



CHEMICALS LEGISLATION AND DANGEROUS SUBSTANCES MANAGEMENT

Practical Guide

Many companies are talking about safety, but at DEKRA we're doing something about it!



Why we are a safe bet for companies looking for peace of mind.

The past few decades have produced numerous innovative technical products that have made our lives more enjoyable. However experience has shown that where there is progress, there is often also danger. It therefore makes sense that obligations for ensuring the safety of people, the environment and material assets are tougher today than ever before.

At DEKRA we can help you to meet these obligations, and in the process safeguard your economic success, including – indeed, especially – when this relates to innovations. As a holistic, sustainably-minded provider of safety-related services, we have made it our goal to be dependable pioneers: working for you, your ideas and products, right around the globe.

At DEKRA, it's not just what we do, but how we do it that makes the difference. Attentive, ongoing dialogue with our customers forms the basis for all our activities. We listen carefully to what you tell us, put ourselves in your shoes to understand your needs, and then work together with you to identify the best available solution. Whether we are supporting you in meeting the requirements of national or international chemicals legislation, classifying substances and mixtures, or managing dangerous substances: whatever we do, our sights are always set on your success.

DEKRA keeps you in the picture.

European chemicals legislation is enormously complex. Environmental and health protection, storage and use, transport and manufacture, substances and articles are all covered by different directives, laws and regulations, some of which overlap with each other. DEKRA can help you retain an overview of the applicable legislation to ensure that everything your company does is legally compliant.



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Consulting on all aspects of chemicals legislation

As a complete service provider with more than 20 years' experience in international chemicals legislation, DEKRA can help you attain your goal of a safe product. Use our full service, or choose individual modules from our comprehensive service range – just as you require.

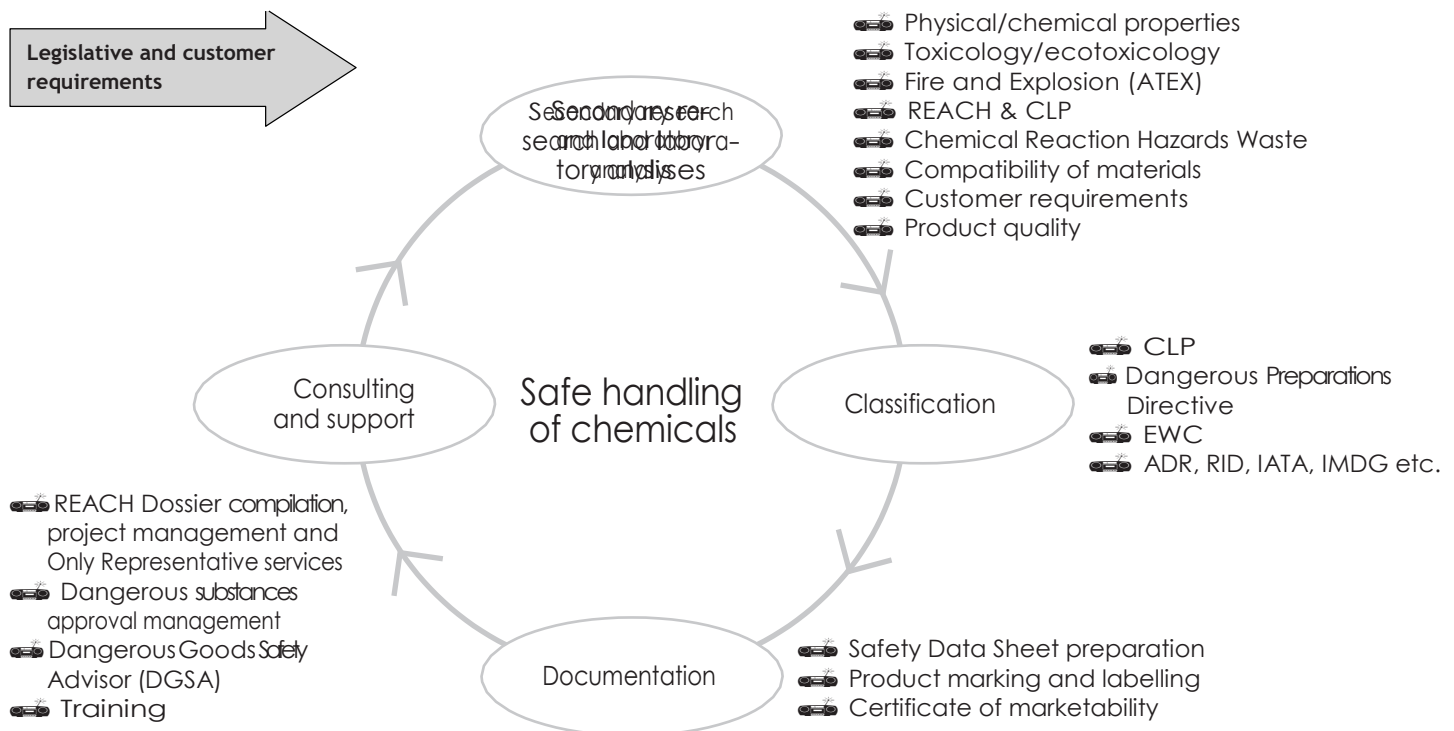
As your external partner, DEKRA can take the pressure off you by supporting you in complying with chemicals legislation requirements. This leaves you free to concentrate on your core activity of producing safe, high quality products for your customers.



