statutory instruments. It also shows where we have no information.

The table also shows which pieces of legislation are from the New Legislative Framework and therefore are CE marking Directives. Lastly it shows where the UK Marking should be applied. Notes: Some regulations are not harmonised across the UK; e.g. packaging and waste and food contact materials.

BEFORE BREXIT		UK Legislation			Post Brexit Comments	CE Marking and UK Marking
All toys						NLF = New legislative framework
EC1907/2006	REACH	All toys	NONE	(EU regulation applies directly in the UK)	To be replaced by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019	NLF: No No CE marking required
2019/1021	Persistent Organic Pollutants Regulation (POP)	All toys	None	(EU regulation applies directly in the UK)	To be replaced by The Persistent Organic Pollutants (Amendment) (EU Exit) Regulations 2019	NLF: No No CE marking required
1272/2008	Classification, Labelling and Packaging Regulation (CLP)	Substances and mixtures	NONE	(EU regulation applies directly in the UK)	Modified by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019	NLF: No No CE marking required
528/2012	Biocidal products regulation	Toys exempted from scope	NONE	(EU regulation applies directly in the UK. Note various enacting provisions)	Amended by: The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019	NLF: No No CE marking required

Appendix B Reach Registration and Supply

The following information has kindly been updated by REACHReady

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<https://www.cia.org.uk/reachready/Brexit/>.

All gold subscribers can email in their specific Brexit questions to our helpdesk at enquiries@reachready.co.uk

The EU REACH Regulation will be brought into UK law by the European Union (Withdrawal) Act 2018. This effectively replicates the existing provisions of REACH with modifications to make it UK specific. The most important implication of this for toy manufacturers will be the effective duplication of REACH registration obligations. In simple terms, a manufacturer supplying substances (either on their own, or in mixtures) to both the UK and the EU market in amounts greater than one tonne per annum will need to ensure that the substances are registered independently in both markets as there is no linkage. Both the EU and UK regulations operate on the principle of 'no data, no market'.

Immediate impact:

This means that if a UK toy manufacturer has an existing UK based REACH registration or you rely on an UK based Only Representative these registrations will no longer be seen as valid under EU REACH the UK withdrawal and **immediate action** needs to be taken.

Maintaining EU Market Access

If an UK company currently holds an EU registration and wants to maintain EU market access, they will be able to transfer the registration to an EU legal entity. ECHA's new [guidance](#) on how to transfer your UK REACH registration provides practical instructions on how to set up the transfer within REACH IT. This process will allow substances that already have been registered by UK companies under REACH to be legally placed on the EU 27 market after the UK withdrawal from the EU. A few points to note include:

- The UK company's EU successor needs to be set up in REACH IT and share their UUID to allow the UK company to begin the process in REACH IT
- A transfer agreement needs to be put in place REACHReady recommends using a suspensive condition clause to overcome the current uncertainties as regards the exact Brexit date please see the joint CIA and Cefic [guidance](#) for suggested wording for these contracts
- As of the UK withdrawal date UK companies will no longer have access to registrations and notification in REACH IT, they will maintain access to their message box where they will receive messages regarding the status of their transfer
- The successor will need to pay the invoice for the transfer by the due date if not the transfer in REACH IT will automatically be undone and the registrations will be returned to the UK company where after the withdrawal date, they will be void

ECHA are advising companies to continue preparing for a 'new, flexible' withdrawal date highlighting that companies will need to make their own business decisions about the timing of initiating the transfer, or to terminate the transfers initiated but not yet completed.

Maintaining UK market access

If you are currently a UK based manufacturer or importer that holds a valid EU REACH registration these can be grandfathered into the UK system once the UK has left the EU. UK companies will have to set up an account in the new UK REACH IT System (currently not available – still in testing) and submit a notification to the HSE within 120 days of the UK leaving the EU followed by the full dossier within 2 years of the UK leaving the EU.

For those UK companies currently relying on their EU supplier's EU REACH registrations as downstream users, these companies will become new UK importers under REACH. These companies will have to submit a notification within 180 days of the UK leaving the EU on the substances they are importing (only the data they currently have) to the HSE via the UK REACH IT System. Followed by a full registration dossier within 2 years of the UK leaving the EU. However, if the EU company appoints an UK based Only Representative this will relieve the UK importer of their obligations to notify and submit a full dossier to the HSE. The UK importer would become a downstream user under UK REACH.

For further detailed information on what data is required in the notification please see the guidance by Defra : <http://www.hse.gov.uk/brexit/uk-reach-additional-guidance.pdf>

Detailed guidance is available from the Health and Safety Executive (HSE) here <http://www.hse.gov.uk/brexit/reach.htm> and <http://www.hse.gov.uk/brexit/ag-scenario-table.pdf>

ECHA has also provided guidance and questions and answers: <https://echa.europa.eu/uk-withdrawal-from-the-eu>

The following tables illustrate the three common procurement scenarios that are likely to affect toy manufacturers:

Case 1: Substances currently directly imported from a third country such as China. This is the scenario that is likely to have the most significant impact on manufacturers.

Case 2: Substances currently directly sourced from the EU. This has low impact for placing on the market in the EU and moderate impact for placing in the UK market.

Case 3: Substances currently sourced from the UK. This has low impact for placing on the market in the UK and immediate impact for placing on the EU market.

CASE STUDY 1 Substances currently supplied from a third country such as China.

