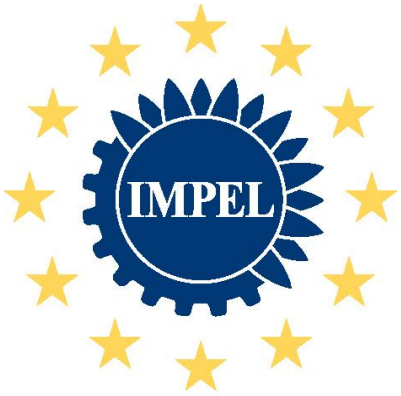
# Linking the

# Directive on Industrial Emissions (IED)

# and

# the REACH Regulation

Final report: 15 November 2013




European Union Network for
the Implementation and Enforcement
of Environmental Law

**Introduction to IMPEL**

The European Union Network for the Implementation and Enforcement of Environmental Law (IMPEL) is an international non-profit association of the environmental authorities of the EU Member States, acceding and candidate countries of the European Union and EEA countries. The association is registered in Belgium and its legal seat is in Brussls, Belgium.

IMPEL was set up in 1992 as an informal Network of European regulators and authorities concerned with the implementation and enforcement of environmental law. The Network's objective is to create the necessary impetus in the European Community to make progress on ensuring a more effective application of environmental legislation. The core of the IMPEL activities concerns awareness raising, capacity building and exchange of information and experiences on implementation, enforcement and international enforcement collaboration as well as promoting and supporting the practicability and enforceability of European environmental legislation.

During the previous years IMPEL has developed into a considerable, widely known organisation, being mentioned in a number of EU legislative and policy documents, e.g. the 6th Environment Action Programme and the Recommendation on Minimum Criteria for Environmental Inspections.

The expertise and experience of the participants within IMPEL make the network uniquely qualified to work on both technical and regulatory aspects of EU environmental legislation.

Information on the IMPEL Network is also available through its website at: www.impel.eu

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**Executive summary:**

The industrial activities listed in Annex I of the Directive on Industrial Emissions (2010/75/EU) are – in one way or another – related to the manufacture or processing of chemical substances and on top of that to possible releases or emissions of pollutants. At the same time chemical substances are regulated under the REACH Regulation. Therefore IMPEL decided to carry out the project "Linking the Directive on Industrial Emissions (IED) and the REACH Regulation". The project team consisting of one representative of the European Chemical Agency, one representative from the Forum for exchange of Information on Enforcement of REACH and CLP Regulationsin in the European Chemical Agency, 6 representatives from 5 IMPEL Member States and a representative of the Forum Secretariat was asked to explore a set of core questions and to identify whether there is a need for follow-up projects on the item. The questions were:

1. How do obligations from the REACH Regulation interact with IED statutory duties concerning permitting and inspection?
2. Which information required for compliance with the REACH Regulation can be used for IED permitting and inspection activities?
3. Which information required for IED permitting and inspection can be used for purposes of the REACH Regulation?
4. Do similarities between IED and REACH inspection tasks exist and how can they be used best for all parties (meaning that the same or similar tasks have to be fulfilled under both).

The evaluation of existing literature on the item showed that there are only a few studies. None of them covers a complete assessment of the interlinks between the REACH Regulation and the IED.

After an introduction to relevant procedures under the IED (with focus on chemical substances and pollutants) and the relevant REACH processes (with focus on the REACH generated information and its availability) a systematic analysis of the interlinks and synergies of the REACH Regulation with the IED was carried out (providing answers to question 1, 2 and 3). It showed how downstream users / operators can benefit from the information generated under REACH and IED for cross-legislation compliance. Best practice examples from the participating IMPEL member states for templates / tools / flow sheets and supporting guidance show that competent REACH and IED authorities try to bring the information generated under the two pieces of legislation together and to optimise their daily work.

Several questions could not be answered by the project team. The question whether IED permit writers and inspectors are obliged to check the operators' compliance with REACH obligations in their work remained open. It is strongly recommended to do so, because it might produce tensions if for example the IED authority grants a permit to an installation using or producing a restricted substance. On top of that competent REACH and IED authorities should cooperate closely to exchange information, avoid double work and carry out joint inspections.

The project team recommends carrying out a follow-up project (including a workshop) on the item.