DEKRA services

We offer made-to-measure consulting services including laboratory analyses, classification of dangerous substances, and preparation of Safety Data Sheets.

In addition, for ensuring on-site compliance with the legislation, our experienced specialists are available to visit your company's site, acting as Dangerous Goods Safety Advisors or assisting in hazard assessments.



Any assessment of a chemical must be backed up by reliable data about the risks that it presents. Parameters such as physico / chemical properties, toxicity information, ecotoxicity data and many others must first be determined before any meaningful conclusions can be drawn.

Annexes VII to X of the REACH Regulation prescribe a wide range of tests. Comprehensive data exists for the approx. 3,500 substances that are already registered, but no such information is available for at least 30,000 other frequently-used substances. To obtain data for these substances, it is necessary to use secondary research, via specialist databases containing large bodies of laboratory data and study results. DEKRA has the necessary specialist knowledge and depth of experience to quickly and effectively locate the relevant data and verify bibliographic references.



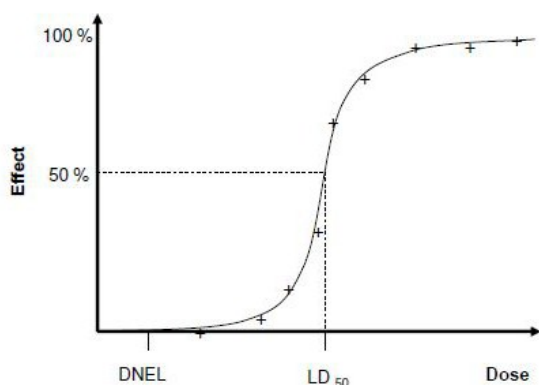
Laboratory studies - DEKRA operates seven laboratory sites worldwide, each with their own area of focus:

- Environmental analysis
- Product analysis and physico/chemical properties
- Explosion prevention
- Materials testing

Our laboratories can quickly and reliably determine a wide range of parameters including all of the necessary physico/chemical properties required under REACH & CLP where our laboratories are fully GLP compliant, heavy metal contents, and PAH contamination data. They can also verify the content of substances from the REACH candidate list in finished articles. We also have a state-of-the-art X-ray fluorescence (XRF) spectrometer for testing the RoHS compliance of electrical equipment.

Our trusted network of selected partners allows us to offer a vast range of specialist testing – comprehensively covering all of your potential needs. Here too we act as a complete supplier, coordinating all work carried out and validating the quality of the results obtained.

Dose-effect study, toxicity



DEKRA services

DEKRA experts can efficiently and reliably determine the substance parameters you require, either in laboratory research or on the basis of existing data.

In choosing which method to use, we always place a strong emphasis on our customers' needs and initial situation.

REACH and international chemicals legislation



REACH (EC Regulation 1907/2006), which entered into force in 2007, marked the start of a period of major change in European chemicals legislation that will affect not just Europe, but non-European countries as well.

