



ACCESS TO THE UK CHEMICAL MARKET AFTER THE END OF THE TRANSITION PERIOD

GUIDANCE

May 2020

THE SOCIETY OF MOTOR MANUFACTURERS AND TRADERS LIMITED



GUIDANCE

REQUIREMENTS FOR COMPANIES WISHING TO GAIN OR KEEP ACCESS TO THE UK CHEMICALS MARKET AFTER THE END OF TRANSITION PERIOD (31 DECEMBER 2020)

EXECUTIVE SUMMARY

This guidance seeks to draw attention to the actions needed by UK- or EU-based companies in order to maintain compliance with UK chemicals regulations after the end of the Transition Period on 31 December 2020.

Specifically it highlights the actions you need to take if you want to continue UK business and are:

- A holder of a current EU REACH registration;
- Waiting for a decision on a new or updated EU REACH registration;
- A UK-based Downstream User or Distributor of an EU-REACH registered substance;
- A UK-based holder or Downstream User of an EU REACH authorisation;
- · Awaiting a decision on an EU REACH authorisation; or
- Relying on a Product and Process Orientated Research and Development ("PPORD") exemption from registration.

This guidance also includes automotive industry recommendations designed to provide a consistent and efficient approach to chemicals compliance.

In order to protect ongoing business, we strongly urge you to familiarise yourself with this guidance, (which was prepared in cooperation with the Department for the Environment, Food and Rural Affairs (DEFRA)) understand your obligations, and start to implement the necessary compliance actions without delay.



INTRODUCTION

After withdrawal from the EU ("Brexit") on 31 January 2020, the UK entered a Transition Period (TP), during which the UK continues to follow EU-REACH and other EU regulations. The TP is due to end on 31 December 2020, after which the SMMT Hazardous Materials Working Group (HMWG) expects the UK to implement UK-REACH as a copy, as far as possible, of EU-REACH in terms of the detailed requirements and overall policy.

However, UK-REACH deviates from EU-REACH where necessary to facilitate requirements that would otherwise be inoperable if directly followed. For example all EU-REACH references to the "Agency" (i.e. to the European Chemicals Agency, "ECHA") refer in UK-REACH to the UK Health & Safety Executive (HSE), while EU-REACH references to the "Commission" refer in UK-REACH to the UK Secretary of State for the Department of Environment, Food and Rural Affairs (DEFRA).

"Comply with UK REACH" is the name of the UK-REACH equivalent of the EU-REACH-IT system for managing data related to notifications, registrations, authorisations, etc. As far as possible it is designed to use data in the same formats as EU-REACH-IT.

Additional provisions are added to UK-REACH as Article 127A to P in order for companies to be able to manage the transition from EU-REACH, as summarised in this Guidance below.

NOTES ON THIS GUIDANCE:

- This Guidance is intended only to cover the key issues related to post-Brexit UK chemicals compliance; for a thorough understanding of EU-REACH, on which UK-REACH will be based, please refer to the Automotive Industry Guideline on REACH ("AIG-REACH", available at http://www.acea.be/reach).
- Under the Northern Ireland (NI) Protocol, at the end of the TP, NI will continue to follow EU rules on agricultural and manufactured goods, and so will remain covered by EU-REACH. Therefore references to "UK" in this Guidance should be understood to exclude Northern Ireland.





- References to "EU" should also be understood to include all "EEA" countries, i.e. EU countries plus Iceland, Liechtenstein and Norway (but not Switzerland).
- Deadlines are shown in relation to the Transition Period End ("TP-End", which this guidance assumes to be 31 December 2020).
- This Guidance is subject to change, depending on the outcome of the UK/EU trade negotiations and any amendments to UK-REACH and/or EU-REACH.
- This Guidance is based on the best understanding of the SMMT Hazardous Materials Working Group (HMWG) at the time of publication. Users of this Guidance are reminded that it is each company's responsibility to comply with the current text of the UK-REACH Regulation as the only authentic legal reference applicable to UK chemicals compliance.

May 2020





REGISTRATION SCENARIOS

All Scenarios below refer to the situation at TP-End, i.e. 11pm UK time on 31 December 2020.

Registration requirements apply only to substances manufactured or imported at > 1 tonne per annum (tpa) per legal entity.

