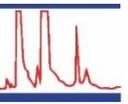


Quick guide to *substance* regulation



Drug Precursors

EU: Drug Precursors
Regulation (EC) 273/2004

EU: Monitoring trade
between EU and third
countries in drug precursors
Regulation (EC) 111/2005

NL: Drug Precursors
Leaflet Customs

NL: Drugs
Opium Act

Explosive Precursors

EU: Explosives precursors
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NL: Explosives precursors
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WW: Chemical Weapons
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Environment

EU: Export and import of
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Regulation (EC) 1005/2009

General

EU: REACH
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NL: Substances of Very
High Concern
Activiteitenbesluit

EU: Specific rules for chemical
substances and products sold
for a certain use
Biocides, PPPs, food additives

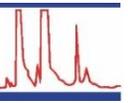
Major Accidents

EU: major accident hazards
with dangerous substances
Seveso (EU) 2012/18

Not exhaustive (see disclaimer on last page)

Last updated: January 2018

Drugs Precursors



EU: Drug Precursors *Regulation (EC) 273/2004 **

This Regulation establishes harmonised measures for the control and monitoring of substances that are frequently used for the illicit manufacture of drugs. The goal is to prevent the diversion of such substances.

Annex I of the regulation contains two categories of substances. If a substance is listed here, extra requirements apply.

Check [here](#) if substance is listed

EU: Monitoring trade between EU and third countries in drug precursors *Regulation (EC) 111/2005 **

This regulation lays down rules for the monitoring of trade between the EU and non-EU countries in substances used for the illicit manufacture of drugs. The regulation applies to imports, exports and transit of drug precursors. The goal is to prevent the diversion of such substances.

Depending on whether a substance is listed in category 1, 2 or 3 of the Annex of the regulation extra requirements apply.

These include requirements concerning:

- import and export authorisations for the drug precursors;
- labels and documentation of drug precursors;
- licenses for operators;
- inspections of drug precursor consignments;
- import and export controls;
- special controls at EU level in areas where the risk of diversion is high (e.g. free zones and transshipment zones).

Check [here](#) if substance is listed

NL: Drugs *Opium Act*

The Opium Act criminalises production, trade and export of drugs. The Opium Act contains two lists of drugs, differentiated by their risk levels.

Check [here](#) if substance is listed

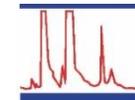
NL: Drug Precursors *Leaflet Customs*

Several known drug precursors are not covered by official legislation. Therefore the Dutch authorities urge companies to report suspicious transactions, disappearances and theft of certain substances.

Check [here](#) on page 5 if substance is listed

* See also the *Wet voorkoming misbruik chemicaliën*; this law does not contain any lists of substances

Explosive Precursors



EU: Explosives precursors *Regulation (EU) 98/2013*

This Regulation establishes harmonised rules concerning the making available, introduction, possession and use of substances or mixtures that could be misused for the illicit manufacture of explosives. The goal is (a) to limit their availability to the general public and (b) ensure reporting of suspicious transactions throughout the supply chain.

Annex I contains substances may not be made available to the general public unless a licensing regime or registration regime is in place. Annex 2 contains substances for which suspicious transactions must be reported.

Check [here](#) if substance is listed

NL: Explosives precursors *Leaflet Nationaal Coördinator Terrorismebestrijding*

Several possible explosives precursors are not covered by official legislation. Therefore the Dutch authorities urge companies to report suspicious or unusual transactions of certain substances on a voluntary basis.

Check [here](#) if substance is listed

WW: Chemical Weapons *Chemical Weapons Convention*

The Convention aims to eliminate chemical weapons by prohibiting their development, production, acquisition, stockpiling, retention, transfer or use by States. States must in turn enforce prohibition by persons and companies within their jurisdiction. Moreover, chemical weapons and their production facilities must be destroyed. Per October 2016, about 93% of the world's declared stockpile of chemical weapons had been destroyed.

The convention distinguishes three classes of controlled substances based on the quantities of the substance produced commercially for legitimate purposes.

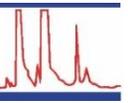
Check [here](#) if substance is listed

EU: Control of exports, transfer, brokering and transit of dual-use items *Regulation (EC) 428/2009*

This regulation sets out an EU-wide system to control the export, transfer, transit and brokering of dual-use items. Dual-use items can be used for both civil and military purposes. Export authorisation is required to export a dual-use item from the EU to a non-EU country.

Annex I provides a yearly updated (long) list of dual-use items that require authorisation. The export of certain dual-use items not listed in Annex I may be subject to authorisation if there is reason to believe that they are intended for certain military uses or in certain countries ([here](#)). Dual-use items may be traded freely within the EU, with the exception of some sensitive items (Annex IV).

Check [here](#) if substance is listed



EU: Export and import of hazardous chemicals *Regulation (EU) 649/2012*

This Regulation ensures the EU participation in the Rotterdam Convention. It provides for a prior informed consent procedure for certain hazardous chemicals and pesticides traded internationally.

