NEW EU CHEMICALS POLICY – REACH

Authors:
Zita Dudutytė, Baltic Environmental Forum – Lithuania
Jana Simanovska, Guna Krūmiņa, Baltic Environmental Forum – Latvia
Kitty Kislenko, Baltic Environmental Forum – Estonia

Design:
Lolita Piterniece, Jelgavas tipografija

Cartoons:
Alvis Inne, Jelgavas tipografija

This publication is prepared within the project “Communication about REACH to wide range of stakeholders in the Baltic States” – **REACH BALTICS** – granted by the European Commission, DG Environment and implemented jointly by the Baltic Environmental Forum - Latvia, Estonia and Lithuania.

© **Baltijas Vides Forums, Latvija**
Peldu iela 26/28
LV-1050 Rīga, Latvija
http://www.bef.lv

© **Baltijos aplinkos forumas, Lietuva**
Vivulskio g. 14/8-6
LT-03221 Vilnius, Lietuva
http://www.bef.lt

© **Balti Keskkonnafoorum, Estonia**
Rävala 8-40
10143 Tallinn, Estonia
http://www.bef.ee

© Published by: Jelgavas tipografija, 2006
ISBN: 9984-9850-7-5

Publication is printed on the recycled paper

This publication is targeted to chemicals producing and using industry as well as to importers of chemicals. Nevertheless, the information provided will support also other interested groups, especially inspectors in the preparation to take the new tasks and responsibilities under the upcoming new Chemicals policy.

The publication is based on the **draft text of the REACH Regulation as agreed by the Competitiveness Council on 13 December 2005**. However, the numbering of Annexes in this publication refers to already revised numbering of Articles and Annexes, which corresponds to the final numbering of draft REACH regulation after the first reading. The list of Annexes and references to the draft text version of 13 December 2005 is enclosed in the page 15.

Many good ideas for this brochure have come from very different sources: draft regulation, studies, other publications, presentations and discussions from a number of workshops and other events, comments of experts from state authorities etc. Therefore Baltic Environmental Forum would like to thank all who has actively directly or indirectly contributed to the preparation of this brochure.

HOW IT CAME TO REACH AND WHAT DOES THAT MEAN?

Principally, REACH was born with the European Commission's White paper on a "Strategy for a future chemicals policy" in 2001. It drew up a new approach to the EU's chemicals policy, addressing the following objectives:

- high level of protection of human health and the environment;
- maintenance and enhancement of the competitiveness and innovation of the EU chemicals industry;
- greater transparency and openness regarding information on chemicals.

The first legislative proposal on **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH) was published in October 2003.

In December 2005 the Council reached a political agreement and the European Parliament finalised the first reading of the draft regulation on REACH. The common Council position on after the first reading reached by 27 June 2006.

REACH elements

- **Registration** of substances, which are produced or imported in volumes ≥ 1 t per year per manufacturer or importer,
- **Evaluation** of certain substances,
- **Authorisation** of the use of certain substances with particularly hazardous properties,
- **Restrictions** of the use of certain substances.

It is expected that REACH Regulation will be approved and will come into force in year 2007.

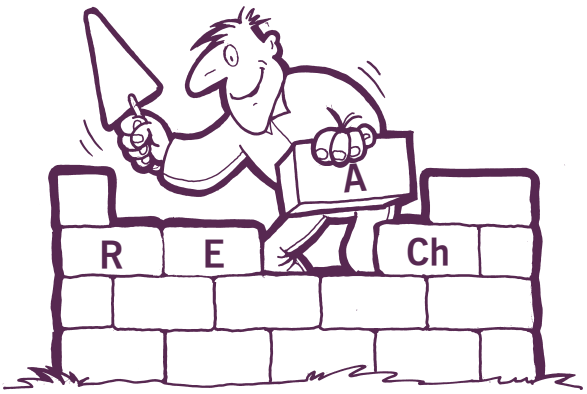
When coming into force, REACH Regulation shall be applied throughout the EU, directly in all Member States at the same time (i.e. it will not be possible to negotiate on transitional period).

REACH is based on the following principles:

- **No Data** on chemical - **No Market,**
- **Industry must proof** that chemical is safe for foreseen use,
- Whole **Life cycle of chemical** to be considered,
- **Precautionary principle** to be applied,
- **Risk-based approach** is applied,
- **More information** on chemicals shall be made **publicly available,**
- **Principle of substitution** to be applied if relevant.

REACH regulation will concern not only every company producing or importing chemicals, but also the ones handling chemicals.

The new European Chemicals Agency will be established (in Helsinki) to manage the whole system.



WHY REACH IS NECESSARY?

The need for the new system has risen due to the fail of the current policy control chemicals sufficiently and ensure the safety of people and environment.

Gaps in current legislation

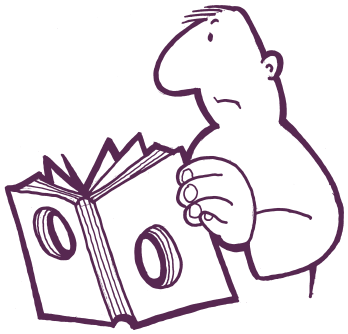
- Slow process to classify the substances (= to include into EU List of Dangerous Substances).
- Slow chemicals risk assessment process.
- Not clearly defined responsibilities along the supply chain.
- Not fairly distributed responsibilities between industry and authorities.
- Lack of knowledge on properties of chemicals.
- Different requirements for existing and newly introduced substances.

