## BREXIT countdown

### Brexit and REACH: an overview for a worst case scenario (no deal – Hard Brexit)

Only few days remain until March 29th, 2019, the deadline for UK to leave EU.
What are the perspectives after such a date for the REACH legislation on the whole?

In the event of a no-deal (hard Brexit), the UK would ensure **UK legislation replaces EU legislation** via the EU Withdrawal Act; UK has to establish a regulatory framework and build **domestic capacity** to deliver the functions currently performed by ECHA. The legislation would preserve REACH principles as far as possible.

UK would continue to be able to monitor and evaluate chemicals in the UK to reduce the risk posed to human health and the environment, a key pillar of the EU Reach regulation! It would also minimize disruption to the supply in chemicals. Existing standards of protection of human health and the environment would be maintained. The Health and Safety Executive (HSE) would act as the lead UK regulatory authority from the day the UK leaves the EU and building on its existing capacity and capability.

The new regulatory framework would:

- enable the registration of new chemicals through a UK IT system that is similar to the existing EU IT system; provide specialist capacity to evaluate the impact of chemicals on health and the environment;

- ensure sufficient regulatory and enforcement capacity in the HSE, the Environment Agency (EA) and other regulators, enabling them to recommend controls in response to the hazards and risks of substances

- provide for an appropriate policy function in Department for Environment, Food & Rural Affairs (DEFRA) and the devolved administrations.

***What no-deal would mean for chemical companies?***

a. UK Companies registered with REACH would no longer be able to sell into the EEA market without transferring their registrations to an EEA-based organization. UK Companies would therefore need to take action to preserve their EEA market access. Furthermore, businesses with existing EU REACH registrations or authorizations being automatically grandfathered into the UK regime would have to validate them with the UK authority (the HSE). Companies will need to open an account on the new UK IT system and provide some basic information on their existing registration within 120 days and on their existing authorizations within 60 days of the UK leaving the EU. This IT system is being tested with a range of different users so that it is ready to support registrations of chemicals in the UK from March 2019. Companies with grandfathered registrations would have two years from the day the UK leaves the EU to provide the UK authority (the HSE) with the full data package that supported their original EU registration and is held on the ECHA IT system.
   If a business wished to place new chemicals on both the EEA and UK markets, in a 'no deal' scenario, they would have to make two separate registrations, one to ECHA and one to the UK. The information and data package needed would be the same for both, just a different administration processes.

b. UK downstream users currently importing chemicals from an EEA country would face new registration requirements as the related registrations of their providers will no longer be valid. Under the UK's replacement for REACH, importers would have a duty to register chemicals.

Similarly UK downstream users of authorizations would no longer be able to rely on authorization decisions addressed to companies in the remaining EEA countries.

c. Non UK companies importing chemicals to UK will no longer be recognized as EEA companies; therefore they will need to register under the new UK system using a OR like system in UK or relying to UK importers (see previous point).

d. Non EU companies using an UK OR needs to select another OR within the EEA countries and assuring this OR has submitted a valid Reach registration covering its supply chain.

**In details specific cases:**

***UK based REACH registrant***

Only an EU/EEA-based company can register a substance under the REACH Regulation. If your company is based in the UK and has registered a substance under REACH, the registration will no longer exist after the UK withdraws from the EU. This also means that you will no longer have to update the REACH registration dossier after 30 March 2019. If you want to continue doing business in the EU/EEA after the UK's withdrawal, you have the option of appointing an only representative to manage your registrations. You also have the option of moving your operations related to the registered substance to a legal entity within the EU. A registrant is responsible for the substances covered by their registrations. This means that the responsible staff and relevant documentation must be present at the address of the registrant – setting up a company on paper only in the EU-27 or EEA is not sufficient.

