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NEWSLETTER Special issue

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BREXIT: IMPACT ON THE REGISTRATION OF CHEMICALS IN THE EU AND THE UK

Dear Subscribers,

On 29 March 2017, the United Kingdom notified the European Council of its intention to leave the European Union. Unless a ratified withdrawal agreement establishes another date or the European Council, in accordance with Article 50(3) of the Treaty on European Union and in agreement with the United Kingdom, unanimously decides that the Treaties cease to apply at a later date, all Union primary and secondary law will cease to apply to the United Kingdom from 30 March 2019, 00:00h (CET) ('the withdrawal date'). The United Kingdom will then become a non-EU country.

Currently it is completely open whether there will be a Brexit with a transition phase of 21 months (Mar 2019 - Dec 2020) since a transition phase will only be applicable if a comprehensive withdrawal agreement is in place.

Industry thus needs to get prepared for the Brexit that may come either as a soft or a hard exit of the United Kingdom (UK) from the European Union (EU), in its worst case even without a withdrawal agreement (No-Deal-Brexit).

For the EU side, the EU Commission issued a series of Brexit preparedness notices that set out the consequences for a number of important business sectors. Among them are notices incl. Q&A's for medicinal products, plant protection products, and biocides.

For chemicals regulations, ECHA has provided guidance by means of a number of Q&A's that address the manifold implications of the UK's withdrawal from the EU.

The chemical industry is encouraged to ensure that its value chains between the EU and the UK are thoroughly assessed and prepared for the UK withdrawal date.

In this special edition of the SCC Newsletter, we are happy to provide you with a summary of the currently available guidance and our impact assessment relating to chemicals to date. We will continue to closely monitor the evolution of the Brexit negotiations and the clarification of the recommended actions that the actors in the supply chain should take in order to ensure business continuity for the both the EU-27 and the UK markets.

Please contact Dr Thomas Roth, Head of Chemicals Department (thomas.roth@scc-gmbh.de) if you would like to obtain more information or need further support.

Brexit implications in regard to key REACH provisions

- **Registration**: registrations of UK-based manufacturers or importers will become void.
- **Evaluation**: UK-based entities/actors will no longer be involved.
- **Authorization**: authorizations of UK-based manufacturers or importers will become void.
- **Restriction**: UK suppliers are not bound to REACH substance restrictions anymore.
- **Communication in the Supply Chain**: UK suppliers are not bound to REACH communication obligations anymore (e.g. SDS, SVHC).

Registration: Options for different actors in the supply chain

The regularly updated Q&A's on the ECHA website provide comprehensive guidance for a wide range of potential business situations and issues with REACH provisions. Here is the link to the ECHA Q&A website. https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/theukswithdrawalfromtheeu.

UK manufacturers

- Could transfer substance registration to an EU-27 based Only Representative (OR) at the time of UK withdrawal. Issue: the exact effective date of OR appointment needs to be contractually fixed by means of a suspensive condition clause.
- Otherwise, the EU-27 based importers may register these substances.
- Note: only UK-based manufacturers may appoint an EU-27 OR, but not UK-based importers.

UK OR's

- Important: many OR's of non-EU manufacturers are currently based in the UK.
- UK OR may relocate its office to an EU-27 member state prior to Brexit.
- Non-EU manufacturer may change its OR to EU-27 ('Legal Entity Change')
- EU-27 importer may submit its own registration.

UK-based Lead Registrants

- UK-based Lead Registrants (LR) will lose their legal status as a consequence of Brexit. Options to ensure the functioning of the joint submission are:
- The LR role needs to be transferred to an EU-27 company prior to the UK withdrawal date.

- In any case, joint submission members for concerned substances are strongly advised to proactively align on the appointment of the future Lead Registrant, to make clear contractual agreements, and to execute the LR change in REACH-IT.