Consequences for industry

- Bad quality or missing Safety Data Sheets (SDS) → improper risk assessment, risk management and risk reduction measures → workers affected by hazardous chemicals → diseases or other adverse health effects.
- Suppliers are not providing sufficient information.
- Difficult to find cost effective and reasonable substitution to hazardous chemicals → too little information on properties of substitutes.
- Unsatisfied clients, scandals due to unexpected hazardous properties of substances in articles.

Consequences for general public

- Consumers are exposed to many industrial chemicals with partly unknown consequences via environment, air in living rooms, articles (e.g. textiles, toys), food.
- Consumers facing skin and respiratory diseases (allergies), other diseases or other adverse health effects.
- Environment is exposed to persistent, bioaccumulative and toxic chemicals, which accumulate also in animals we eat (e.g. fish).



New chemicals policy will contribute heavily solving many of these problems, especially those, which relate to better knowledge on the properties of chemicals and communication along the chemicals supply chain.

HOW EVERYONE CAN BENEFIT FROM REACH?

BENEFITS for COMPANIES

- Better knowledge on the intrinsic properties of chemicals creates preconditions for:
  → better quality of SDS,
  → exposure based risk assessment, proper risk management and risk reduction measures → less adverse health effects, professional diseases and sick leaves,
  → less scandals due to hazardous substances appearing in the articles to consumers,
  → more intensive research and product development in the companies,
  → easier substitution of hazardous substances and avoidance of repeated substitution → increased consumers' trust to the companies.
- Simplified legal system → less legal acts.
- Clear responsibilities → less unjustified claims.

GENERAL BENEFITS

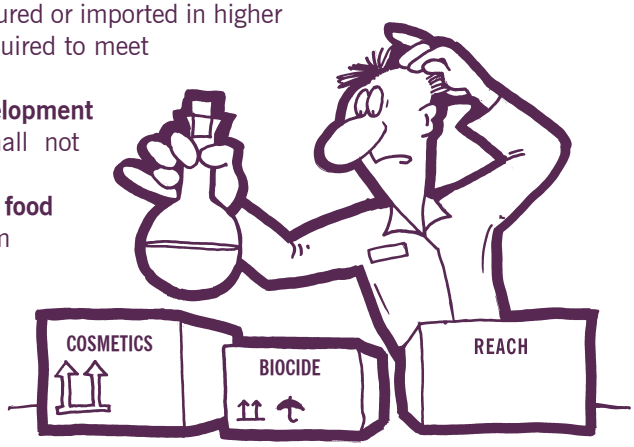
- Hazardous substances avoided or substituted with less hazardous ones in widely used products → safer products.
- Emissions of particularly hazardous substances to environment will be reduced/avoided → safer environment for living.
- The number of tests involving vertebrates minimised.
- Increased transparency of information → easier to choose more environment and consumer friendly products.

WHAT SUBSTANCES FALL UNDER REACH?

REACH Regulation applies to:
→ **manufacture**, **placing on the market or use of substances** on their own, in preparations or in articles
→ **placing on the market of preparations**.

REACH Regulation **is not applied** to:
- radioactive substances;
- substances, on their own, in a preparation or in an article, which are subject to customs supervision, are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
- non-isolated intermediates;
- the carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air;
- waste (**Attention!** Only as defined by waste legislation!).

In addition, the requirements under REACH Regulation are **reduced** for some substances, groups of substances or some specific uses of substances:
- if substance is used in **medicinal products** (both human and veterinary), **food or feeding stuffs** → registration, evaluation and authorisation requirements shall not apply (**Attention!** If the same substance is used for different purpose, then all provisions of REACH Regulation should be followed!);
- if substance is listed in the **Annex IV*** (those substances considered to be well known and causing minimum risk) → registration and evaluation requirements shall not apply;
- if substance is listed in **Annex V*** (e.g. substances occurring in nature if they are not chemically modified) → registration and evaluation requirements shall not apply;
- if substance is **re-imported** to EC (i.e. it has been already registered before and exported) → registration and evaluation requirements shall not apply;
- if substance resulting **from the recovery** process has been registered before → registration and evaluation requirements shall not apply;
- **on-site isolated intermediates** or **transported isolated intermediates** → registration and authorisation requirements shall not apply;
- **polymers** → registration and evaluation requirements shall not apply;
- some groups of preparations (**medicinal products** (both human and veterinary), **cosmetic products, food or feeding stuffs**) → the requirements for information flow in the supply chain shall not apply;
- substances, which are subject of **product and process orientated research and development (PPORD)** → excluded from registration for 5 (max. extension possible +5 or +10 (exclusively for medicinal products)) years (**Attention**! Still these substances shall be notified to Agency!); they may be exempted from authorisation but not necessary; may be exempted from restriction but not necessary;
- **active substances** for use in plant protection products (PPP) and biocides → considered as registered; authorisation shall not apply;
- substances used as **motor fuel**, **fuel in mobile or fixed combustion plants of mineral oil products** and **fuel in closed systems** → authorisation shall not apply;
- already **notified new substances** (according current legislation) → considered as registered (**Attention!** If substances is manufactured or imported in higher tonnages, some additional information may be required to meet requirements for registration under REACH!);
- substances used for **scientific research and development** → exempted from authorisation; restrictions shall not apply;
- substances used in **cosmetic products** and in **food contact materials** → may be exempted from authorisation and restrictions.



