Home Office

Notification of recent changes to Drug Precursor Chemical Regulations

From 30 December 2013, several amendments to existing Drug Precursor Chemical legislation (EU Regulations 1258/2013 and 1259/2013) came into effect which may affect you and your business.

Full text of the amending Regulations can be found on the European law website.

Regulation (EU) No 1258/2013 of the European Parliament and of the Council of 20 November 2013 amending Regulation (EC) No 273/2004 on drug precursors

Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

Category 1 Precursors

APAAN (alpha phenylacetoacetonitrile)

With effect from 30 December 2013, alpha phenylacetoacetonitrile, better known as APAAN (with CN Code 2926 90 95 and CAS No 4468 48 8) is now controlled, domestically and for the purposes of import/ export, as a Category 1 Precursor Chemical.

Existing Category 1 (domestic) licence holders will need to immediately apply to amend their licences if handling APAAN.

Those not holding a valid Category 1 licence, but who either presently handle or intend to handle APAAN will need to apply for a licence, following the guidance on our website, before they can lawfully possess the substance.

Norephedrine

The CN code for Norephedrine has been amended to 2939 44 00. Licence templates will be amended in due course, but please note for your reference and use these codes with immediate effect.

Category 2 Precursors

'Category 2' will remain as an umbrella definition but, the Category will be sub-divided into Categories 2A and 2B. There will be no changes or additions to the chemicals controlled within Category 2, but it will be subdivided as follows:

- Category 2A – Acetic Anhydride
- Category 2B – Potassium Permanganate, Phenyl Acetic Acid, Anthranillic Acid, Piperidine.

Sub-division will mean some additional controls will apply, domestically, to Acetic Anhydride (AA).

With effect from **30 June 2015**, end users of AA (using or expecting to use in excess of 100 litres/ annum (calendar year)) must hold a Home Office Category 2 Precursor Chemical Registration.

If you believe you will need a Registration as a result of this change, guidance to help you submit an application can be found on our website.

'Category 4' precursors – medicinal products containing ephedrine or pseudoephedrine (outside of EU)

For the purposes of export control only, a new category (Category 4) of Precursor Chemical has been introduced with effect from 30 December 2013. This will specifically affect medicinal products (both for human or veterinary use) containing either pseudoephedrine or ephedrine; wider control of these substances as category 1 Precursor Chemicals, when in non-medicinal product format, is unchanged.

Companies, typically pharmaceutical wholesalers, *with immediate effect*, will need to obtain a Home Office export licence where they are intending to ship these products outside of the EU. Exports will be subject to the Pre-Export Notification (PEN) process, whereby the importing country must 'validate' the proposed shipment.

The total length of time taken for an export application can be up to 27 working days, 15 days of which includes a PEN clearance period. This must be factored into your application timings, and applications made via our electronic portal, the National controlled Drug System (NDS).

You may also, before you first apply, need to provide us a list of your relevant preparations to be uploaded on to NDS.

Exports within the EU are not subject to Home Office licence and are unaffected by these changes.

Any questions?

Domestic licensing or registrations

DFLU.dom@homeoffice.gov.uk or 0207 035 8972

Import or export enquiries

DFLU.ie@homeoffice.gov.uk or 020 7035 6330