No.	Scenario at TP-End	Objective	Actions / Options	Deadline
1	UK-based holder of an EU REACH registration (sole, joint or lead registrant; manufacturer, formulator, Only Representative or	Access the UK market ("grand-fathering" a)	FIRST 1.1 Notify substance to HSE b AND THEN 1.2 Substit full Degistration of	120 days (30 April 2021) 2 years
	importer)		1.2 Submit full Registration c	(31 December 2022)
2	EU-based holder of an EU REACH registration (sole, joint or lead registrant; manufacturer, formulator, Only Representative or importer)		EITHER FIRST 2.1 Transfer registration to UK-based affiliate address (in which case that company will no longer hold an EU-REACH registration after TP-End) d	TP-End (31 December 2020)
		Access the UK market	AND THEN Follow Actions 1.1 & 1.2 (i.e. grandfathering) OR FIRST 2.2 Set up Only Representative under UK-REACH e	2 years (31 December 2022) Bring into effect at TP-End (31 December 2020)
			AND THEN Follow Actions 4.2.3 & 4.2.4 (i.e. Downstream User notification/registration)	2 years (31 December 2022)





No.	Scenario at TP-End	Objective	Actions / Options	Deadline
3	UK-based registrant awaiting an ECHA or EU Commission decision for: New registration or update	Maintain your use or supply for a use in the UK	3.1 Resubmit your registration dossier to the UK HSE	After TP-End (after 31 December 2020) AND before substance exceeds 1 tpa
4	New Registration: UK- based (manufacturer, formulator, Only Representative or importer)	Access the UK market	4.1 Submit new Registration	After TP-End (after 31 December 2020) AND before substance exceeds 1 tpa

Registration Notes

- a. "Grandfathering" of EU-REACH registration is the transitional measure whereby UK-based companies holding existing EU-REACH registrations are able to effectively copy those same registrations directly into UK-REACH without business interruption and without registration fees. Without the grandfathering provision, such companies would have to suspend their activities until they were able to complete new UK-REACH registrations. "Grandfathering" is available to companies that EITHER:
 - Hold the registration as a UK legal entity at TP-End (on 31 December 2020) this makes grandfathering also available to EU-based companies that transfer their EU-REACH registrations to UK-based entities in preparation for Brexit (Art. 127A.2 UK-REACH); or,
 - Held the registration as a UK legal entity at any time from 29 March 2017 to TP-End (31 December 2020) this makes grandfathering available to UK-based companies that transferred their EU-REACH registrations to EU-based entities in preparation for Brexit (Art. 127A.3 UK-REACH).





- b. Notification of a substance for an intended grandfathering of the registration is free of charge via "Comply with UK REACH", and comprises basic information already available to registration holders:
 - EU-REACH registration number and registration date
 - Identity of registrant (manufacturer or importer)
 - Identification of the substance
 - Information on the manufacture and use of the substance
 - Indication as to which of the relevant information on manufacture and use has been reviewed by an assessor
 - Summary of any ECHA decision which relates to the registration, and uses
 - Applicable tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1 000 tonnes or over 1 000 tonnes)

(Art. 127B UK-REACH).

- c. Grandfathering registration under UK-REACH requires the same data (relevant to the same tonnage bands) as does EU-REACH registration, and is free of charge via "Comply with UK REACH". As with EU-REACH registration, registrants must either hold or obtain letters of access to all the required registration dossier data, which may be subject to costs imposed by the data holders (Art. 127 UK-REACH).
- d. For more details about how to transfer an EU REACH registration, see the guidance available on the ECHA website (https://echa.europa.eu/de/uk-withdrawal-from-the-eu).
- e. UK-REACH mirrors the EU-REACH provisions for Only Representatives (Art. 8 UK-REACH), so that under UK-REACH, a non-UK supplier who is a substance manufacturer, formulator or producer of articles with intentional release can establish an "Only Representative" in the UK to fulfil that supplier's UK-REACH obligations as an importer. In this case, the non-UK supplier must provide all UK customers with a letter confirming the appointment of the Only Representative, and relying on the letter, the supplier's UK customers avoid becoming UK importers and instead remain





downstream users or distributors (for more details of how this works under EU-REACH, see AIG-REACH Chapter 4.5). Furthermore, the UK-based Only Representative can benefit from the transitional arrangements for a UK-based Downstream User (see Actions 4.2.3 & 4.2.4 below).