* The numbering of Annexes in this publication refers to the revised numbering of Articles and Annexes. The list of Annexes and references to the draft text version of 13 December 2005 is enclosed in the page 15.

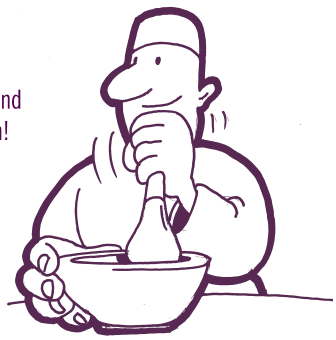
WHO YOU ARE AND WHERE YOU STAND ACCORDING REACH?

REACH is based on the principle that it is up to **manufacturers**, **importers** and **downstream users** to ensure that they manufacture, place on the market or use substances in a safe way, i.e. that no risk for adverse effect to human health or the environment occur. Each of the mentioned actors has different tasks, responsibilities and obligations to follow in order to reach this goal.

Therefore it is important, firstly, to define where you stand in the supply chain - **the identification of roles will serve you to clarify your overall obligations under REACH**. Each actor in the supply chain may have various roles, not just one, i.e. **different roles may apply to different substances you handle!**

Before going further, let's clarify your role - follow the scheme below for each of the substance/ preparation/ article you produce, import and/or handle. You need to answer each question!

- Do you produce substances by synthesis, refining, extraction or any waste recovery activity within EU?
  - yes → Manufacturer of substances (M)
  - no ↓
- Do you import substances as such or in the preparations from countries outside EU?
  - yes → Was the substance/ preparation produced in EU?
    - yes → Re-importer
    - no → Importer (I)
  - no ↓
- Do you **only** store substances and preparations?
  - yes → Storage provider → No obligations under REACH
  - no ↓
- Do you distribute substances/ preparations produced in EU?
  - yes → Distributor → An active role in communication of information down and up the supply chain!
  - no ↓
- Do you contract others to produce preparations for you?
  - yes → Owner of brand → Obligations under REACH depends on contract
  - no ↓
- Do you use substances and preparations in industrial processes to provide services or produce articles?
  - yes → Do you mix preparations to place on the market?
    - Are you contracted to produce preparations?
    - Are your preparations used further in preparations?
    - Are your preparations used for the production of articles or final use?
    - yes → Formulator (F)
  - yes → Do you use substances/preparations in production of articles:
    - adding them as processing aid
    - incorporating them into articles?
    - yes → Industrial user (IU)
    - yes → Producer of article
  - no ↓
- Do you use substances and preparations outside industrial processes to provide services or produce articles?
  - yes → Professional user (PU)
  - no ↓
- Do you refill substances/preparations from one container to another?
  - yes → Re-filler



Note: This scheme is based on RIP 3.5-1 final report.

ELEMENTS OF REACH: REGISTRATION

Any **manufacturer or importer of a substance**

- either **on its own** or
- in one or more **preparation**(s) or
- contained **in the articles** and intentionally released under normal or reasonably foreseeable conditions of use and where the use has not been registered,

in quantities of 1 tonne or more per year shall gather information on the properties, uses and safe management of the substances and submit a registration to the European Chemicals Agency.
Once REACH is fully in place, **non-registered substances produced or imported in amounts exceeding 1 tonne per year can no longer stay on the EU market or be placed on the EU market**.

The information required in the technical dossier for registration depends on the volume of chemical:

Common information for all registrations	Annex VI*	• General registrant information • Identification of the substance • Manufacture and use of the substance • Classification and labelling • Guidance on safe use • Information on exposure (1-10 t/yr)
≥ 1 t/yr	+ Annex VII* (data to be provided)	• Physicochemical properties • If classified as dangerous: – Basic human health data (skin and eye irritation, skin sensitisation, mutagenicity, acute toxicity by oral route) → in vitro – Ecotoxicological information (short-term toxicity to Daphnia, growth inhibition, biotic degradation) – Other available information
≥ 100 t/yr	+ + Annex VIII* (data to be provided)	• Human health data (skin and eye irritation (in vivo), mutagenicity (in vitro), acute toxicity by inhalation and dermal route, repeated dose toxicity, reproductive toxicity, toxicokinetics) • Ecotoxicological data (short-term toxicity on fish, abiotic degradation, fate in environment – adsorption/ desorption)
≥ 1000 t/yr	+ + + Annex IX* (testing plan to be provided if data are insufficient)	• Physicochemical properties (stability in organic solvents, dissociation constant, viscosity) • Human health data (repeated dose toxicity, reproductive toxicity (pre-natal development, two-generation) • Ecotoxicological information (long-term toxicity on invertebrates, fish, identification of degradation products, fate and behaviour in environment – bioaccumulation in aquatic species, effects on terrestrial organisms)
≥ 1000 t/yr	+ + + + Annex X* (testing plan to be provided if data are insufficient)	• Human health data (long-term repeated toxicity, two-generation reproductive toxicity, carcinogenicity) • Ecotoxicological information (deeper on degradation and fate and behaviour in environment, long-term toxicity for terrestrial organisms, long-term toxicity to sediment organisms and long-term reproductive toxicity to birds)
Exemptions, rules for adaptation of standard tests	Annexes VI – X*, Annex XI*	

