

Drug Licensing & Compliance, 4th Floor, Fry Building, 2 Marsham Street, London, SW1P 4DF
www.drugs.homeoffice.gov.uk

Notification of recent changes to Drug Precursor Chemical Regulations.

Home Office Drug Licensing & Compliance would like to inform you of several amendments to existing Drug Precursor Chemical legislation (EU Regulations 1258/2013 and 1259/2013) which may affect you and your business.

These Regulations, and the majority of the amendments contained therein, came into effect on **30 December 2013.**

Full text of the amending Regulations can be found at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:330:0021:0029:EN:PDF>
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:330:0030:0038:EN:PDF>

A summary of the key changes are as follows:

Category 1 Precursors-

With effect from **30 December 2013,**

1. "*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.

2. *Amendment of the CN code for **Norephedrine 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, Anthranilic 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.

New 'Category 4' precursors- medicinal products containing ephedrine/ pseudoephedrine NEW EXPORT CONTROL (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/ registrations-

PrecursorGeneralEnquiries@homeoffice.gsi.gov.uk

Or 020 7035 5326

Import-Export enquiries-

DCLUcommsofficer@homeoffice.gsi.gov.uk

Or 020 7035 6330