

## **Regulation of Chemicals and Pesticides**

Guidance for Anyone Making, Selling, or Distributing Chemicals in the UK and EU on How to Comply with Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Chemical Regulations

November 6, 2020

The Medicines and Healthcare products Regulatory Agency (MHRA) has published new guidance titled "How to comply with REACH chemical regulations." UK REACH (the UK's independent chemicals regulatory framework) starts on January 1, 2021. UK REACH and EU REACH rules need to be followed by anyone making, selling, or distributing chemicals in the UK and the EU. UK REACH will maintain EU REACH's principles (including (i) the "no data, no market" principle; (ii) the "last resort" principle on animal testing, a.) The government intends to extend the deadlines for submitting data under UK REACH transitional provisions subject to scrutiny by parliament and the devolved administrations. The guidance includes these extension dates rather than those currently provided in UK REACH legislation.

Government Advice on how trading in drug precursor chemicals will be affected from 2021. Published 14 October 2020

October 14, 2020

Drug precursor chemicals are controlled by the Home Office because they can be used to produce illicit drugs. They can also have legitimate commercial uses. You will need to apply for an import and/or export licence when trading with EU countries in certain categories of drug precursor chemicals from 1 January 2021.

Current rules for trading in these chemicals with countries outside the EU will apply to trade with the EU. You may need to apply for a domestic licence or registration. Applications usually take 12 to 16 weeks to process once we've received the Disclosure and Barring Service (DBS) checks for all those named on the licence. You cannot apply for an import or export license if you do not hold a domestic licence. The Home Office may need to send a pre-export notification (PEN) depending on the category of chemical and the individual country's requirements.

## CHANGES to trading arrangements for each category of drug precursor chemicals

**Category 1 substances** (the most sensitive substances, such as piperonal, chloroephedrine and ergometrine)

- You'll need a domestic drug precursor chemical licence if you're using drug precursors in the UK or trading with any other country.
- You'll need to apply for an import or export licence.
- The Home Office will issue a PEN.

**Category 2A substances** (less sensitive substances and pre-precursors, such as acetic anhydride, piperidine, and phenylacetic acid)

- You'll need to register with the Home Office for a licence if you want to trade with the EU.
- You'll need to apply for an export licence. You will not need an import licence.



• The Home Office will issue a PEN.

## **Category 2B substances**

- You'll need to register with the Home Office for a licence if you want to trade with the EU.
- You'll need to apply for an export licence. You will not need an import licence.
- The Home Office may issue a PEN depending on the requirements of the country you're exporting to.

**Category 3 substances** (bulk chemicals that can have different uses, such as toluene, methyl ethyl ketone (MEK), and sulphuric acid)

- You'll need to <u>register with the Home Office for a licence</u> if you export to the EU in quantities which exceed between 20kg and 100kg per year, depending on the chemical.
- You'll need to apply for an export authorisation if you're exporting above certain quantities. You will not need an import licence.
- The Home Office may issue a PEN depending on the requirements of the country you're exporting to.

Category 4 substances (medicinal products containing ephedrine or pseudoephedrine)

- You'll need to register with the <u>Home Office for a licence</u> if you want to export to the EU.
- You may need to apply for an export licence depending on the requirements of the country you're exporting to. You will not need an import licence.
- The Home Office may issue a PEN depending on the requirements of the country you're exporting to.

## How to Comply With Pesticide Regulations in Great Britain From January 1, 2021

October 6, 2020

The UK Department for Environment, Food & Rural Affairs has published new <u>guidance</u> on "How to comply with pesticide regulations from 1 January 2021" to help those using, producing or placing pesticides ensure they meet regulations.

The new guidance covers the following matters:

- The UK's regulator: The Health and Safety Executive (HSE) will continue to operate as the UK's regulator.
- **Producing or placing pesticides on the market:** On January 1, 2021, Great Britain will establish independent pesticides regulatory rules. To produce or place pesticides on the market, you must be authorised under the new laws; for the time being the new laws will be similar to existing laws.
- **Producing or placing feed on the market:** To produce or place food/feed on the market, you must comply with regulations for Maximum Residue Levels (MRLs). Currently, statutory



MRLs are set on an EU-wide basis under <u>EC Regulation 396/2005</u>. Previous <u>guidance</u> explains that from January 1, 2021, the HSE will set MRLs based on its own assessments (as well as making its own decisions on active substance approvals and Plant Protection Product (PPP) approval).

- Existing Plant Protection Product (PPP) authorisations and MRLs: These will continue be valid in Great Britain from January 1, 2021. Previous <u>guidance</u> explains that existing PPP authorisations will remain valid until their current expiry date and existing MRLs will remain valid until they are amended. Authorised PPPs can be placed on the market and used in the same way as before.
- **Northern Ireland:** Under the terms of the Northern Ireland Protocol, the EU pesticides legislation will continue to apply after January 1, 2021.