Registration DOES NOT mean testing! It means DATA COLLECTION from different alternative sources, e.g. modelling ((Q)SAR), read-across from other substances, existing in vivo and in-vitro testing, epidemiological data etc. **New tests should be considered as a last resort**. If data are not sufficient for substances of high tonnages (>100 t/yr), first testing plan should be submitted to Agency and the tests can be performed only after testing plan is approved.

* The numbering of Annexes in this publication refers to the revised numbering of Articles and Annexes. The list of Annexes and references to the draft text version of 13 December 2005 is enclosed in the page 15.

The steps of CSA:
- Human health hazard assessment
- Human health hazard assessment of physicochemical properties
- Environmental hazard assessment
- PBT and vPvB assessment

if substance is dangerous or a PBT or vPvB:
- Exposure assessment incl. exposure scenarios
- Risk characterization.

Exposure scenario means the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate. The exposure scenarios shall address all identified uses of the manufacturer or importer. It should be added to SDS. *Example: May be safely used in the formulations up to 15 % but only if applied by brushing, with gloves (avoiding skin contact) used outside no more than 2 hours a day. This could be a paint, lack, biocide, industrial disinfectant, detergent.*

For the substances above 10 t/year, the Chemicals safety assessment (CSA) shall be performed and documented in Chemical safety report (CSR). CSA shall address the manufacture of a substance and all the identified uses. It shall consider the use of the substance on its own, in a preparation and in an article, through all stages of the life cycle of the substance resulting from the manufacture and identified uses.

Under the REACH Regulation all substances are split into phase-in substances and non phase-in substances.

Any phase-in substance shall be **pre-registered** in order to avoid duplication of testing by sharing data. Manufacturers or importers of the same substance are expected to submit a joint package of hazard data. A system (**SIEF – Substance Information Exchange Fora**) is established to help registrants to find other registrant to share the data. The vertebrates' test data MUST be shared, still, the possibility to "opt out" may be considered if justified (e.g. disproportionate costs, breach of commercial confidentiality, disagreement on the interpretation of results).

Phase-in substances:
- listed in EINECS,
- manufactured in Community but not placed on the market at least once in the 15 years before entry into force of this regulation,
- placed on the market in the Community before entry into force of this regulation and considered as having been notified in accordance with current legislation but does not meet the definition of a polymer.

At the stage of pre-registration registrant should submit to Agency only the name of substance, own name and contacts, envisaged deadline for registration/ tonnage band. There will be only one pre-registration phase between 12 and 18 months of REACH entering into force. Any not pre-registered phase-in substance, which is intended to be placed on the market, should be registered immediately. If the pre-registration is made but registration is not completed in time, the substance is also not allowed to stay on the market.

For the registration of phase-in substances the transitional provisions are applicable. The priority for the most harmful chemicals and those produced in the largest volumes is given as regards the deadlines to provide the data.

Registration deadline	Group of substances	Expected year of registration deadline
3 years	CMRs, if ≥ 1 tonne	2010
3 years	PBTs, vPvB (R50/53), if ≥100 t	2010
3 years	≥ 1000 tonnes	2010
6 years	100-1000 tonnes	2013
11 years	1-100 tonnes	2018

Non-phase in substances after REACH enters into force should be registered before it can be manufactured or marketed.

The Regulation also places a duty to register any **substance present in a finished product (or article)** if:
- the total amount of the substance is >1 tonne per year per producer or importer and
- it is **intended** to be released under normal or reasonably foreseeable conditions of use.

In addition, producer or importer will need to notify to Agency the substances in articles if:
- they are identified as being of very high concern,
- the total amounts are equal or more than 1 tonne per year per producer or importer and,
- the substance is present in those articles above a concentration of 0.1%.

The obligation to notify does not apply if exposure to humans and the environment can be excluded and producer or importer supply appropriate instructions to the recipient of the article.

What REGISTRATION means for you? If you are…	
Manufacturer/ Importer (M/I)	**Downstream users (F+IU+PU)**
■ Pre-register substances if you want to go for registration later. ■ Obtain and compile information for technical dossier on substance. ■ Submit the registration according the deadlines (≥1t/a). ■ Obtain information from downstream users to complete CSA → evaluate risk for each identified use through whole life cycle, define the risk reduction measures. ■ Prepare CSR (≥10 t/a) and attach exposure scenario to SDS as Annex. ■ Take part in SIEF and consortia to find others working with the same substances and to share data. ■ Obligatory share the data on vertebrate animal studies. ■ Obligatory to share other testing date if other potential registrant asks.	■ Contribute to registration with information on your use and conditions of use. ■ ! Be aware – as a downstream user you are interested, that your suppliers registers your substance and that your use is included in the dossier, otherwise you will loose the substance or will need to act on your own.