DOWNSTREAM USER SCENARIOS

All Scenarios below refer to the situation at TP-End, i.e. 11pm UK time on 31 December 2020.

Registration requirements apply only to substances manufactured or imported at > 1 tonne per annum (tpa).

No.	Scenario at TP-End	Objective	Actions / Options	Deadline
4.1	in articles f) from a UK-based Downstream User or Distributor of an EU-REACH registered substance Receive substances or mixtures (directly or	substances or mixtures (directly or in articles <i>f</i>) from a	4.1.1 No registration obligations apply – take no further action g	Not applicable
		substances or	EITHER 4.2.1 Rely on/encourage the EU supplier to appoint a UK-based Only Representative to undertake UK-REACH registration obligations <i>i</i>	After TP-End (1 January 2021) AND before placing products on the market
4.2		in articles f) from an EU-based supplier	OR 4.2.2 Change source to a UK registered supplier j OR FIRST 4.2.3 Notify substance import to UK HSE k AND THEN EITHER	TP-End (31 December 2020) 180 days (29 June 2021) 2 years
			4.2.4 UK-based Downstream User submits full Registration /	(31 December 2022)





No.	Scenario at TP-End	Objective	Actions / Options	Deadline
			OR	
			4.2.5 Rely on your EU supplier, who has appointed a UK-	2 years
			based Only Representative in the meantime, to take over the	(31 December 2022)
			UK-REACH registration obligations <i>m</i>	

Downstream User Notes

- f. In general, an imported or manufactured substance is subject to registration where the substance is on its own, it is a component in mixtures, or it is present in articles if there is intended release of the substance (Art. 6 & 7 UK-REACH).
- g. A UK-based Downstream User or Distributor receiving substances or mixtures (directly or in articles) from a UK-based supplier remains a Downstream User after TP-End, and therefore has no additional obligations under UK-REACH; instead they will be relying on their supplier complying with UK-REACH, and so may choose to confirm that their supplier is maintaining their registrations under UK-REACH.
- h. A UK-based Downstream User or Distributor may avoid becoming an Importer at TP-End under UK-REACH if their existing EU-based supplier appoints an Only Representative (Action 4.2.1), or if the UK-based company changes instead to a UK-based supplier (see Action 4.2.2).
- *i.* If a Downstream User company intends to rely on its EU-based supplier having a UK-based Only Representative, then the Downstream User should ensure that they possess the supplier's Only Representative appointment letter.
- *j.* If a Downstream User company intends to rely on its EU-based supplier having a UK affiliate (e.g. sales office), then the Downstream User should ensure that the invoice address used for the supplier is within the UK.
- k. If the UK-based Downstream User or Distributor accepts the role of Importer under UK-REACH, they must first notify the HSE of the details of the substance that they are importing (Action 4.2.3), in order to benefit from the 2 year transitional period for full registration (Action 4.2.4). Notification





of a substance for an intended registration is free of charge via "Comply with UK REACH", and comprises basic information about the substance and the Notifier:

- EU-REACH registration number
- Identity of registrant (manufacturer or importer)
- Identification of the substance to the extent it is available to the Downstream User
- Classification and labelling to the extent it is available to the Downstream User
- Identification and application of appropriate measures to control risks identified in the Chemical Safety Report (for >10 tpa only)
- Safety data sheets (for >10 tpa only)
- Details of any authorisations or restrictions
- Any other available and relevant information necessary to enable appropriate risk management measures to be identified and applied
- Applicable tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1 000 tonnes or over 1 000 tonnes)

The notification requirement is limited in that it only applies to each substance imported at > 1 tonne per year of which the Downstream User is aware (Art. 127E.6 & 7 UK-REACH). If the Downstream User becomes aware after the 180 day deadline, they are advised to contact UK HSE to discuss the optimal steps to compliance.

I. Full registration under UK-REACH requires the same data (relevant to the same tonnage bands) as does EU-REACH. Registration by a UK-based Downstream User or Distributor is regarded as a new registration, and is therefore subject to UK HSE registration fees. As with EU-REACH registration, registrants must either hold or obtain letters of access to all the required registration dossier data, which may be subject to costs imposed by the data holders.