EU-27 Customers of UK Suppliers

EU-27 Customers of UK Suppliers could switch supply prior to Brexit:

- Manufacturer based in EU-27
- Importer based in EU-27
- Non-EU Manufacturer with an OR in EU-27

Alternatively, they could consider

- Own registration as Importer, prior to actual importation ("stock registration")
- Issues are: registration fee & time, clarification of data sharing/LoA cost

Authorization

- UK manufacturer/formulator may transfer its authorization to an EU-27 OR ('Legal Entity Change')
- Non-EU manufacturer may transfer its authorization from a UK OR to an EU-27 OR ('Legal Entity Change')
- EU-27 Customer of UK manufacturer/formulator may switch supply to an EU-27 authorization holder
- EU-27 Customer of UK manufacturer/formulator may consider applying for its own authorization
- Note: UK-based importers may not transfer authorizations.

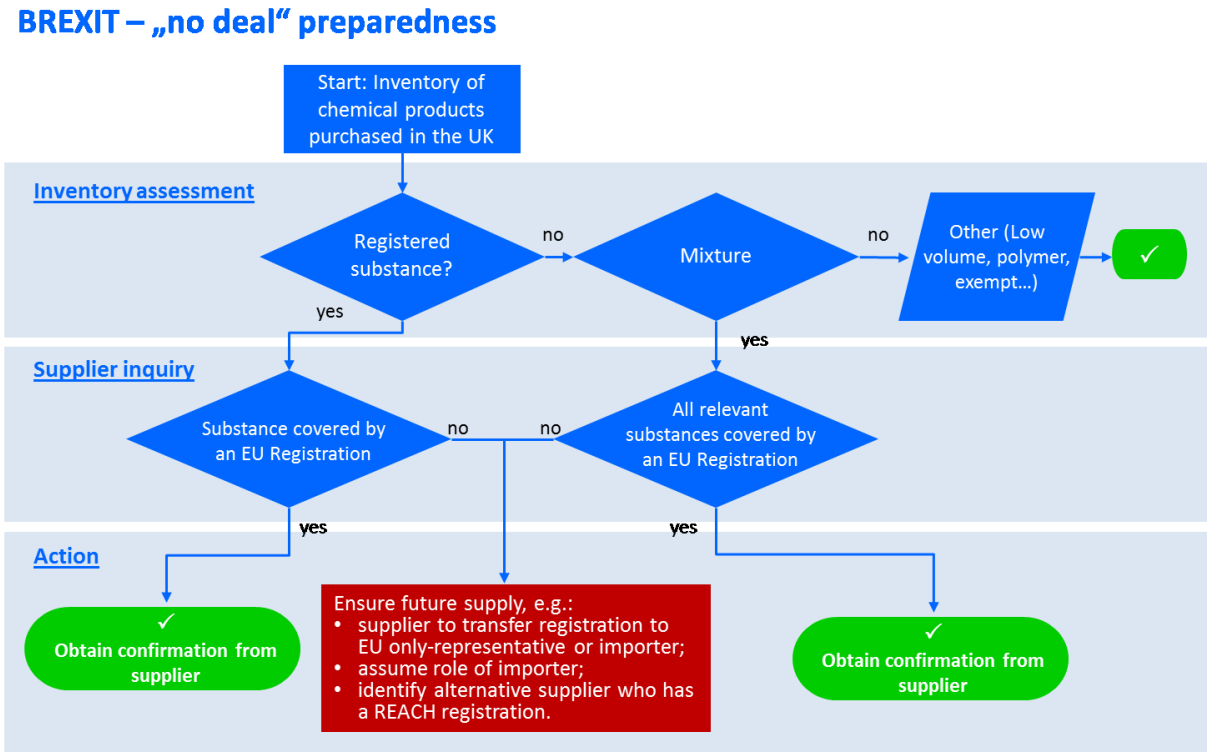
Restriction

- EU-27 customers of UK entities should hold their suppliers to continued fulfillment of the REACH legal obligations by means of contractual agreements

Communication in the Supply Chain

- EU-27 customers of UK entities should hold their suppliers to continued fulfillment of the REACH legal obligations by means of contractual agreements e.g. continued supply of eSDS, continued information about SVHC in articles.

