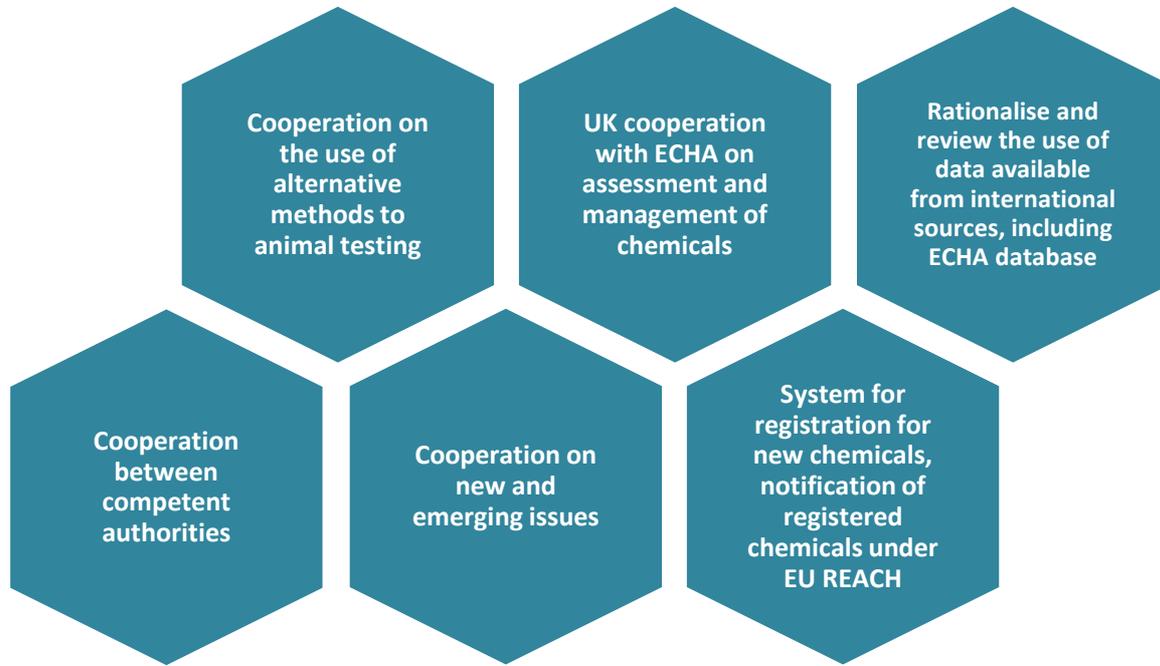


## CTPA POSITION PAPER THE UK COSMETICS INDUSTRY STANCE ON THE FUTURE FOR THE UK REGULATORY FRAMEWORK FOR CHEMICALS

### Negotiation arguments and UK REACH proposal



## Why Is It Important?

**Reduce risk of compromising the safety for the consumer and the environment**

- Safety for the consumer and the environment is the priority for the cosmetics industry. Cooperation on safe use of chemicals, assessment and restrictions will be key to environmental protection and human health.
- Cooperation of the UK with ECHA to review and manage chemicals will enable the industry to maintain and maximise safety for the environment and human health in the European continent.
- Exchange of information between UK and EU on chemicals will enable the chemicals industry to continue to maintain an alert system of any safety concerns on chemicals and address them in a collaborative way.
- Cooperation will support innovation and research to manage chemicals safely and promote the move to the use of less dangerous chemicals. This will also help maintain competitiveness at industry and authority levels.
- Cooperation will ensure that the UK will have a common voice with the EU to have a stronger impact at international level.

**Ensure UK business continuity**

- The UK is a key trade partner of the EU. The chemicals supply chain is fully integrated and disruptions will affect both the UK and the EU, if duplication of existing registration is imposed.
- Cooperation and collaboration between the UK and the EU post-Brexit will avoid the rise of trade barriers and enable marketing and use of chemicals in the European continent.
- Accessing the ECHA database only for review purposes will avoid companies duplicating existing registrations, therefore minimising the huge impact on cost and resources to companies, and reducing the risk of losing access to chemicals in both markets. Please see the relevant section on data access in this paper for more information.
- It will be extremely difficult for businesses to cope with sudden changes and divergent legislations, as the cost to businesses would be increased greatly in a short amount of time.