ELEMENTS OF REACH: EVALUATION

Evaluation procedure under REACH Regulation can be targeted to dossier or substance.

Dossier evaluation is performed by Agency and consists of two parts:

- examining any testing proposal set out in a registration to avoid unnecessary testing;
- verifying that the information in the technical dossier is in compliance with the requirements;

To ensure that registration dossiers comply with the Regulation, the Agency shall select a percentage of those dossiers, no lower than 5 % of the total received by the Agency for each tonnage band, for compliance checking.

Substance evaluation

Substance may undergo evaluation if there is a concern over potential risks of substance to human health or the environment. Prioritization of substances with a view to evaluation will be made on a risk-based approach (i.e. considering information on hazard, exposure and tonnage). The evaluation will be carried out by CA of Member states based on the Community rolling action plan. If the competent authority considers that further information is required, the registrant shall submit the information required to the Agency by the deadline set. The competent authority shall examine any information submitted, and shall draft any appropriate decisions within 12 months of the information being submitted.

Once the substance evaluation has been completed, the conclusions may lead to the restriction or authorization procedures.

What EVALUATION means for you? If you are…	
Manufacturer/ Importer (M/I)	**Downstream users (F+IU+PU)**
■ Provide additional information to Agency for evaluation process by defined deadline	■ Provide additional information to supplier for evaluation process on demand

ELEMENTS OF REACH: AUTHORISATION

The Authorisation system is aimed at addressing substances of very high concern. It concerns:

- carcinogens, mutagens and toxic to reproduction substances (CMRs) of 1 and 2 categories,
- persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances;
- substances of an equivalent concern, such as those having endocrine disrupting properties or those having PBT or vPvB properties, which do not fulfil the criteria, and for which there is scientific evidence of probable serious effects to humans or the environment.

Such substances will be prioritised by the Agency and may be included in Annex XIV* to REACH.
Substances included in Annex XIV* shall, after the certain date (so-called sunset date) not be used, unless the use is authorized.
Applications for authorisation shall be submitted to the Agency. Manufacturer(s), importer(s), and/or downstream user(s) of the substance may apply for one or several substances, for one or several own uses or uses intended for placing substance on the market.

Authorisations shall be granted for specific uses if:

- applicant shows that the risks posed by a substance are adequately controlled;
- applicant shows that socio-economic benefits of a use outweigh the risks;
- there are no suitable alternative substances or technologies available.

Decision on granting/refusing authorisations will take into account opinions of the Agency Committees on risk assessment and socio-economic analysis.
With the authorization scheme REACH promotes the principle of substitution of dangerous substances by less dangerous.

What AUTHORISATION means for you? If you are...

Manufacturer/ Importer (M/I)	Downstream users (F+IU+PU)
■ Apply for authorization (prove that risk is adequately controlled, prepare socio-economic analysis). ■ Include information on authorization in SDS. ■ Include the authorization number on the label before placing substance on the market.	■ If the substance is authorised, check compliance with authorization conditions. ■ Use suppliers authorization if authorised use corresponds to yours. ■ If substance is used in different way or for different purpose than authorized by supplier, take action: • apply for authorization yourself, • look for alternatives, • change the process, • look for another suppliers. ■ **F**: Include information on authorization in SDS. ■ Include the authorization number on the label before placing preparation containing the authorized substance on the market. ■ Notify the Agency if you use the substance authorized by the actor up the supply chain.

* The numbering of Annexes in this publication refers to the revised numbering of Articles and Annexes. The list of Annexes and references to the draft text version of 13 December 2005 is enclosed in the page 15.

ELEMENTS OF REACH: RESTRICTIONS

Substances, which are determined to be subject to marketing and/or use restrictions pose an unacceptable risk at Community level, shall be regulated. Restrictions may take the form of a ban on the use of a substance or marketing and use restrictions applying to all or some uses.

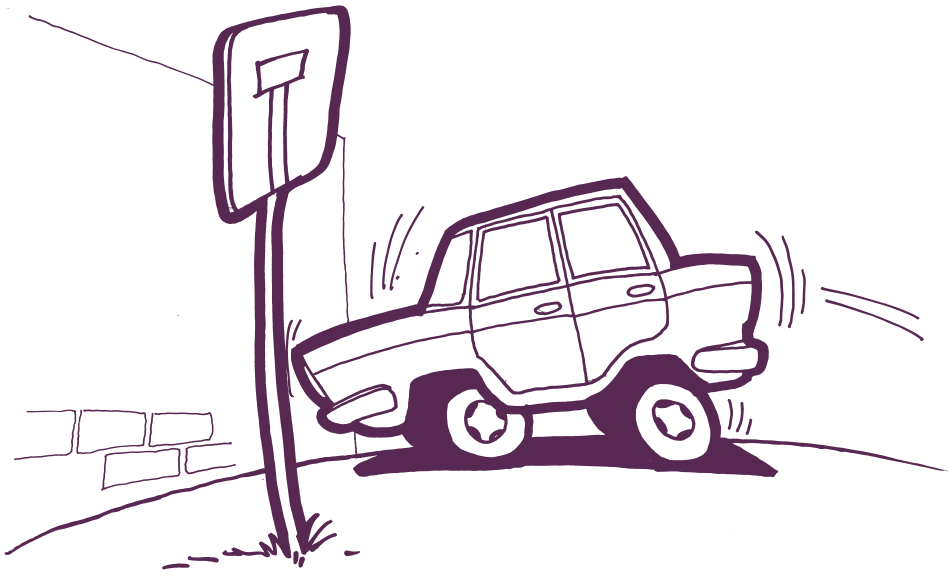
The restrictions procedure under REACH is similar to the current legislation on marketing and use restrictions under Directive 76/769/EC, which is already well known for you and therefore do not mean real changes for you. These existing restrictions will be taken over by REACH.