Here is a schematic decision tree that you could use in oder to conduct a first inventory assessment:



Source: Joint Cefic/CIA briefing note, 10 October 2018

Export into the UK – implications of a 'no deal' scenario

The UK Government already published guidance on the future framework for regulating chemicals in the UK (24 September 2018), in the case of a 'no deal' scenario. https://www.gov.uk/government/publications/regulating-chemicals-reach-if-theres-no-brexit-deal.
The Health and Safety Executive (HSE) would act as the lead UK authority. A new UK IT system that is similar to the ECHA IT system is currently under development and will enable the registration of chemicals from end of March 2019 on.

UK-based companies with existing REACH registrations/authorizations

- Existing REACH registrations and authorizations will be carried over into the new UK IT system and are thus 'grandfathered'. To ensure business continuity on the UK market, UK firms would need to open a new account and to provide some basic information on their existing registration **within 60 days** after the UK has left the EU. **Within 2 years** from the withdrawal date, companies with grandfathered registrations would have to provide the HSE with the full data package that supported the original registration and that is hosted on the ECHA IT system.

UK downstream users (i.e. without EU REACH registration)

- UK companies that are importing chemicals from the EU will become importers after the Brexit day. To avoid business disruption, an **interim arrangement** has been set up that would require such companies to provide some basic information on the chemicals **within 180 days** of the UK leaving the EU. They would need to move to a full registration at a later date. A concrete deadline will be determined after the review of the approach.

Companies wishing to place chemicals on both the EU and UK markets after Brexit, in a 'no deal' scenario, would have to ensure two separate registrations are in place, one to ECHA and one to the UK. The information and data package would however be the same for both markets.

Brexit implications with respect to CLP (classification, labelling, and packaging of chemicals)

After the day of the UK Withdrawal from the EU, UK-based companies no longer need to comply with the EU CLP Regulation (Regulation (EC) No 1272/2008). Its provisions may, however, continue to apply in the UK since the UK Government has indicated that it will convert existing EU legislation directly into the UK legal system.
EU-27 based companies currently sourcing substances and mixtures from the UK will become importers under CLP after Brexit. They will need to comply with all the duties of importers under CLP and so will be responsible for classification, labelling and packaging of the product. They may also have a notification obligation to the Classification and Labelling inventory (ECHA), for substances as such or mixtures above the concentration limits that trigger classification.
The UK Government has issued a technical notice (12 October 2018) that outlines the framework of the future CLP regulatory system in the UK in case of a 'no deal' Brexit for industry guidance. The UK would establish a standalone chemicals regime, in which the UK classification and labelling provisions would be based on the existing EU regulatory regime. Functions currently under ECHA responsibility for the EU would be transferred to Health and Safety Executive (HSE) in the UK. Companies would thus interact with HSE for UK CLP obligations, e.g. submission of notifications of classification of chemicals.
The technical notice provides reassurance for several key provisions: "The majority of CLP would remain applicable in the UK […] and all the labelling requirements would remain in place too, including the principles for the different labelling elements, the location of the label on the packaging, and exemptions where applicable. […] The packaging requirements would also stay the same, including those requirements for child resistant closures and tactile warning devices. The testing arrangements, including the

prohibition of testing on humans and non-human primates for the purposes of CLP, will still apply."

While the existing provisions would still apply in most areas, there would however be important changes:

- **"Once we [UK] leave the EU, HSE would have the ability to put in place new arrangements for mandatory classification and labelling."**
- **"Companies would be required to use new UK arrangements and IT tools provided by HSE. These IT tools would be a mandatory UK classification and labelling list (of substances) and a UK notification database. The new arrangements will be operational after 29 March 2019, if there's no deal."**
- **"Responsibility for chemicals being imported into the EU from the UK would rest with whoever is the EU-based importer – the importer may therefore need details of the chemicals involved from the UK-based company."**

For Your Readiness Assessment

To recap, here are some important questions that you should answer yourself in order to assess your preparedness for Brexit:

- Have you checked whether any supplier of your procured chemical substances is resident in the UK and whether this supplier is the lead registrant for the respective substance?

- For any substances with UK supply, have you checked whether the respective UK supplier has established or is planning to establish a subsidiary in the EU-27 which a registration could legally be transferred to?

- For any concerned substances, have you checked whether the respective UK supplier is able and willing to transfer the registration to an OR (Only Representative) within EU-27?