***UK Based authorization holder under REACH***

After the UK's withdrawal from the EU, EU legislation will no longer apply to the UK. This means that, for example, if your UK-based company holds or is covered by a REACH authorization for certain uses of an Annex XIV substance, the conditions of the authorization no longer apply to you. Authorizations granted to UK-based companies will no longer exist, so EU-based companies relying on such authorizations will need to find suppliers with valid authorizations in the EU-27/EEA, or apply for new authorizations themselves. A UK-based company can transfer its application or authorization e.g. to an only representative in the EU. It's recommended that you make a formal agreement with the only representative that takes effect at the same time as the UK's withdrawal. The transfer shall be notified in REACH-IT as early as possible during the 'Brexit window' between 12 and 29 March 2019 following the instructions in the 'How to transfer your UK REACH registrations prior to the UK withdrawal from the EU' guide.

***Manufacturer or formulator outside EU/EEA***

If you have appointed an only representative that is located in the UK, you can appoint a new only representative, located within the EU-27/EEA. The new appointment must take place ahead of the UK withdrawal and be notified to ECHA (through the 'Legal entity change' functionality in REACH-IT) without undue delay. If your substance has been registered by a UK-based importer, that registration will not exist after the UK's withdrawal. This means that to continue having access to the EU market, the imported substance will need to be registered by an EU-27/EEA-based legal entity. To this end, you can appoint an only representative located within the EU-27/EEA to carry out the required registration of the imported substance. Alternatively, your customers within the EU-27/EEA will each have to register the substances they import.

***UK based OR (Only Representative)***

If you represent a non-EU company and you are based in the UK, you will no longer be able to act as an only representative after the withdrawal, unless you relocate to an EU-27 or EEA country. Otherwise, to remain legally on the EU market, the non-EU manufacturer that appointed you will need to find a new only representative, based in one of the EU-27 or EEA countries. The registrations will have to be transferred to that new OR.

***EU-27 based company***

If your company is based in one of the remaining EU-27 or EEA countries, EU legislation and obligations will continue to apply to you. However, your business partners in the UK will need to adjust their operations to follow the new UK chemicals legislation. If you purchased a chemical substance from a UK-based company that registered a substance under REACH, you will no longer be able to rely on the substance being legally registered after the UK has left the EU. For the substance to remain legally registered, the UK-based manufacturer from which you bought the chemical will need to appoint an only representative established in one of the EU-27 or EEA countries. Alternatively, you can choose to register the substance yourself as an importer. If your UK-based supplier is currently an importer of the chemical from outside the EU/EEA, they have the option of moving their importing activity to the EU-27 or EEA. Otherwise, you will need to register the substance as the EU-importer.

*1. Joint Registration with a UK based company*

Things will also change if your company is a member of a joint submission with a UK-based company as the Lead Registrant. A registration made by a UK-based company will no longer exist after the UK's withdrawal from the EU

*2. C&L Notifications*

If you plan to import substances from a UK-based company into the EU after the UK's withdrawal, it is you, not the UK-based company, who will have to submit the C&L notifications to ECHA. A C&L notification must also be submitted for substances in mixtures, when the concentration of the substance triggers the classification of the mixture. A separate C&L notification is not needed when you have registered the substance. Any mixture that you import will need to comply with the CLP Regulation

*3. PIC Regulation*

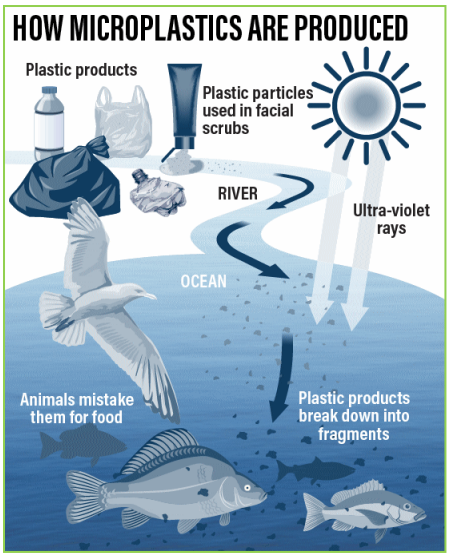
As an EU-27 company, you will need to start notifying exports to the UK of chemicals under the PIC Regulation. After the UK withdraws from EU, UK companies on the other hand will no longer have obligations under PIC Regulation. This also means that UK companies will no longer have to notify their exports through e-PIC or have access to the application; export notification submitted by any UK-based company will ne disabled.