Up until 6 years after entry into force of the Regulation, a Member State may maintain any existing and more stringent restrictions on the manufacture, placing on the market or use of a substance.

Proposal for restriction can be initiated by Commission or Member State considering that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled.

What RESTRICTIONS mean for you? If you are…

Manufacturer/ Importer (M/I)	Downstream users (F+IU+PU)
■ Include the information on restrictions (conditions) in SDS. ■ Check that you comply with any restrictions on use of the substance.	■ Check that you comply with any restrictions (conditions) on use of the substance. ■ **F**: Include information on restrictions (conditions) in SDS.



INFORMATION FLOW IN THE SUPPLY CHAIN

Communication along the supply chain is expected to increase significantly with REACH.

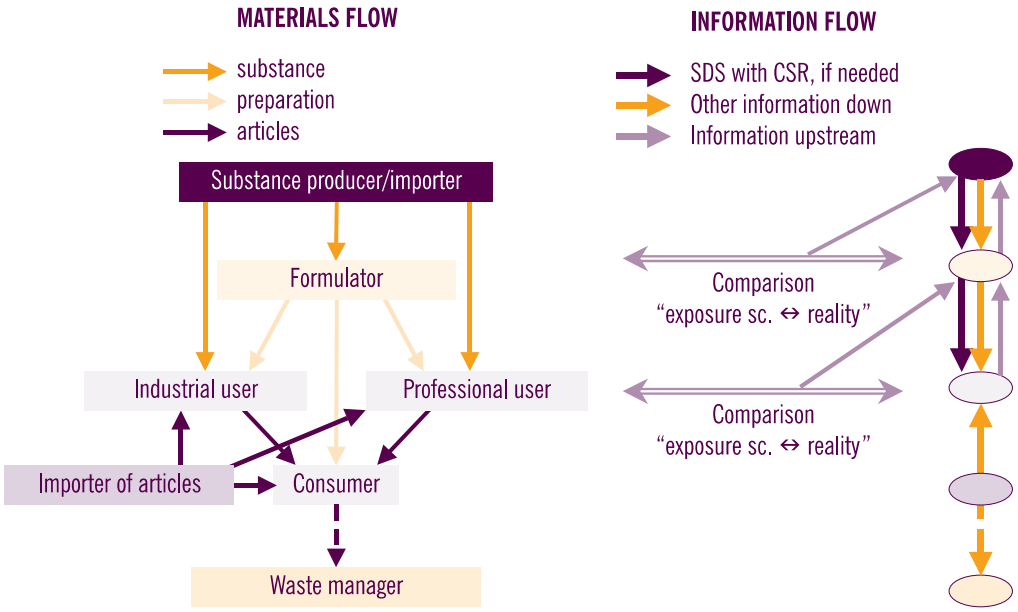
The communication requirements of REACH shall ensure that not only manufacturers and importers but also downstream users and distributors have the information needed for safe use of the chemicals. Information relating to health, safety and environmental properties, risks and risk management measures is required to be passed both down and up the supply chain, and between **all actors** in that supply chain.

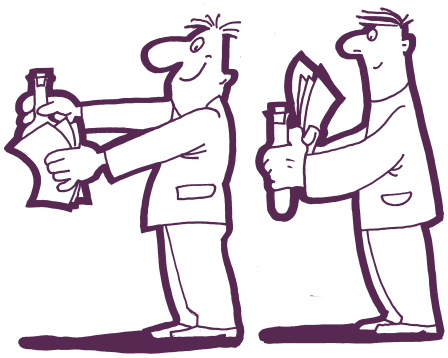
Communication down the supply chain mainly focuses on:

- transfer of safety data sheet (SDS) for all dangerous substances (the provisions of the current SDS Directive (91/155/EEC) are carried over into the REACH Regulation); where chemical safety assessments are performed according to the registration requirements, relevant exposure scenarios shall be annexed to the SDS and shall thus be passed down; SDS should be consistent with the results of the chemical safety assessment;
- where SDS is not required, a minimal list of information (registration number, details regarding authorisation or restrictions, other relevant information) needs to be forwarded;
- where a producer or importer of articles has notified the Agency in relation to substances of very high concern (SVHC), this information must be passed down as well.

Any actor in the supply chain shall also communicate the information to the next actor or distributor up the supply chain when having new information on hazardous properties or any other information which might be of relevance judging on appropriateness of risk management measures.
Furthermore, REACH highly promotes that the information on uses and conditions of uses would be communicated by user to supplier because it has to be taken into account when preparing the registration dossier.

Distributors play an important and very active role in the communication down and up the supply chain – he shall pass on the information to the next actor.