**Avoid the risk of increasing animal testing**

- The cosmetics industry in the EU does not test on animals as the animal testing bans on finished products and ingredients have been in place since 2004 and 2009 respectively (and earlier in the UK).
- Collaboration and sharing of information and data on chemicals and alternative methodologies will avoid the risk of repeating unnecessary animal testing, which is something that the cosmetics industry cannot condone.

**Environment is a common interest and priority for both the UK and the EU**

- The UK has been a major contributor into REACH and a key stakeholder into the creation of the chemicals database for over 15 years until Exit day. Continuity of this collaboration will be key in order to continue to contribute to the scientific discussions, but more importantly to manage chemicals safely and protect the consumer and environment. We ask the UK to negotiate data access mechanisms to the information on chemicals registered at least up to Exit day, in order to avoid huge impact on the industry (both UK and EU).
- Exchange of information on concerns on chemicals post-Brexit will be key to ensure chemicals are managed safely and the impact on the environment is minimised.
- Due to geographical proximity and full regulatory integrations, the UK and the EU should remain closely aligned on chemicals regulation and management.

## Issues with Data Access –SOLUTION PROPOSAL

Article 119(1) of the EU REACH Regulation obliges ECHA to make information on substances held by the Agency publicly available online, free of charge. ECHA therefore publishes information included in the registration dossiers in the section '[Information on Chemicals](#)' on its website, under the title 'Registered Substances'. This information is freely available for all European citizens so they can be informed of any potential risks of the chemicals that they are using; it can also be reviewed for Government chemical review programmes at regional, national and international levels. Please refer to Annex I of this position paper for more information on the data publicly available on the ECHA database.

Information on chemicals can be used under specific [Terms and Conditions](#). For example, it is not allowed to use the data publicly available for registration purposes under other REACH regimes; however, there are no restrictions if the data are used for review by competent authorities as mentioned above.

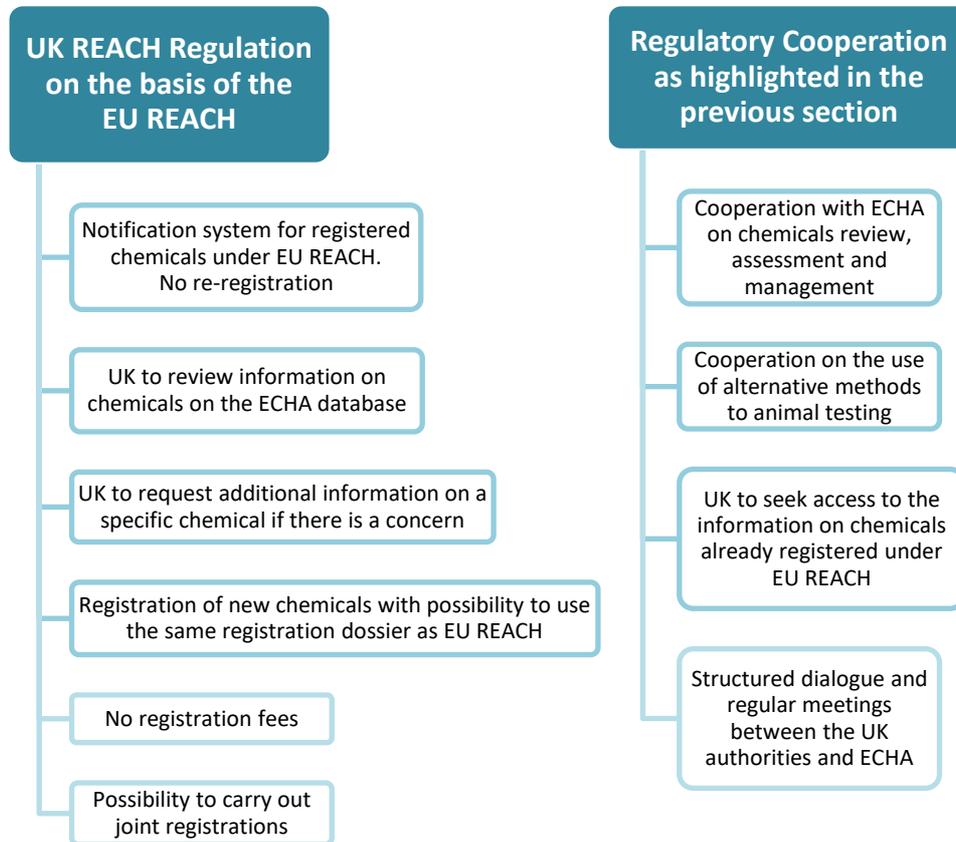
- a) Companies required to re-register substances would find it very challenging due to data ownership, and the direct use of data publicly available by a registrant under another REACH regime is not allowed. The industry would be facing exactly the same issues that were flagged for UK REACH SI under a 'no deal' Brexit. Also, under EU REACH regulation the use of the information on the database to pursue separate registrations cannot be done without companies repeating the relevant studies themselves. Article 10 of EU REACH states *"Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration"*. Article 25(3) covers studies older than 12 years; Article 27(6) covers submission groups and gives the ability to refer to studies companies do not directly own where they have paid for the right to do so; Article 30(3) is applicable to animal testing and if there is a need to repeat it the entity commissioning the test does not disclose costs information.
- b) Direct transfer of data from ECHA database into a UK database is not allowed
- c) UK competent authorities to review data on the ECHA database is allowed. This is the easiest option considering that all information on chemicals (apart from some confidential specific information such as trade names) is publicly available on the ECHA database. Please see guidance on Information to Chemicals.