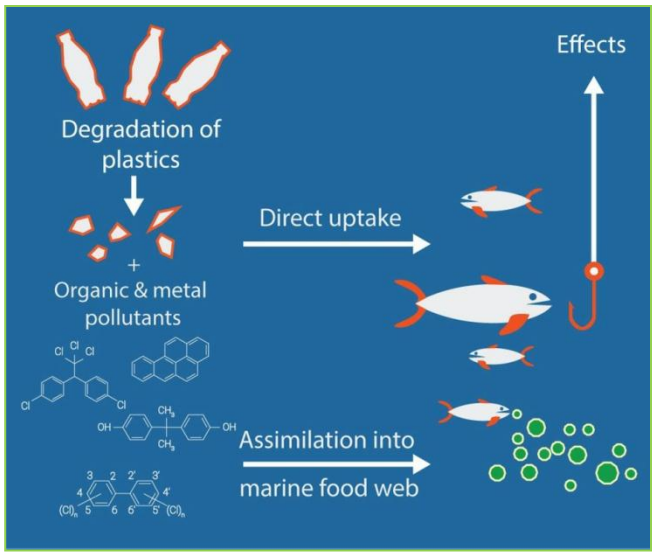
***EU-27 downstream user of an authorized substance***

REACH authorizations granted to UK suppliers will no longer exist after the UK withdraws from the EU. If you rely on such an authorization and want to continue using the substance, you can apply and become an authorization holder of the substance yourself. Remember that UK-based manufacturers and formulators can transfer their authorization to an only representative based in one of the remaining EU-27 Member States or the EEA. UK-based only representatives can transfer their authorization or pending application for authorization to a new only representative based in the EU-27/EEA, appointed by the non-EU manufacturer. Please note, however, that UK-based importers cannot transfer their authorization to an only representative in the EU-27/EEA.

## A NEW CHALLENGE: MICROPLASTICS

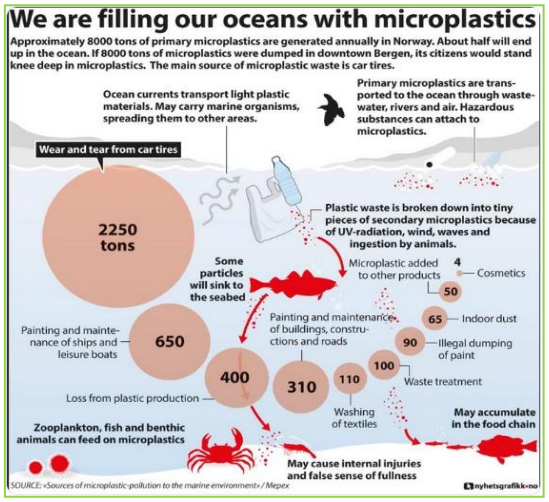
Microplastics are defined as extremely small pieces of plastic debris in the environment resulting from the disposal and breakdown of consumer products and industrial waste. Recently a wide concern on how microplastics can affect the environmental condition as well human health both directly as contained in products and/or indirectly via environmental pollution is growing.




It has been estimated that a huge amount of microplastics are released every year in the natural environment. (See Figure n. 1 as example)

***Figure n. 1***




An increasing number of scientific literature is available nowadays trying to approach the huge problem of microplastics and trying to evaluate if an important risk to environmental and human health really exists. Figure n. 2 represents and interesting case.