What COMMUNICATION ALONG THE SUPPLY CHAIN means for you? If you are…

Manufacturer/ Importer (M/I)	Downstream users (F+IU+PU)
■ Obtain information (on uses, use conditions) from downstream users to complete CSA → evaluate risk for each identified use through whole life cycle, define the risk reduction measures. ■ Forward information down the supply chain through SDS to enable safe use. ■ Forward down minimal information if SDS not required.	■ Follow the risk management measures identified in any safety data sheet. ■ Inform suppliers if you consider that the RMM they specify are inappropriate. ■ Check compliance with an exposure scenario, if one is received from the supplier is followed. ■ Decide action to take if conditions of use are outside the exposure scenario: - inform supplier and request that your use becomes an identified use, - prepare own CSR for substance or preparation used ≥ 1t/yr (+ **F:** add exposure assessment to SDS) → inform Agency. ■ Inform suppliers of any new or additional information on the hazards of substances ■ **F**: Compile information together for preparation and forward it down the supply chain to enable safe use through SDS (with annexed CSR, if required). ■ **F**: Forward down minimal information if SDS not required.

HOW TO GET STARTED WITH THE PREPARATION FOR REACH?

The core stones of the preparation of company for the implementation of REACH are:

- analyzing consequences
- building new competences
- drawing action plan.

In order to achieve it, the following steps to be managed:

	Producer/ Importer (M/I)	Downstream users (F+IU+PU)
FIRST STEPS	☑ If not available, set up electronic chemicals inventory in your company on the level of the substance	
	☑ Identify your role (s) under REACH for each substance you handle in the company	
	☑ Screen the substances you produce/import/use in the company: • Which substances are imported from outside the EU and which bought within EU; • Sort the chemicals used in your company according the amount ranges 1-10 t/year, 10-100 t/year, 100-1000 t/year, ≥1000 t/year; • Identify whether substances are new substances (included into ELINCS) or existing (included into EINECS); • Check for use of CMRs, PBT, vPvB or substances of similar concern	
NEXT STEPS	☑ Check relevance of the substances to your business → identify key-products and set the priorities → some substances might need to be refused when REACH comes	
	☑ Investigate market (market prices, number of producers/importers/suppliers and their key-products, availability of alternatives…)	
	☑ Try to collect information of usage of substances	☑ Check the use and risk management measures identified in SDS and applied in the company
	☑ Check the availability of information on substances you would like to register (what data are needed according Annexes VII-X, collect available data, evaluate the gaps and possible solutions (incl. (Q)SAR, possible exemptions)	☑ Check if your use is identified in pre-registration process ☑ Communicate with your suppliers and get preparing (defining future strategy) together
	☑ M/I/F: put efforts already now to improve quality of SDS → more specific info on RRM, check own SDS, check supplied SDS	
	☑ Draw the timetable for the implementation of the REACH requirements specifically for your company with the defined milestones and the actions plans for their implementation	
	☑ Estimate impact of REACH to company (monetary)	

INFORMATION SOURCES & GUIDANCES

REACH proposal and process:

EC DG Enterprise:	http://europa.eu.int/comm/enterprise/chemicals/index.htm
EC DG Environment:	http://europa.eu.int/comm/environment/chemicals/index.htm
European Chemicals Bureau:	http://ecb.jrc.it/
European Chemicals Agency:	http://www.hel2.fi/eca/eca.html

Explanatory texts & supporting tools

- Flowcharts on the new EU chemicals legislation REACH: http://europa.eu.int/comm/environment/chemicals/reach.htm
- Methodologies, tools and technical guidance for REACH implementation developed within the REACH Implementation Projects (**RIPs**): http://ecb.jrc.it/RIP/

REACH Implementation Projects (RIPs):
RIP 1: REACH Process description
RIP 2: Development of IT systems (REACH-IT)
RIP 3: Guidance Documents for industry
RIP 4: Guidance Documents for authorities
RIP 5: Setting up the Pre-Agency
RIP 6: Setting up of Agency
RIP 7: Commission preparation for REACH

→

RIP 3: Guidance for industry
RIP 3.1: Preparation of Technical dossier for Registration
RIP 3.2: TGD on preparing Chemical Safety Report
RIP 3.3: TGD on Information Requirements on Intrinsic Properties of substance
RIP 3.4: Data sharing (Pre-registration)
RIP 3.5: Downstream User Requirements
RIP 3.6: Classification and Labelling under Global Harmonised System
RIP 3.7: Preparation of Application Dossier for Authorisation
RIP 3.8: Requirements for articles
RIP 3.9: TGD on Socio-Economic Analysis
RIP 3.10: TGD for characterisation and checking of Substance Identity

Help desks:
Regulation obligates the Member States to establish national helpdesks to provide advice to the companies, in particular SMEs, on their responsibilities and obligations under Regulation and to help them to comply with the requirements. For the time being there are no established such help-desks in the Baltic States.