The central requirements of REACH are as follows:

- Registration: any manufacturer or importer of a substance must submit data regarding the danger that it presents ("no data, no market").
- Evaluation: evaluation covers 'compliance checking' by ECHA and national authorities. 'Dossier Evaluation' to minimise animal testing and 'Substance Evaluation' to identify any substance which may be considered for regulatory action.
- Authorisation: authorisation will be required for the use of certain dangerous substances that represent an unacceptable level of risk (Annex XIV).
- Restriction: the use of certain dangerous substances will be limited to specific applications (Annex XVII).

Some countries outside the EU have enacted similar legislation. In 2010, China introduced mandatory notification of substances, as did Turkey in 2011. Other countries, including Korea, will do so over the next few years.

To be sure of access to the market, it is very important that manufacturers, importers and downstream users are aware of all relevant regulations and that they act in sufficient time. Importers of substances must register the components of their mixtures. Importers of articles such as toys must provide information on any "substances of very high concern" (as per the candidate list) that their products might contain. Non-EU manufacturers may appoint an only representative in order to avoid

2007	1.6 REACH enters into force
2008	1.6-30.11 Pre-registration 28.10 First candidate list
2009	30.11 Notification of uses
2010	30.11 Registration of <ul style="list-style-type: none"> • chemicals >1,000 t/a • CMR substances • R50/53 substances supplied at >100 t/a 1.12 CLP classification of substances
2011	21.2 First 6 substances added to Annex XIV 1.6 Notification of substances on the candidate list in articles
2012	30.5 Notification of uses
2013	21.2/21.8 Authorisation application deadlines 1.6 Registration of substances supplied at >100 t/a
2014	21.2 Authorisation application deadlines 21.8 Sunset date for several substances
2015	Sunset dates for several substances 1.6. Classification of mixtures under CLP
...	...
2017	30.5 Notification of uses

DEKRA services

DEKRA has been assisting companies in meeting the requirements of REACH since 2006, and of non-EU chemicals legislation since 2010.

We act as the exclusive representative for numerous companies worldwide, and provide advice on complying with legislation to companies throughout the EU.

Hazard assessment and instructions for safe use

Where chemicals are handled in workplaces, a hazard assessment must be carried out to determine the specific dangers present. The requirements for this hazard assessment are set out in national legislation such as GefStoffV (Dangerous Substances Ordinance) in Germany or the Control of Substances Hazardous to Health (COSHH) in the UK. The Control of Major Hazards (SEVESO II) also requires hazard and risk assessments.

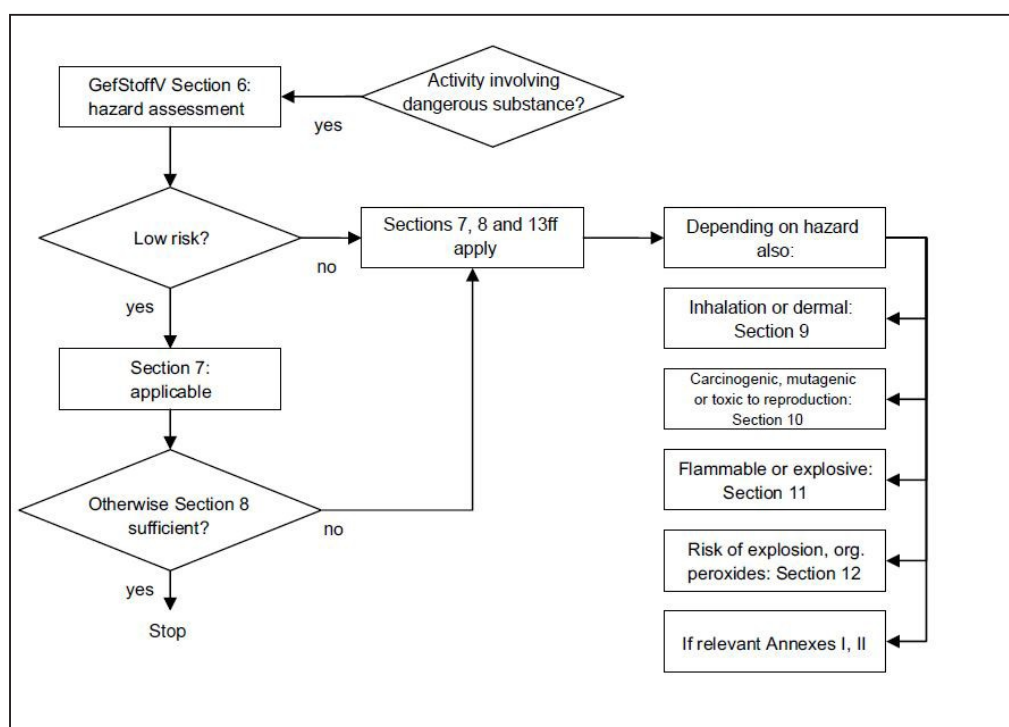
These documents complement REACH & CLP by using a similar approach with the need to perform a risk assessment.