When UK competent authorities review information on the ECHA database and identify a specific concern on a chemical:

- Article 118(2) of EU REACH provides for disclosure of information under emergency situations for human/environment, however this only covers some of the information owned by ECHA.
- Article 120 of EU REACH allows for cooperation with third countries. *"Notwithstanding Articles 118 and 119, information received by ECHA may be disclosed to any government or national authority of a third country or an international organisation in accordance with an agreement concluded between the Community and the third party concerned under Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals (31) or under Article 181a(3) of the Treaty, provided that both the following conditions are met:*
  - (a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;*
  - (b) the third party protects the confidential information as mutually agreed."*

Therefore, mechanisms for data access should be incorporated into the regulatory cooperation agreement between the UK and the EU.

## The UK REACH Framework in Detail



### Regulatory cooperation to provide:

- for the UK to review information on chemicals on the ECHA database;
- the UK to access additional data on existing chemicals, if a specific concern is raised. This will be important because UK-registered substances are likely to have lower tonnage bands vs EU27, therefore requiring less information to be submitted;
- the UK to collaborate with ECHA in terms of technical and scientific assessment separately from RAC and SEAC (e.g. as Switzerland).

**Notification system** and monitoring responsibilities for chemicals already registered under EU REACH manufactured or imported into the UK above 1 tonne per year after Exit day (provided the import quantity is covered by the tonnage band registered under EU REACH).

- To allow the UK authority to know which existing chemicals are available on the UK market.
- The notification would not require re-registration of the chemicals but just the provision of information on the chemical's identity (CAS number), manufacturer or importer and quantity.

**Registration system** for new chemicals manufactured or imported into the UK above 1 tonne per year after Exit day.

- Registration of new chemicals under both EU and UK REACH.
- Possibility to use the same dossier for registering the same chemical under EU and UK REACH (however if the chemical is imported in both regions in different tonnage bands, the dossier has to be adapted).

Also to be included in the UK REACH law:

- a provision for reducing the requirements for animal testing for low tonnage and low hazard chemicals, by means of a tiered approach to assessment;
- review of deadlines;
- the assessment of chemicals shall be risk-based and different depending on tonnage level;
- greater consideration should be given to read-across data.