- Have you considered alternative sources/suppliers (from the EU-27) for your substances affected by Brexit?

- Have you checked whether it makes sense to perform an own registration as future importer of registered chemical substances?

- Have you checked whether procured chemical substances of non-EU suppliers have been registered in the EU by UK-based Only Representatives (OR) and how these OR's are planning to secure their legal status in the EU-27?

- Have you checked whether procured authorised substances have been registered by a UK manufacturer?

- Have you checked whether the respective UK manufacturer has established or is planning to establish a subsidiary in the EU-27 which the authorisation could legally be transferred to?

- Have you checked whether an own (cost-intensive) authorisation is a viable option?

- In case products containing SVHC are imported into the EU, have you ensured that all applicable obligations are added to any contract with UK partners in order to fulfil the requirements/obligations according to REACH Article 7(2)ff?

Our recommendations for the most relevant scenarios

EU REACH registrations:

- Solution for substances that were REACH registered by UK-based Only Representatives (OR) - **transfer the OR role to SCC**!
  No worries, OR transfers are “business as usual” for SCC and won’t cost a fortune!
- Solution for substances that were REACH registered by UK-based manufacturers or importers – **registration either by SCC as OR or by an EU-27 importer / downstream user supported by SCC**.

  No worries, SCC has gained experience in the field of REACH registration since the very beginning in 2008!

Substances marketed in the UK:

- Solution for such substances that need to be registered according to new regulation (under preparation) in the UK for continued supply - **UK registration via SCC in collaboration with its experienced UK-based partner consultant!**

Project cost and agency fees will depend on the currently unknown details for registration provisions – but we estimate that the project cost might be in a similar range as for generation and submission of an EU Member dossier for REACH.

To sum up, what is your degree of preparedness for the Brexit? Come and talk to us if you want to enhance your ability to stay agile and to secure your supply chains in Europe!

Please contact Dr Thomas Roth, Head of Chemicals Department (thomas.roth@scc-gmbh.de) if you would like to obtain more information or need further support.

CALENDAR

CRD – One Day Efficacy Biopesticide Workshop: Requirements and Assessment under EC 1107/2009
in York, United Kingdom
6 December 2018

Please meet SCC at the upcoming CRD Efficacy Biopesticide Workshop, taking place in York on 6 December 2018.

This one day workshop will provide an overview of the European Legislation, data requirements, and associated guidance for the efficacy evaluation of biopesticide active substances and plant protection products (Regulation EC 1107/2009). For more information, please visit the event website.
Anke König-Wingenfeld, Assistant Manager Regulatory Affairs, Agrochemicals and Biopesticides – Biostimulants, Fertiliser, IPM, will be happy to meet you in York. Please do not hesitate to speak to Anke about your company's regulatory needs for biopesticides, including efficacy assessments, trial planning & monitoring.

AGES – Plant Protection Products – Efficacy evaluation in high growing crops based on leaf wall area
in Vienna, Austria
7 December 2018

Jasmin Philippi, Assistant Manager Regulatory Affairs, Agrochemicals and Biopesticides, will join the workshop. Jasmin would be happy to take the opportunity to discuss with you your regulatory needs regarding plant protection products.
Experts from the AGES Institute for Plant Protection Products offer a workshop to address several current developments and updates in the field of leaf wall area. For more information please visit the AGES website.

European Biostimulants Interective Summit in Madrid, Spain
23 - 24 January 2019

Please meet
Anke König-Wingenfeld, Assistant Manager Regulatory Affairs, Agrochemicals and Biopesticides – Biostimulants, Fertiliser, IPM, at the European Biostimulants Interactive Summit 2019 in Madrid, Spain.
The two-day event will bring together key industry stakeholders from the biostimulants industry to give insights into the current challenges being faced and what opportunities lie ahead. Find out more about the summit on the event's official website.
Anke looks forward to meeting you in Madrid and discussing with you your registration needs for biostimulants and biopesticides as well as any other regulatory or scientific issues you might want to address.

Do you have any comments, questions or suggestions?
Drop us an E-mail at newsletter@scc-gmbh.de.

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