Today, as a result, the safety measures are less rigidly bound to the simple classification of the substance. The hazard assessment determines what specific measures must be taken. Consequently, in certain cases, a toxic substance can now be considered to present a "low risk" in certain circumstances.

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Dangerous Goods Safety Advisor (DGSA)



"Dangerous goods" are hazardous substances or mixtures that are intended to be transported. In addition, objects containing dangerous goods are themselves classified as dangerous goods.

All companies and persons involved in shipping and transport are directly responsible for ensuring that any processes involving dangerous goods take place safely and in compliance with the relevant regulations. Transport within companies that pass along public thoroughfares, and more generally the carrying of related products and objects, is likewise regulated by dangerous goods legislation.

Sender

- Permissibility of transporting dangerous goods
- Duties of notification and documentation

Carrier

- Duty to verify shipment compliance with regulations
- Duty to check shipping unit and driving personnel
- Loading regulations and securing of loads

Filler

- Permissibility of transport containers
- Fill levels and safety requirements

Packer

- Fill levels, material compatibilities
- Packaging approved for product
- Labelling and lettering

Filler

- Permissibility of transport containers
- Fill levels and safety requirements
- Duty to provide instruction

Shipper

- Use of qualified, trained personnel
- Suitability of shipping units
- Vehicle equipment
- Adherence to limited quantities
- Completeness of documentation

Companies and responsible persons may only use qualified, specially-trained personnel for all tasks involved in the handling of dangerous goods.

DEKRA services

Our experienced experts can act as Dangerous Goods Safety Advisors for you for all modes of transport and, if required, also as expert witnesses in relation to special circumstances.

We can also provide you with all services necessary for the handling of dangerous goods, from consultancy on shipping processes to made-to-measure in-house training sessions for your staff.

On site dangerous substances management

DEKRA services

For more than ten years, DEKRA has been assisting a number of large companies in implementing their on-site dangerous substances management systems. Our experts can professionally assess the risks associated with using substances. In this way, we can protect our customers' employees, and at the same time relieve managers of some of the tasks for which they, as employers, are responsible.



Users of dangerous substances at work need to adhere to a large number of rules and conditions: Safety Data Sheets provide information on the dangers that a particular substance or mixture presents; national legislation sets out detailed requirements for the protection of employees in companies; and site-specific procedures will also apply, determining where and how a substance is used.

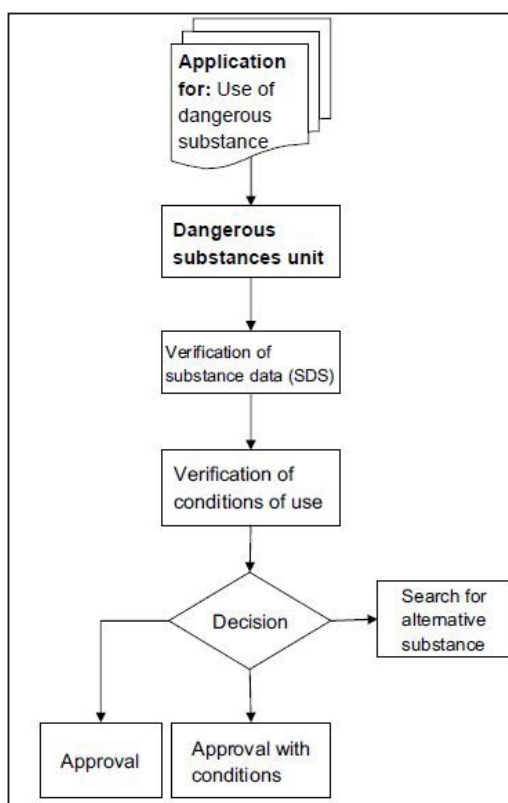
The careful on site handling of dangerous substances is an essential element of sustainable operations management. Accidents involving – or caused by – dangerous substances can result in plant downtime and financial losses. They can also damage a company's image.