***Figure n. 2***

ENVIRONMENT

From Fish to Humans, A Microplastic Invasion May Be Taking a Toll

Tiny bits of plastic have seeped into soil, fish and air, posing a threat to animal and human health

By Andrea Thompson on September 4, 2018

In this contest, ECHA has submitted a restriction proposal for ***microplastic particles that are intentionally added to mixtures used by consumers or professionals***. If adopted, the restriction could reduce the amount of microplastics released to the environment in the EU by about 400.000 tonnes over 20 years.
On January 30, 2019, ECHA published its official REACH restriction proposal for intentionally added microplastics. It may literally ban the use of international added microplastics in cosmetics, medical devices, detergents, fertilizers and plant protection products gradually.
ECHA defines microplastic as a ***material consisting of solid polymercontaining particles***, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ x ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3. CEFIC calls this definition too broad. Once released, microplastics can be extremely persistent in the environment, accumulate in terrestrial and aquatic environments, posing a big threat to terrestrial and aquatic organisms.

The Agency has assessed the health and environmental risks posed by intentionally added microplastics and has concluded that an ***EU-wide restriction would be justified***.
ECHA's assessment found that intentionally added microplastics are most likely to accumulate in terrestrial environments, as the particles concentrate in sewage sludge that is frequently applied as fertilizer. A much smaller proportion of these microplastics is released directly to the aquatic environment.
The persistence and the potential for adverse effects or bioaccumulation of microplastics is a cause for concern. Once released, they can be extremely persistent in the environment, lasting thousands of years, and practically impossible to remove. Currently it is not possible to determine the impact of such long-term exposure on the environment.
Data available on effects is limited, particularly for the terrestrial environment, which makes risk assessment difficult. Due to their small size, microplastics and nanoplastics – even smaller particles that are created from the further degradation of microplastics – may be readily ingested and thereby enter the food chain. The potential effects on human health are though still not well understood.
Overall, the use of microplastics in products that result in release to the environment are not adequately controlled.
ECHA's proposed restriction targets ***intentionally added microplastics*** in products from which they will inevitably be released to the environment. The definition of microplastic is wide, covering small, typically microscopic (less than 5mm), synthetic polymer particles that resist (bio)degradation. The scope covers a wide range of uses in consumer and professional products in multiple sectors, including cosmetic products, detergents and maintenance products, paints and coatings, construction materials and medicinal products, as well as various products used in agriculture and horticulture and in the oil and gas sectors.
ECHA has assessed the socio-economic impact of the proposed restriction and is aware that the restriction is likely to result in different costs depending on the type of product affected. However, implementing the restriction is expected to be cost-effective in all sectors, including the agricultural sector, identified in the proposal as the biggest source of intentionally added microplastics.
Several EU Member States have already introduced bans on the use of microplastics in certain types of products, largely concerning wash-off cosmetic products.

Microplastic is proposed to be banned as a substance on its own or in a mixture as a microplastic in a concentration ***equal to or greater than 0.01% w/w***. The restriction will apply to the following products gradually.

- *Cosmetics and other mixtures containing microplastics: Since entry into force date (EIF)*
- *Leave-on cosmetics: 6 years after EIF*
- *Medical devices and in vitro diagnostic devices: 2 years after EIF*
- *Laundry detergents and other mixtures used for household care: 5 years after EIF*
- *Fertilizing products: 5 years after EIF*
- *Plant protection products: 5 years after EIF*

However, the proposed restriction does not apply to:

- *Mixtures containing microplastics used at industrial sites.*
- *Medicinal products for human or veterinary use.*
- *Substances or mixtures where microplastics are contained by technical means throughout their use to prevent releases to the environment and incinerated or disposed as hazardous waste at the end of their life-cycle*
- *Substances or mixtures where the physical properties of microplastic are permanently modified when the substance or mixture is used such that the polymers no longer fulfil the meaning of a microplastic*
- *Substances or mixtures where microplastics are permanently incorporated into a solid matrix at the point of use*

ECHA's Committee for Risk Assessment and Committee for Socio-economic Analysis are currently checking the conformity of the restriction proposal and are expected to formulate their opinions in the coming months and too give stakeholders enough time to prepare for the six-month public consultation scheduled to start in March

## Targeted public consultations on harmonized classification and labeling

ECHA has launched targeted public consultations on additional information provided for two proposals for harmonized classification and labeling.