Although the notification requirement (Action 4.2.3, note g above) is limited to substances imported at > 1 tonne per year of which the Downstream User is aware, it is important to note that that the registration requirement within 2 years applies to every substance imported at > 1 tonne per year, and so the Downstream User has the obligation to identify all such substances (Art. 127E UK-REACH).

m. There is no legal obligation on a company that has made the Downstream User notification to follow through with the full registration, so it is acceptable if the EU supplier's Only Representative completes the registration within the 2-year deadline, thereby relieving the UK-based Downstream User of the obligation to register. In this case, the Downstream User should amend their notification in "Comply with UK-REACH" by changing the tonnage down to zero, but this is not mandatory.

AUTHORISATION SCENARIOS

All Scenarios below refer to the situation at TP-End, i.e. 11pm UK time on 31 December 2020.

Authorisation is a specific term applied to any use of substances listed on Annex XIV of EU- or UK-REACH, for which there is no minimum tonnage limit.

No.	Scenario	Objective	Actions / Options	Deadline
5	UK-based holder of an EU- REACH authorisation	Maintain your use or supply for a use in the UK	5.1 Provide the UK HSE with the technical information relating to the authorisation	60 days (1 March 2021)
6	UK Downstream User of an EU-REACH authorisation held by an EU-based company	Maintain your use or supply for a use in the UK	6.1 Confirm that you are an existing authorised DU AND THEN 6.2 Notify the authorisation details to UK HSE n	60 days (1 March 2021) 60 days (1 March 2021)



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No.	Scenario	Objective	Actions / Options	Deadline
7	Awaiting an ECHA or EU Commission decision for: Authorisation application from a UK-based applicant where the ECHA has adopted its final opinions but the Commission has not made a final decision	Maintain your use or supply for a use in the UK	 FIRST 7.1 Notify the DEFRA Secretary of State of the application; AND THEN 7.2 Supply the Secretary of State with copies of the application, the information included in it, and any other information provided to ECHA by the applicant for the authorisation which was material to the formation of ECHA's opinions; AND THEN 7.3 Give the Secretary of State copies of the final opinions ECHA sent to the applicant. 	180 days (29 June 2021) 180 days (29 June 2021) 180 days (29 June 2021)
8	Awaiting an ECHA or EU Commission decision for: Authorisation application from an EU-based applicant where the Commission has not made a final decision	Maintain your use or supply for a use in the UK beyond 18 months after TP-End	8.1 Apply to the UK HSE for a UK REACH authorisation o	18 months (30 June 2022)





No.	Scenario	Objective	Actions / Options	Deadline
9	Awaiting an ECHA or EU Commission decision for: Authorisation application from a UK-based applicant where the ECHA has not adopted final opinions	Maintain your use or supply for a use in the UK beyond 18 months after TP-End	9.1 Resubmit your application to the UK HSE o	18 months (30 June 2022)

AUTHORISATION NOTES

- **n.** The required authorisation details include:
 - Existing EU authorisation;
 - Any conditions set out in the existing EU authorisation;
 - Identity of the supplier of the substance.
- Applications for Authorisation that have EU-REACH Latest Application Dates falling between 29 Mar 2017 and 31 Dec 2020, and have EU-REACH sunset dates falling after TP-End (31 December 2022), will have a UK-REACH Latest Application Date set to 18 months after TP-End (30 June 2022).



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PRODUCT AND PROCESS ORIENTATED RESEARCH AND DEVELOPMENT (PPORD) SCENARIOS

PPORD exemptions apply only to substances manufactured or imported at > 1 tonne per annum (tpa).

No.	Scenario	Objective	Actions / Options	Deadline
	Temporarily exempt from the obligation to register through a PPORD Continue R&D use in the UK		FIRST 10.1 Comply with the standard PPORD information requirement of Article 9(2)	120 days (30 April 2021)
10			AND THEN 10.2 Notify the UK HSE of the number and notification date assigned by ECHA	120 days (30 April 2021)
		AND THEN 10.3 Supply the UK HSE with copies of any additional necessary information given to ECHA.	120 days (30 April 2021)	

SUBSTANCE GROUPS

Substance Information Exchange Forums (SIEFs) are no longer required to be in operation under EU-REACH, and therefore will not be directly carried over into UK-REACH. Instead "Substance Groups" are planned to allow registrants under UK-REACH to cooperate on joint substance registrations via the UK-REACH data system, "Comply with UK REACH".