## ANNEX I: Information on Chemicals – ECHA Database

Article 119(1) of the [Registration, Evaluation, Authorisation of Chemicals \(REACH\) Regulation](#) provides for ECHA to make information on substances held by the Agency publicly available online and free of charge. ECHA therefore publishes information included in the registration dossiers in the section '[Information on Chemicals](#)' on its website, under the heading 'Registered Substances'. This information is available for all European citizens so they can be informed of any potential risks of the chemicals that are in use. Furthermore, as stated in the ECHA guidance on the [Dissemination and Confidentiality under the REACH Regulation](#), the information can also be reviewed for Government chemical review programmes at national, regional and international levels.

The information published covers:

- the identity of the substance;
- the results of studies on its intrinsic properties and hazard profiles;
- the levels where no adverse effects are expected for human health or the environment;
- the substance's classification and labelling;
- as guidance on the substance's safe use.

If not claimed confidential, ECHA will also publish the substance's degree of purity essential for classification and labelling, total tonnage band, (robust) study summaries, information in the safety data sheet and the trade name. A complete list of the information disseminated on the ECHA database can be found in Article 119 of the REACH Regulation and in more detail in the ECHA guidance [Dissemination and Confidentiality under the REACH Regulation](#).

Even if not all information can be made confidential, in certain cases, information can be withheld and made confidential if the registrant submitting the information also indicates they wish to keep the information confidential, and submits a justification as to why publishing the information would be potentially harmful to the commercial interests of the registrant or any other party concerned. Such justifications will be assessed by ECHA in accordance with Article 119(2) of REACH, and where the justification is accepted as valid by ECHA, the information concerned will not be published. Claiming information confidential may be subject to a fee.

ECHA has also developed InfoCards and Brief Profiles for substances, which are significantly based on the data submitted in REACH registrations.

Information on chemicals can be used under specific [Terms and Conditions](#). For example, it is not allowed to use the data publicly available for registration purposes under other REACH regimes; this means that companies in a third country cannot take and use the information on the ECHA database to register the substance under the third country's REACH framework. To be able to do so, companies in the third country have to request access and buy the data from the EU REACH registration holder, or lead registrant if the substance was registered by a Joint Submission Group. This becomes very challenging as data access can become very costly and there are associated intellectual property issues. The same restrictions apply to the transfer of data from the ECHA database into a third country's REACH database. However, under these Ts&Cs there are no restrictions to use the data in the ECHA database for review by competent authorities as mentioned above.

## EXAMPLE Salicylic acid

Search for Chemicals

I have read and I accept [the legal notice](#) [ADVANCED SEARCH](#) >

Page 1 of 6 | 50 Items per Page | Showing 1 - 50 of 263 results. | -- First | Previous | Next | Last --

Name	EC / List no.	CAS no.	BP
Salicylic acid	200-712-3	69-72-7	BP

By clicking on the name of the substance, you are then directed to the substance's [InfoCard](#), containing preliminary information on the substance.

### Substance information

Infocards are automatically generated based on industry data. [What is an infocard?](#)

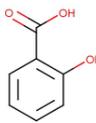
[See a problem or have feedback?](#)

### Salicylic acid

Translated names 21 | CAS names 1 | IUPAC names 7 | Trade names 1 | Other identifiers 5

#### Substance identity

EC / List no.: 200-712-3  
CAS no.: 69-72-7  
Mol. formula: C7H6O3



#### Hazard classification & labelling

  
**Danger!** According to the harmonised classification and labelling (ATP13) approved by the European Union, this substance is harmful if swallowed, causes serious eye damage and is suspected of damaging the unborn child.

#### Properties of concern

**R** Suspected to be Toxic to Reproduction

#### How to use it safely

- Precautionary measures suggested by manufacturers and importers of this substance.
- Guidance on the safe use of the substance provided by manufacturers and importers of this substance.