- Study reports containing additional information on toxicity to reproduction have been submitted by ECHA for the substance **flumioxazin (ISO)**; N-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2H-1,4-benzoxazin-6-yl)cyclohex-1-ene-1,2-dicarboximide (EC -, CAS 103361-09-7).

- The lead registrant of the substance **1-isopropyl-4-methylbenzene; p-cymene** (EC 202-796-7, CAS 99-87-6) has indicated the availability of an unpublished acute toxicity study in Daphnia magna that would potentially change the classification proposal for hazards to the aquatic environment. The study has been provided in the form of a robust study summary in IUCLID format.

Interested parties are invited to submit their comments to both targeted public consultations by **11 February 2019**.

## Targeted CLH consultations

New proposals and intentions to harmonize classification and labeling

Proposals to harmonize the classification and labeling have been submitted for:

- **N,N-dimethyl-p-toluidine** (EC 202-805-4, CAS 99-97-8); and
- **6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid** (EC/CAS -).

New intentions have also been received for:

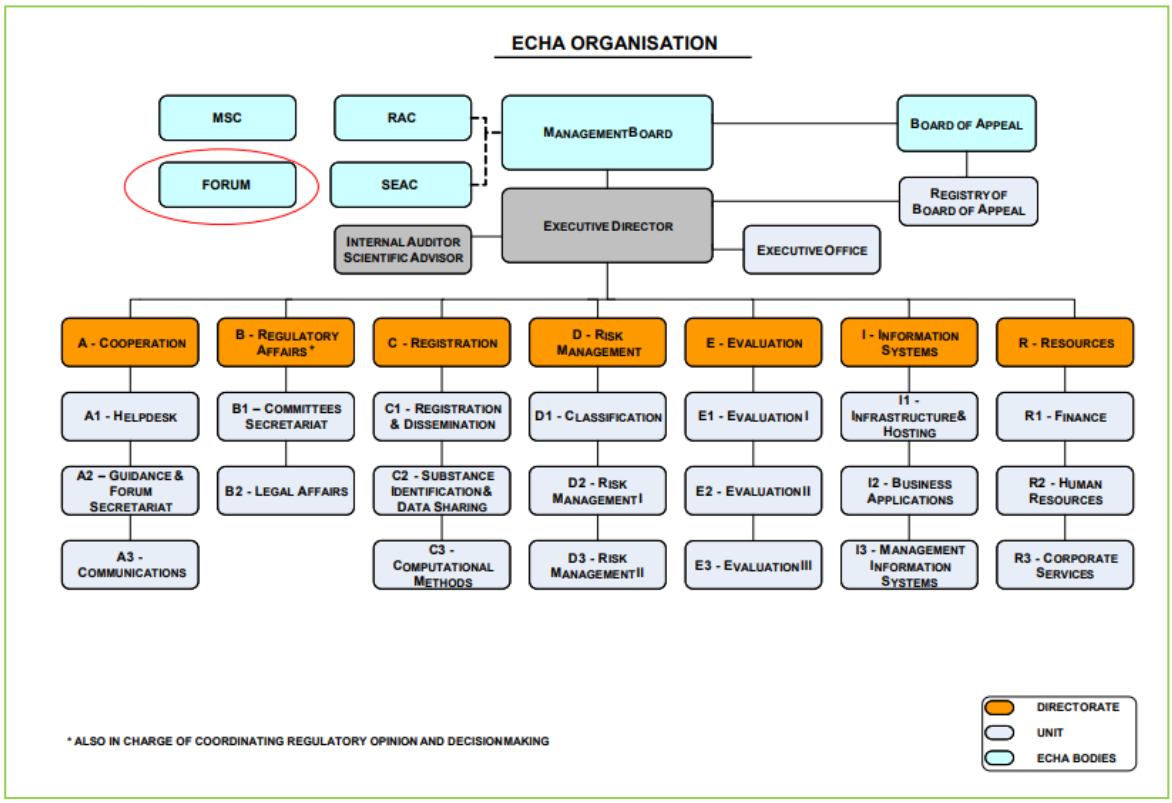
- **silver nitrate** (EC 231-853-9, CAS 7761-88-8);
- **2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate**; 2,2-bis(acryloyloxymethyl)butyl acrylate; trimethylolpropane triacrylate (EC 239-701-3, CAS 15625-89-5); and
- **metribuzin (ISO)**; 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4H)-one (EC 244-209-7, CAS 21087-64-9).