- A Notifier of a substance for an intended registration grandfathering is automatically entered into the relevant "Substance Group", i.e. they are put in contact with all the other companies who have notified to grandfather their registrations by the end of the 120 day notification deadline.
- A Downstream User or Distributor notifying a substance imported from the EU is not automatically entered into the relevant "Substance Group", but may apply to join.





UK DEFRA is expected to set the rules under which Substance Groups must operate, but in summary, members of each Substance Group will be expected to:

- Come to an agreement on how the Substance Group members will work together and how testing data costs will be shared
- Confirm the substances notified are sufficiently similar to allow for joint registration
- Agree on which member will be the Lead Registrant (this is not necessarily the same as the Lead Registrant under EU REACH)
- Exchange existing testing data in order to avoid the duplication of animal studies
- · Identify needs for further studies and make arrangements to perform them
- Agree on the classification and labelling of the substance
- Prepare a joint lead dossier of data for registration of the substance

Further details on "Substance Groups" are planned to be made available on the UK HSE website (https://www.hse.gov.uk/).





KEY INDUSTRY RECOMMENDATIONS FOR DOWNSTREAM USERS

1. All: Familiarise yourself with this Guidance, understand your obligations, and start to implement the necessary compliance actions without delay.

- Start as soon as possible to raise awareness of Brexit chemicals compliance issues with your company's senior management.
- Recognise that compliance is likely to require allocation of staff and cost resources, and that you may need to supplement your own company's staff with external consultant or other specialist services - don't underestimate the amount of work and technical knowledge that will be involved.
- Engage with your trade associations' chemicals regulations working groups to gain and share helpful information.

2. All: Decide on your business strategy with respect to chemicals registration and authorisation

- Identify any chemicals (substances, mixtures or articles with intentional release of the substance) relevant to your business.
- Identify your current role under EU REACH for each chemical, using the "Scenarios" in this Guidance.
- Decide on the compliance approach, using the "Actions / Options" in this Guidance.

3. UK-based Downstream Users: Where possible, change to UK-based suppliers or ensure Only Representatives are assigned

- Identify affected supplied chemical products (i.e. which have suppliers outside the UK).
- Identify the products for which suppliers will set up affiliates or Only Representatives in the UK make arrangements to switch to those UK invoice addresses or refer to the non-UK supplier's Only Representative appointment letters.
- Identify any products / substances from non-UK suppliers that are likely to be dropped from the market (i.e. not supported by registrants in the supply chain).
- For any remaining products, make plans to source from other UK-based suppliers where available, and if not, decide whether to eliminate the use of these products / substances or to accept the Importer role after TP-End.
- Work with suppliers to identify any re-imported (exempt) substances.
- Confirm with suppliers that any imported intentionally released substances are registered for that use.





• For any imported intentionally released substances that are not registered for that use, decide whether to eliminate the use of these products / substances or to accept the Importer role after TP-End.

4. UK-based Downstream Users: Identify registration obligations

- Identify volumes of any products imported from outside the UK, for which you cannot rely on the suppliers' UK-based affiliates or Only Representatives.
- For these products, collect 100% substance composition data for any EU-to-UK supplies this will likely take time before you are able to gather all the requested information from your supply chain, but the composition data is essential to understand your imported substance obligations.
- Ensure that you are able to manage any proprietary information confidentially e.g. only specified personnel with direct regulatory roles should have access to any confidential composition data.
- Match compositions to volumes imported into the UK and aggregate by substance per Importer legal entity.
- Identify any substances (either as substances, or in mixtures, or in articles with intentional release of the substance) for which the imported volume exceeds the 1 tpa registration threshold.

5. All: Prepare for registrations and other new obligations

- Open an account in "Comply with UK REACH", the new UK-REACH-IT system.
- Make each remaining identified notification (as Registrant, Downstream User, Authorisation holder/user, PPORD exemption holder).
- Join relevant Substance Groups in order to follow registration plans for your substances.
- Provide resources to meet remaining substance registration obligations.
- Continue to work with your suppliers, in case they do set up UK-based Only Representatives and take on the registration obligations within 2 years of TP-End.
- Through the Substance Groups, make the required registrations within 2 years of TP-End.





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