#### About this substance

This substance is manufactured and/or imported in the European Economic Area in 1 000 - 10 000 tonnes per year.  
This substance is used by consumers, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

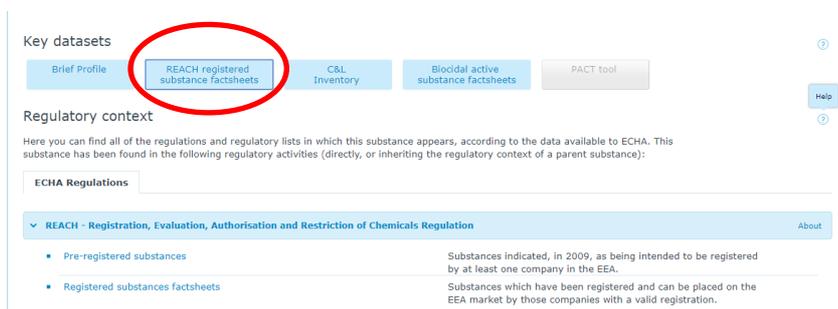
#### Biocidal Uses

This substance is being reviewed for use as a biocide in the EEA and/or Switzerland, for: disinfection, veterinary hygiene, food and animals feeds.

#### Consumer Uses

This substance is used in the following products: cosmetics and personal care products, air care products, perfumes and fragrances, polishes and waxes and washing & cleaning products.  
Other release to the environment of this substance is likely to occur from: indoor use as processing aid and outdoor use as processing aid.

From the InfoCard, you can access the REACH registration information by clicking on the related icon as specified below.



The subsequent [page](#) allows access to the EChem portal (the ECHA portal on information on chemicals) by clicking on the symbol as indicated below.

[View all Registered Substances](#)

Name	EC / List no.	CAS no.	Registration type	Submission type	Total tonnage band	
Salicylic acid	200-712-3	69-72-7	Full		1 000 - 10 000 tonnes per annum	
Salicylic acid	200-712-3	69-72-7	Intermediate		Intermediate Use Only	

The [registration dossier](#) of the substance in the example contains the information listed below:

- general information (identification, compositions, registration data, administrative data – registration numbers, contact person);
- classification and labelling and PBT (Persistent, Bioaccumulative, Toxic) assessment;
- manufacture, use and exposure;
- physical and chemical properties;
- environmental fate and pathways (including stability, biodegradation, bioaccumulation, transport and distribution, environmental data);
- ecotoxicological information (aquatic toxicity, terrestrial toxicity);
- toxicological information (toxicokinetics, acute toxicity, irritation/corrosion, sensitisation, repeated dose toxicity, genetic toxicity, carcinogenicity, toxicity to reproduction, specific investigations, exposure related observations in humans, additional toxicological data);
- analytical methods;
- guidance on safe use;
- assessment reports.

## Salicylic acid



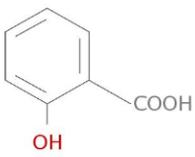
EC number: 200-712-3 | CAS number: 69-72-7

- General information
- Classification & Labelling & PBT assessment
- Manufacture, use & exposure
- Physical & Chemical properties
- Environmental fate & pathways
- Ecotoxicological information
- Toxicological information
- Analytical methods
- Guidance on safe use
- Assessment reports
- Reference substances

### General information

Identification | Compositions | Registration data | Administrative data | Contact Persons responsible for the SDS

### Identification

	Display Name:	Salicylic acid
	EC Number:	200-712-3
	EC Name:	Salicylic acid
	CAS Number:	69-72-7
	Molecular formula:	C7H6O3
	IUPAC Name:	2-hydroxybenzoic acid

### Type of substance

Composition:	mono-constituent substance
Origin:	organic

### Total tonnage band

Total range:	1 000 - 10 000 tonnes per annum
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### REACH

Registered as:	FULL
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## ANNEX II: REACH Swiss Model

The [Swiss model](#) accepts existing registrations under EU REACH and provides for notifications of new chemicals on the Swiss market. The information that has to be submitted for the notification (Article 27 of Swiss REACH) includes:

1. Import quantity
2. Identity of the importer who does the notification
3. Manufacturing process and mode of use of the chemical
4. Classification and labelling of the chemical
5. Instructions for safe use of the chemicals
6. Evaluation of exposure to the chemical
7. Physico-chemical properties
8. Properties that are dangerous to human health
9. Properties that are dangerous for the environment
10. Chemical Safety report as per Article 28 for substances imported above 10 tonnes
11. Safety information for substances classified as PBT and vPvB
12. Any additional relevant information

The Swiss model allows for authorities to request access to full information on substances if there is a specific concern with a chemical. There are other requirements for specific dangerous substances, or PBT/vPvB, SVHCs and nanomaterials (Article 48 of Swiss REACH).

Article 80 also provides for authorities to request full visibility of all information relating to a specific substance already registered under EU REACH, should a specific concern be raised.

## ANNEX III: Impact Assessment of re-registration of chemicals

### CTPA UK REACH Questionnaire Feedback on the 'no deal' REACH plan (17 June 2019)

This document provides evidence from current EU REACH registrants of the economic and logistical impact the 'no deal' Brexit UK REACH SI would have on the cosmetics industry. It also sets out how companies are currently unable to fulfil their obligations under this 'no deal' legislation and the reasons why.

#### Feedback from industry

CTPA received the following answers from raw material suppliers, retailers and distributors. The document will be updated as further responses are received. The questionnaire has been shared with both UK and EU Government.

- Overall, due to the highly uncertain political landscape, most companies are not able to provide detailed information on their contingency plans for UK REACH and on their commercial plans to negotiate data access for the purpose of UK REACH. Compliance with UK REACH requires a financial commitment that companies can only take once it is certain that there will be a 'no deal' scenario. The negotiation of data access is a financial and commercial decision that companies will assess on a case-by-case basis and that companies will start only when it is sure that it will be needed.
- The European Chemicals Agency (ECHA) is not in favour of duplication of data and costs, however it is constrained by political negotiations beyond its control. Data access for compliance with UK REACH will therefore be a purely commercial decision for the companies owning the data.

Among the companies who replied to the CTPA questionnaire:

- **All companies have taken actions to ensure initial compliance with EU REACH** (e.g. transfer of registration to EU entities from UK-based registrants or lead registrants) for continuity of supply to the EU.
- **None of the companies could ensure compliance with UK REACH and continuity of supply to the UK after the two years transition period**, when full registration of chemicals manufactured or imported into the UK will be required. The decision will be determined by the company's ability to sustain the financial cost of submitting the full registration under UK REACH, which will depend on how viable/important the UK market will be in the future.
- Only **2 out of 9** companies are considering negotiating data access with UK-based companies for the purpose of UK REACH. These two companies could not provide any specific figures of costs for data access as this will be decided on a case-by-case basis: different substances were subject to different costs of registration and testing, which would determine the possible cost for data access together with the commercial interest of that substance. We have an example of costs for two different substances:
  - substance A → €120,000 cost for registration; €55,000 cost for testing to generate additional data;
  - substance B → €14,000 cost for registration; €11,000 cost for testing to generate additional data.
- Only **1 out of 9** companies has appointed a UK-based Only Representative to carry out the Downstream User (DU) import notifications to help their UK-based customers who are currently

- DUs. It is extremely difficult for companies to prepare due the uncertain political landscape, as this requires commitment of costs that not all companies, particularly SMEs, can afford under uncertain circumstances.
- Only **1 out of 9** companies who are UK-based registration holders for EU REACH confirmed that they will do the preliminary registration within 120 days from Exit, as required under the UK REACH SI; however, the company could not confirm it will complete the full registration after two years of transition period. It is extremely difficult for companies to prepare due the uncertain political landscape, as this requires commitment of costs that not all companies can afford.
- UK-based companies who are currently distributors (and therefore Downstream Users) cannot guarantee continuity of supply of chemicals into the UK market. It will depend on whether they will be able to afford the cost of registering the substances.
- EU-based companies who are currently distributing into the UK with registrations valid under EU REACH, see a 'no deal' Brexit and the UK REACH plan as a “**serious threat to their businesses**”, as quoted by one of the companies who gave feedback. These companies will lose direct market access to the UK and will only be able to continue marketing chemicals in the UK if they appointed an Only Representative in the country; this would require disclosing confidential substance information that they are not prepared to share with third parties.

