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MOTOR INDUSTRY

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

GUIDANCE

Version 3

THE SOCIETY OF
MOTOR MANUFACTURERS
AND TRADERS LIMITED

BREXIT GUIDANCE – REQUIREMENTS FOR COMPANIES WISHING TO GAIN/KEEP ACCESS THE UK CHEMICALS MARKET

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, understand your obligations, and start to implement the necessary compliance actions without delay.

INTRODUCTION

After withdrawal from the EU ("Brexit") on 31 January 2020 and the end of the Transition Period (TP) on 31 December 2020, the UK government has implemented 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, after the end of the TP, NI continues to follow EU rules on agricultural and manufactured goods, and so remains covered by EU-REACH. Therefore references to "UK" in this Guidance should be understood to exclude Northern Ireland. There is separate guidance on importing qualifying NI goods (QNIGs) manufactured, formulated or produced in Northern Ireland. The definition of QNIGs is available on legislation.gov.uk. Importers importing non-QNIGs have an obligation to hold a GB registration as importers.*
- *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", i.e. 31 December 2020).*
- *This Guidance is subject to change, depending on any amendments to UK-REACH and/or EU-REACH and/or the NI Protocol.*

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- *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.*
- *The Guidance has been updated government guidance on 30 July 2021.*

19th October 2021

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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 importer)	Access the UK market ("grand-fathering" [a])	***FIRST*** 1.1 Notify substance to HSE [b]	120 days from TP-End (30 April 2021)
			AND THEN 1.2 Submit full Registration [c]	- **2 years** from 28 October 2021 (27 October 2023) – for substances ≥1000 tonnes/year; ≥1tpa for carcinogenic, mutagenic or toxic for reproduction substances; ≥ 100 tpa for substances very toxic to aquatic organism; Candidate List (CL) Substance (as at 31 Dec 2020). - **4 years** from 28 October 2021 (27 October 2025) – for substances ≥100 tpa; CL substances as at 27 October 2023 - **6 years** from 28 October 2021 (27 October 2027) – for substances ≥1 tpa.

No.	Scenario at TP-End	Objective	Actions / Options	Deadline
2	**EU-based holder of an EU REACH registration** (sole, joint or lead registrant; manufacturer, formulator, Only Representative or importer)	Access the UK market	***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)
			AND THEN Follow Actions 1.1 & 1.2 (i.e. grandfathering)	- **2, 4 or 6 years** from 28 October 2021 (Deadline details are as for Action 1.2)
			OR FIRST 2.2 Set up Only Representative under UK-REACH [e]	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, 4 or 6 years** from 28 October 2021 (Deadline details are as for Action 1.2)
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 equals or 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 equals or 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) (Article 10(a)(i))
- Identification of the substance (Article 10(a)(ii))
- Information on the manufacture and use of the substance (Article 10(a)(iii))
- Indication as to which of the relevant information on manufacture and use has been reviewed by an assessor (Article 10(a)(viii))
- 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).

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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 (including a NI-based manufacturer of non-QNIG) 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	**UK-based Downstream User or Distributor of an EU-REACH registered substance** or NI-imported non-QNIG	Receive substances or mixtures (directly or in articles [f]) from a UK-based supplier	4.1.1 No registration obligations apply – take no further action [g]	Not applicable

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No.	Scenario at TP-End	Objective	Actions / Options	Deadline
4.2		Receive substances or mixtures (directly or in articles [f]) from an EU-based supplier [h]	***EITHER*** 4.2.1 Rely on/encourage the EU supplier to appoint a UK-based Only Representative to undertake UK-REACH registration obligations [i]	After TP-End (1st January 2021) ***AND*** before placing products on the market
			OR 4.2.2 Change source to a UK registered supplier [j]	TP-End (31 December 2020)
			OR FIRST 4.2.3 Notify substance import to UK HSE [k]	300 days after TP-End (27 October 2021)
			AND THEN EITHER 4.2.4 UK-based Downstream User submits full Registration [l]	- **2, 4 or 6 years** from 28 October 2021 (Deadline details are as for Action 1.2)
			OR 4.2.5 Rely on your EU supplier, who has appointed a UK-based Only Representative in the meantime, to take over the UK-REACH registration obligations [m]	- **2, 4 or 6 years** from 28 October 2021 (Deadline details are as for Action 1.2)

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).

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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, 4 or 6 years (from 28 October 2021) 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)

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- 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 300 day deadline, they are advised to contact UK HSE to discuss the optimal steps to compliance.

l. 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, 4 or 6 years (from of 28 October 2021) 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, 4 or 6 years deadline (from of 28 October 2021), 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 after TP-End (1 March 2021)
6	**UK Downstream User of an EU-REACH authorisation held by an EU-based or** NI-based **company**	Maintain your use or supply for a use in the UK	***FIRST*** 6.1 Confirm that you are an existing authorised DU	60 days after TP-End (1 March 2021)
			AND THEN 6.2 Notify the authorisation details to UK HSE [n]	60 days after TP-End (1 March 2021)
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;	180 days after TP-End (29 June 2021)
			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;	180 days after TP-End (29 June 2021)
			AND THEN 7.3 Give the Secretary of State copies of the final opinions ECHA sent to the applicant.	180 days after TP-End (29 June 2021)

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No.	Scenario	Objective	Actions / Options	Deadline
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 after TP-End (30 June 2022)
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 after TP-End (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.

o. 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
10	**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 after TP-End (30 April 2021)
			AND THEN 10.2 Notify the UK HSE of the number and notification date assigned by ECHA	120 days after TP-End (30 April 2021)
			AND THEN 10.3 Supply the UK HSE with copies of any additional necessary information given to ECHA.	120 days after TP-End (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". UK REACH will include a substance inquiry system (similar EU REACH Article 26) to facilitate the principle of 'one substance, one registration' which will be retained under 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.

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- 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/).

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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.

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- 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, 4 or 6 years from 28th October 2021.
- Through the Substance Groups, make the required registrations within 2, 4 or 6 years from 28th October 2021.

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