		Current REACH Registration Status					
	Description	You have an existing UK based REACH registration	Supplier has an existing UK based REACH registration	No existing registration	Supplier has existing EU based registration	UK based Only Representative appointed	EU based Only Representative appointed
1A	Import substances > 1 tonne from non-EU/EEA country and supply in the UK only	Grandfather the current EU REACH registration into UK system. Notify HSE using the UK REACH IT system within 120 days of UK leaving EU, followed by full dossier within 2 years of UK leaving the EU		Notify HSE using the UK REACH IT system to take on role as importer; or encourage supplier to appoint a UK Only Representative		Ensure UK based Only Representative has submitted notification using REACH IT system within 120 days of UK leaving EU and that they will submit full registration within 2 years	Notify HSE using the UK REACH IT system to take on role as importer; or encourage supplier to appoint a UK Only Representative
1B	Import substances > 1 tonne from non-EU/EEA country and supply to Europe only	Ensure EU/EEA customers hold a valid EU REACH registration as an importer; or ensure your non-EU/EEA supplier appoints an EU based Only Representative		Ensure EU/EEA customers hold a valid EU REACH registration as an importer; or ensure your non-EU/EEA supplier appoints an EU based Only Representative		Ensure the non-EU/EEA manufacturer appoints an EU based Only Representative	No action required
1C	Import substances > 1 tonne from non-EU/EEA supplier and supply to UK and Europe	UK supply: Grandfather the current EU REACH registration into UK system Notify HSE using the UK REACH IT system within 120 days of UK leaving EU, followed by full dossier within 2 years of UK leaving the EU. EU supply: Ensure EU/EEA customers hold a valid EU REACH registration as an importer; or ensure your non-EU/EEA supplier appoints an EU based Only Representative		UK supply: Notify HSE using the UK REACH IT system to take on role as importer; or encourage supplier to appoint a UK Only Representative EU supply: Ensure EU/EEA customers hold a valid EU REACH registration as an importer; or ensure your non-EU/EEA supplier appoints an EU based Only Representative		UK supply: Ensure UK based Only Representative has submitted notification using REACH IT system EU supply: Ensure the non-EU/EEA supplier appoints an EU based Only Representative	UK supply: Notify HSE using the UK REACH IT system to take on role as importer; or encourage supplier to appoint a UK Only Representative EU supply: No action required

CASE STUDY 2 Substances currently supplied from the EU

		Current REACH Registration Status					
	Description	You have an existing UK based REACH registration	Supplier has an existing UK based REACH registration	No existing registration	Supplier has existing EU based registration	UK based Only Representative appointed	EU based Only Representative appointed
2A	Import substances > 1 tonne from EU/EEA supplier and supply in the UK only			Notify HSE using the UK REACH IT system within 180 days of UK leaving the EU, followed by full registration dossier within 2 years of UK leaving EU to take on role as importer; or encourage supplier to appoint a UK Only Representative	Notify HSE using the UK REACH IT system within 180 days of UK leaving the EU, followed by full registration dossier within 2 years of UK leaving EU to take on role as importer; or encourage supplier to appoint a UK Only Representative	If UK OR appointed by EU supplier, they would take the notification and registration duties from the UK importer who would become a downstream user	
2B	Import substances > 1 tonne from EU/EEA supplier and supply to Europe only			Ensure the EU supplier has registered the substance in the EU	No action required		
2C	Import substances > 1 tonne from EU/EEA country and supply to UK and Europe			<p>UK supply: Notify HSE using the UK REACH IT system within 180 days of UK leaving the EU, followed by full registration dossier within 2 years of UK leaving EU to take on role as importer; or encourage supplier to appoint a UK Only Representative</p> <p>EU supply: Ensure the EU supplier has registered the substance in the EU</p>	<p>UK supply: Notify HSE using the UK REACH IT system within 180 days of UK leaving the EU, followed by full registration dossier within 2 years of UK leaving EU to take on role as importer; or encourage supplier to appoint a UK Only Representative</p> <p>EU supply: No action required</p>	If UK OR appointed by EU supplier, they would take the notification and registration duties from the UK importer who would become a downstream user	

CASE STUDY 2 Substances currently supplied from the UK

		Current REACH Registration Status					
	Description	You have an existing UK based REACH registration	Supplier has an existing UK based REACH registration	No existing registration	Supplier has existing EU based registration	UK based Only Representative appointed	EU based Only Representative appointed
3A	Buy chemicals from UK supplier and supply in the UK only		Ensure supplier has notified HSE within 180 days of UK leaving the EU and submit a full registration dossier within 2 years of UK leaving EU	Ensure UK supplier has notified HSE			
3B	Buy chemicals from UK supplier and supply to Europe only		Ensure EU/EEA customers hold a valid EU REACH registration as an importer; or ensure your UK manufacturer appoints an EU based Only Representative	Ensure EU/EEA customers hold a valid EU REACH registration as an importer; or ensure your UK manufacturer appoints an EU based Only Representative			No action required
3C	Buy chemicals from UK supplier and supply to UK and Europe		<p>UK: Ensure supplier has notified HSE within 180 days of UK leaving the EU and submit a full registration dossier within 2 years of UK leaving EU</p> <p>Europe: Ensure EU/EEA customers hold a valid EU REACH registration as an importer; or ensure your UK manufacturer appoints an EU based Only Representative</p>	<p>UK: Ensure supplier has notified HSE (see comment above)</p> <p>Europe: Ensure EU/EEA customers hold a valid EU REACH registration as an importer; or ensure your UK manufacturer appoints an EU based Only Representative</p>			<p>UK supply: Not applicable</p> <p>EU supply: No action required</p>