Under the PIC procedure the convention requires an importer's prior consent for any of the chemicals it lists before they can be exported.

Check [here](#) if substance is listed

EU: Persistent organic pollutants *Regulation (EC) 850/2004*

This regulation protects human health and the environment by prohibiting, phasing out or restricting the production, placing on the market and use of persistent organic pollutants (POPs). It also lays down rules for dealing with stockpiles and waste containing POPs. POPs are chemical substances which stay in the environment, migrate into the food chain, and threaten human health and the environment.

Substances listed in Annex I are prohibited; substances listed in Annex II are restricted; substances listed in Annex III are subject to release reduction; substances listed in Annex IV are subject to waste management provisions. There are some exemptions.

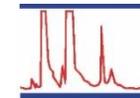
Check [here](#) if substance is listed

EU: Substances that deplete the ozone layer *Regulation (EC) 1005/2009*

This regulation lays down rules on the production, import, export, sale, use, recovery, recycling, reclamation and destruction of substances that damage the ozone layer. It sets out reporting requirements and measures for products and equipment that use these substances.

The production and sale of controlled substances are prohibited, but some exemptions exist.

Check [here](#) if substance is listed



EU: REACH *Regulation (EC) 1907/2006*

This regulation provides a framework for chemicals manufacture and use in Europe. It gives industry the responsibility to ensure that chemicals produced, imported, sold and used in the EU are safe.

It applies to all chemical substances: manufactured, imported, sold, used on their own, in mixtures or in products. Companies must register all chemicals which they manufacture or import in quantities of 1 tonne or more per year. The legislation does not apply to certain groups of substances or to waste, as these are already extensively regulated under other legislation.

See [here](#) to check the exemptions to the regulation

NL: Substances of Very High Concern *Activiteitenbesluit*

Companies must prevent their emissions of substances of very high concern (ZZS). If this is not feasible, the emissions must be limited as much as possible.

Which substance is a ZZS, is determined by various international treaties and legal frameworks (REACH, OSPAR Convention, Water Framework Directive, POP Regulation). To create clarity, RIVM has combined the ZZS from those lists into a single overview (which may not be up to date).

Check [here](#) if substance is listed

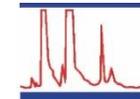
In addition, all substances classified as carcinogenic, mutagen or toxic for reproduction in the SDS are a ZZS - these are not mentioned in the RIVM overview

EU: Specific rules for chemical substances and products sold for a certain use *Biocides, PPPs, food additives*

Extra rules may apply for substances sold for a certain use, such as:

- Plant protection product
 - Regulation (EC) No 1107/2009 [here](#), Dutch registry [here](#)
- Biocide
 - Regulation (EU) No 528/2012 [here](#), Dutch registry [here](#)
- Food enzyme in foodstuffs
 - Regulation (EC) No 1332/2008 [here](#)
- Food additive in foodstuffs
 - Regulation (EC) No 1333/2008 [here](#)
- Food flavouring additive in foodstuffs
 - Regulation (EC) No 1334/2008 [here](#)
- Food contact materials from plastic
 - Plastics intended to come into contact with food, see [here](#)
- Feed Placing on the market and use of feed
 - Regulation (EC) No 767/2009 [here](#)
 - Catalogue of feed materials [here](#)
- Feed Undesirable substances in animal feed
 - Directive 2002/32/EC [here](#)
- Feed Additives for use in animal nutrition
 - Regulation (EC) No 1831/2003 [here](#)
 - EU Register of Feed Additives [here](#)
- Cosmetics
 - EU Database of cosmetic substances and ingredients [here](#)
- Pharma
 - List of products by active substance [here](#)

Major Accidents



EU: major accident hazards with dangerous substances *Seveso (EU) 2012/18*

This Directive lays down rules for the prevention of major accidents involving dangerous substances. It is implemented in The Netherlands in the Besluit risico's zware ongevallen 2015 (Brzo 2015).

The threshold values for the quantity of hazardous substances and mixtures present determine whether a company falls within the scope of the regulation.

Annex I of the regulation determines what substances are classified as dangerous. Part I provides categories of dangerous substances, part II provides named dangerous substances.

Check [here](#) if substance is listed

Sanctions

While not specifically substance-related it is crucial to check if sanctions apply. EU sanctions apply within the jurisdiction of the EU; to EU nationals in any location; to companies and organisations incorporated under the law of a member state - including branches of EU companies in third countries; on board of aircrafts or vessels under member states' jurisdiction. The consolidated list of persons, groups and entities subject to EU financial sanctions prior to transactions, [here](#).

Disclaimer

This Best Supply Chain Practice has been developed by the Responsible Care Committee of the Dutch Chemical Trade Association. It provides general information about regulations applicable at substance level. It does not include other relevant information such as related to transport safety or international sanctions. The content should not be regarded as complete or up-to-date. In case of remarks or questions, please contact the VHCP Secretariat, [here](#).