#### Case Study

A company with a **high presence in the UK**, which is currently a Downstream User of cosmetics and other consumer products, will become an importer of products coming from the EU27 and will therefore have registration obligations under UK REACH.

- The company confirmed that this situation is **not feasible** as it has absolutely no information from the brand owners of these products. The owners are not prepared to release it.

This company also provided data related to its own brands, which gives an estimate of the costs it will incur to comply with UK REACH and sets out how complicated the cosmetics supply chain is:

- 81% of its suppliers have not confirmed the location and plans of the registrant/lead registrant, which is a risk to business continuity.
- The company estimates it will need to conduct just under 3000 notifications/pre-registrations. This will take approximately 6.25 weeks assuming all required information is readily available.
- As for the full registration which will be required after two years from Exit, the company considered the average cost of €50,000 per registration as a whole (however this figure can change based on the substance). This cost would occur to the company as a whole if it registers the substance on its own. However, the company made the assumption that it will register the substance in a joint submission composed of 10 registrants, resulting in a data sharing cost to the company of €5,000. If this is the case for the 3000 substances the company will be responsible for, then the total cost for registering all substances amounts to **€15 million**.
- It is important to highlight that this cost **excludes** any additional costs needed to obtain the necessary analytical data, registration fees, consultants' fees and staff costs. The company has stated: “**this is an impossible burden for our business to carry**”.

## Conclusion

The feedback CTPA received from companies based in both the UK and the EU is very clear. Either companies will not be able to sustain the financial burden that the UK REACH SI, as it currently stands, requires; or companies will stop the supply of chemicals to the UK.

At this point, it is crucial for the UK Government to understand that the UK REACH SI prepared for 'no deal' is **not practically feasible** for chemicals already registered under EU REACH and CTPA urges it should be amended to ensure continuity of business from both the UK and the EU.

More information can also be found on the [research](#) from the Department for the Environment, Food and Rural Affairs (Defra) on the impact of Brexit on chemicals businesses. The research highlighted and confirmed all the challenges that CTPA and its members, along with other chemical sectors and related trade associations, have flagged. The key findings are below.

- Companies are not able to prepare for REACH, due to the uncertainty of the political landscape and the difficulty in mapping what plans registration holders have.
- Re-registration under UK REACH of substances already registered under EU REACH is not viable, risking some substances to be withdrawn from the UK market.
- UK registrations will be challenging due to data access (negotiating time and costs to access data from lead registrants in EU REACH), a not fit-for-purpose IT system, difficulty in contacting lead registrants in EU joint submission groups, short timeframes for making registrations (interviewed companies suggested to increase timeframes of between 5-10 years), suitability of UK Agency to deal with all the work (ECHA has been working on REACH, compliance checks of dossiers and evaluation of substances since 2006 and still hasn't finished).
- UK REACH will lead to supply chain disruptions, increased prices of substances, loss of sales and the UK manufacturing may no longer be competitive vs EU manufacturing. More importantly, it may lead to additional animal testing which would lead to extra costs and risk finding different data and classification for substances. In particular, animal testing is something that the cosmetics industry cannot condone.
- Interviewed companies suggested to put in place arrangements to reduce administrative burdens and ask for full data submission only for substances of concern, whilst not duplicating all the work that has been done for EU REACH.
- The study also provides estimated figures for costs of re-doing registrations under UK REACH. Costs vary per company, but generally range between £1-5 million; a company estimated costs of up to £40 million, and another company estimated costs of approximately £65 million if considering also changes to the supply chain.
- The study showed that there is a clear intention to continue to supply the EU market with chemicals, therefore appointing Only Representatives in the EU, changing the supply chain, etc; the continuity of supplying the UK market is instead not clear and depends on the costs deriving from UK REACH.