For manufacturing plants where many different dangerous substances are used at numerous different locations, a carefully structured system for the management of dangerous substances should be established and maintained.











This should include the following core elements:

- The site should have a suitably qualified dangerous substances unit.
- Departments wishing to use a particular substance should submit an application to the dangerous substances unit.
- The dangerous substances unit will check the relevant documentation (e.g. Safety Data Sheet) and request additional up-to-date information if necessary.
- The dangerous substances unit will check the specific conditions of use for the substance.
- The dangerous substances unit will then either grant approval for the handling of the dangerous substance (possibly with conditions), or will attempt to identify a suitable alternative substance. It will prepare instructions for its safe use and ensure that personnel are instructed as appropriate.

- The dangerous substances unit must inform the department concerned if a new Safety Data Sheet is received that changes the way in which the substance is to be handled.



Dangerous goods – classes, labels and examples

Class	Types of substances and examples	Hazard labels
1	Explosives substances and objects e.g. fireworks, airbag modules, seat belt pre-tensioners	
2	Gases e.g. aerosol cans, objects under pressure	
3	Flammable liquids e.g. fuels, paints and dyes, solvents, adhesives, alcohols	
4	Flammable, spontaneously combustible and self-heating solids e.g. flammable powders and pastes, metallic dusts, used binding agents	
5	Oxidising substances and preparations e.g. hydrogen peroxide solutions, organic peroxides, 2-component adhesives	
6	Toxic and infectious substances e.g. toxic preparations, diagnostic samples, clinical waste	
7	Radioactive materials e.g. measuring devices containing radiation sources	
8	Corrosive substances e.g. batteries, bleaching agents, acidic or highly alkaline liquids	
9	Miscellaneous dangerous goods e.g. substances and preparations dangerous to the environment, lithium batteries	
10	"LQ" dangerous goods in limited quantities	

Glossary

ADR	International list of dangerous goods for carriage by road.
Aquatic organisms	Creatures that live in water.
ChemVerbotsV	German Federal Ordinance governing trade in toxic and similarly dangerous products.
CLP	EU Regulation 1272/2008 on the classification, labelling and packaging of dangerous substances and mixtures.
CMR substances	Substances that are carcinogenic, mutagenic, or toxic to reproduction.
Dangerous Goods Safety Advisor	Expert responsible for adherence to the requirements for the transport of dangerous substances at a specific company.
DNEL	"Derived no-effect level". The highest dose of a toxic substance to which a human can be exposed without it having an effect.
Ecotoxicology	Concerned with the effect of poisons on nature and the environment.
e-SDS	Extended Safety Data Sheet with an annex containing exposure scenarios presenting the risks associated with specific uses.
EWG	European Waste Catalogue.
Exposure scenario	Documents showing extent to which the use of a dangerous substance results in exposure of humans and the environment to that substance.
GLP	"Good Laboratory Practice". Laboratory standard for conducting toxicological studies.
Hazard assessment	Procedure for determining the hazards associated with the in-plant handling of dangerous substances.
Instructions for safe use	Plant document defining how dangerous substances should be handled at a specific workplace.
Marketability	Term used to indicate that a product satisfies all of the legal requirements for a specific jurisdiction (e.g. the EU).
PAHs	Polycyclic aromatic hydrocarbons. Carcinogenic dangerous substances that are often present in soot.
PNEC	"Predicted no-effect concentration". The highest concentration of a dangerous substance in a medium (e.g. water) to which an organism can be exposed without it having an effect.
REACH	EU Regulation 1907/2006 on the registration, evaluation, authorisation and restriction of chemical substances.
RoHS	EU Directive 2005/96/EC on restriction of the use of certain hazardous substances in electrical and electronic equipment.
SDS	Safety Data Sheet, a document consisting of 16 sections in which all safety-relevant data relating to hazardous substances are summarised for the customer.
Toxicology	Discipline concerned with the effect of poisons on humans.
WGK	German Water Hazard Class indicating the extent of damage caused to bodies of water and watercourses and their inhabitants by a dangerous substance.



DEKRA Process Safety

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