## REF 7 approaching

The Reach Enforcement 7 will be focused on ***registration obligation*** including substances registered as intermediates. EU National Enforcement Authorities (NEA) Inspectors will be requested to check whether companies that need to register substances on their own or in mixture after the last registration deadline (i.e. May 31, 2018) have a ***valid registration*** (Art. 6 and 7 of REACH Regulation). The target will be the last tonnage band (1-100 tpa) but is not excluded that inspector can go back to check old tonnage bands (100-1000, > 1000 tpa); hence assessing registration from higher tonnage bands that have been submitted before. Inspectors will check the correctness of registration as substance or as intermediate depending on the use of such substances and the condition applied.

In particular, regarding the intermediate substances registration as for REACH Art. 17 or 18 (light registration procedure), ***they will check that a substance is only manufactured or imported and used under Strict Controlled Conditions (SCC)*** according to the mentioned articles and, possible, to the related ECHA guidance of edited in 2010. This will be a crucial factor for many companies as the registration of an intermediate substance is much less expensive than for a full substance registration. We will see the outcome of such inspections later!

## ECHA organization at a glance



## CHEMSAFE/AFI: WORKSHOP on Biocidal Product (February 8, 2019)

On February 8, 2019, Chemsafe had sponsored an important workshop on biocide product in cooperation with AFI (Associazione Farmaceutici Industria), a famous and very active Italian association in the Pharma, Medical Devices and Biocides fields. The workshop was held at the University of Milan and from 9 AM to 5 PM and was very successful as it hosted around 100 people. The program has been very interesting; talks started with two basic lectures by Officials from the Italian Ministry of Health and proceeded with talks about the Risk assessment on biocidal products, the endocrine disrupting matters, the creation and management of a Task Force, the family approach. At international level two talks described the efficacy package approach and the US FDA requirements respectively. Speakers and auditors were satisfied by the workshop and express many question during the question times. Chemsafe would like to thanks the organizers and all the speakers for their precious support.

*Alice Basilio*

*Paolo Rossi*

*Antonio Conto*

## CHEMSAFE attendance 2019

Milan (ITALY) February 26-2
Regulatory Toxicology, IKN workshop
Teachers: Antonio Conto (Chemsafe), Marco Rodda (Chemsafe)

Baltimore (USA), March 10-14
USA SOT (Society of Toxicology), Exhibition booth + two poster presentations, 4 people

London (USA), March 20-21
BCPA PESTEX, 1 people attending

Nurnberg (GE), May 21-23
MEDTECHLive, Exhibition booth + 3 people

Basel (CH), May 7-9
VITAFOODS 2019, Exhibition booth + oral presentation, 4 people

Rimini (ITALY) June 5-7
AFI 59° SIMPOSYUM, Exhibition booth + MD workshop organization, 6 people

Bruxelles, June 12-13
CHEMICAL WATCH EXPO: GLOBAL CHEMICAL REGULATION, Exhibition booth + oral presentation, 2 people

Helsinki (FI), September 8-11
EUROTOX 2019, Exhibition booth + two poster presentations, 3 people

*End of the newsletter*