More information you can find on the websites of other organizations involved into debates of REACH:

Organisation for Economic Co-operation and Development – OECD:	http://www.oecd.org/
European Chemical Industry Council - CEFIC:	www.cefic.be
Downstream Users of Chemicals Co-ordination (DUCC) Group:	www.duccplatform.org
European Centre for Ecotoxicology and Toxicology of Chemicals:	www.ecetoc.org
European Environmental Bureau:	www.eeb.org
WWF – World wide fund for Nature:	www.panda.org
Greenpeace:	www.greenpeace.org
International Chemicals Secretariat:	www.chemsec.org
European Consumers' Organisation:	www.beuc.org
European Trade Unions Confederation:	www.etuc.org

LIST OF ANNEXES TO REACH REGULATION

Numbering acc. 13 Dec. 2005	Final revised numbering (as given in the publication)	Title of Annex
Annex I	Annex I	General provisions for assessing substances and preparing chemical safety reports
Annex Ia	Annex II	Guide to the compilation of safety data sheets
Annex I c	Annex III	Criteria for substances registered in quantities between 1 and 10 tonnes
Annex II	Annex IV	Exemptions from obligation to register in accordance with Article 2(4)(a)
Annex III section 2	Annex V section 1	Exemptions from the obligation to register in accordance with Article 2(4)(b)
Annex IV	Annex VI	Information requirements referred to in Article 9
Annex V	Annex VII	Standard information requirements for substances manufactured or imported in quantities of 1 tonne or more
Annex VI	Annex VIII	Additional standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more
Annex VII	Annex IX	Additional standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more
Annex VIII	Annex X	Additional standard information requirements for substances manufactured or imported in quantities of 1000 tonnes or more
Annex IX sections 1, 2	Annex XI sections 1,2	General rules for adaptation of the standard testing regime set out in Annexes VII to X
Annex XI	Annex XII	General provisions for downstream users to assess substances and prepare chemical safety reports
Annex XII	Annex XIII	Criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances
Annex XIII	Annex XIV	List of substances subject to authorisation
Annex XIV	Annex XV	Dossiers
Annex XV	Annex XVI	Socio-Economic analysis
Annex XVI	Annex XVII	Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles

ABBREVIATIONS

CMR	Carcinogenic, mutagenic and toxic to reproduction substances
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DU	Downstream User
EINECS	European Inventory of Existing Chemical Substances
EU	European Union
F	Formulator
GHS	Globally Harmonised System on Classification and Labelling of Chemicals
I	Importer
IT	Information Technologies
IU	Industrial user
M	Manufacturer of substances
PBT	Persistent, Bioaccumulative and Toxic substances
PU	Professional user
PPORD	Product and Process Oriented Research and Development
(Q)SAR	(Quantitative) Structure-Activity Relationship
REACH	**R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals
RIP	REACH implementation project
RMM	Risk Management Measures
RRM	Risk Reduction Measures
SDS	Safety Data Sheet
SIEF	Substance information exchange forum
SME	Small and medium size enterprises
TGD	Technical Guidance Document
vPvB	very Persistent very Bioaccumulative

WHOM YOU CAN CONTACT IN YOUR COUNTRY ABOUT REACH?

For Estonia:

Ministry of Social Affairs, Chemical Safety Unit	tel. +372 6269157, heli.laarmann@sm.ee	www.sm.ee
Ministry of Economic Affairs and Communications	tel. +372 6256489, diana.maurer@mkm.ee	www.mkm.ee
Ministry of Environment	tel. +372 6262981, juri.truusa@envir.ee	www.envir.ee
Chemicals Notification Centre	tel. +372 6269396, kemikaal@sm.ee	www.ktk.ee
Estonian Association of Chemical Industry, Hallar Meybaum	tel. +372 6139775, e-mail: info@keemia.ee	www.keemia.ee
Baltic Environmental Forum Estonia, Kitty Kislenko	tel. +372 6604643, kitty.kislenko@bef.ee	www.bef.ee

For Latvia:

Ministry of Environment, Zane Gedroviča,	tel. +371 7026511, zane.gedrovica@vidm.gov.lv	www.vidm.gov.lv
Latvian Environmental, Geological and Meteorological Agency, Arnis Ludboržs	tel. +371 7146138, arnis.ludborzs@lvgma.gov.lv	www.lvgma.gov.lv
Ministry of Economy, Marija Eberšteine	tel. +371 7013133, marija.ebersteine@em.gov.lv	www.em.gov.lv
Association of Latvian Chemical and Pharmaceutical Industries,	tel. +371 7298683, lakifa@lakifa.lv	www.lakifa.lv
Baltic Environmental Forum Latvia, Guna Krūmiņa	tel. +371 7357558, guna.krumina@bef.lv	www.bef.lv
State Sanitary Inspectorate	tel. +371 7819671, vsi@vsi.gov.lv	www.vsi.gov.lv

For Lithuania:

Ministry of Environment, Chemicals Unit	tel. +370 5 2663502, a.bajoraitiene@am.lt	www.am.lt
Ministry of Economy	tel. +370 5 2628903, v.skarzinskas@ukmin.lt	www.ukmin.lt
Environmental Protection Agency	tel. +370 5 2126090, a.katkus@aaa.am.lt	http://aaa.am.lt
Association of Lithuanian Chemical Industry Enterprises	tel. +370 5 2124175, lchpia@tdd.lt	www.chemija.lt
Baltic Environmental Forum Lithuania, Zita Dudutytė:	tel. +370 5 2159288, zita.dudutyte@bef.lt	www.bef.lt