**Disclaimer:**

This report is the result of a project within the IMPEL network. Neither the members of the project team, nor the bodies, they might be working for, are responsible for the use which might be made of this report. It does not represent the official view of the national administrations, the European Chemicals Agency (ECHA) or the European Commission. It should be stressed that this report is of a general nature only, not legally binding and that the information in this document does not constitute legal advice.

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# 1. Introduction

## 1.1 Project background

Directive 2010/75/EU on industrial emissions (IED) lays down rules on integrated prevention and control of plollution arising from industrial activities. The aim is to achieve a high level of protection of the environment as a whole. Permitting (and inspection) of industrial installations covered by the IED is a very complex task because the integrated approach for pollution prevention and control requires an assessment of the "*direct or indirect introduction as a result of human activity, of substances, vibration, heat or noise into air, water or land which may be harmful to human health or the quality of the environment, result in damage to material property, or impair or interfere with amenities and other legitimate uses of the environment*". In the context of this IMPEL project the human activity means the building and operating of industrial installations (with their emissions of chemical substances).

According to Article 1 (1) of REACH the aim of the Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. REACH applies to substances and mixtures and covers the manufacture, placing on the market or use of substances on their own, in mixtures or in articles.

The two pieces of legislation have in common that they deal with chemical substances and their properties. Both of them aim at the prevention of negative effects of substances on the environment and on human health but they provide different instruments to reach this goal.

The main aim of this report is to identify the interaction between the REACH Regulation and IED. Another aim is to identify synergies and to make competent authorities aware of them. Industry may use information collected for the different processes under REACH for permit applications (Art. 12 IED) and vice versa.

The aim of the project is <u>not</u> to look for overlaps between REACH and IED. They were identified in the Commissions' REACH review [Lit. 1]. In the context of the review overlaps meant a situation where two pieces of legislation regulate the same situation which may lead to uncertainties or to unnecessary burdens on operators by imposing the same or similar requirements twice or imposing conflicting requirements on the operators resulting from two different pieces of legislation.

## 1.2 Project objectives

Chapter 2.6 of the Terms of Reference (ToR, Annex II) defines the objectives of the IMPEL project "Linking the Directive on Industrial Emissions (IED) and the REACH Regulation". The project team is asked to explore the following questions:

How do obligations from the REACH Regulation interact with IED statutory duties concerning permitting and inspection?

Which information required for compliance with the REACH Regulation can be used for IED permitting and inspection activities?

Which information required for IED permitting and inspection can be used for purposes of the REACH Regulation?

Do similarities between IED and REACH inspection tasks exist and how can they be used best for all parties.

In this context several other questions occurred:
Do IED and REACH inspectors ask the same questions and check the same things under the different pieces of legislation? Do they do double work? How can this be avoided and how can the collected information be used best by all parties?

### 1.3 Participants and their interest in the project

The project intends to explore the interlink between the IED and REACH and to find possibilities for the decrease of workload for all parties by the exchange of information. Therefore it was necessary to have experts for REACH and for IED permitting and inspection at the table. The project team consists of the following members with the expertise mentioned in brackets: Gisela Holzgraefe (DE, project manager, chemical safety and IED), Parvoleta Angelova Luleva (BG, hazardous chemicals, preventive activities, ECHA Forum representative), George P. Georgiou (CY, labour inspection), Vera Storoni (IT, IED permitting), Marcel Taal (NL, IED, member of Article 13 Forum and of Article 75 Committee), Eva Haug (NO, REACH), Gunn Sørmo (NO, IED), Ainhoa Inza (ES, IED), Monique Pillet (ECHA, Risk Management Identification Unit), Juan Pablo Calvo-Toledo (ECHA, Forum Secretariat).

All of them had been involved in discussions about the link between IED and REACH in their daily work and were - in one way or another - experienced in the practical work with the two pieces of legislation. In some countries supporting guidance / tools are available for the IED permit and inspection authorities (IT, partly DE). In others they are under development (NL, NO, ES). Therefore the participants were motivated to learn from the experience of the others and to find out whether a best and easy way for the daily work of authorities can be found. ECHA was interested in the IMPEL project because of the high common interest in making the most out of the possible synergies between these two pieces of legislation both at authority and at industry level. The Forum is interested in the interlinks between REACH and IED in terms of benefits for coordinated enforcement of the two instruments and the coordiantion among the enforcement authorities, including joint inspections, where appropriate.

### 1.4 Methodology

As an input for the project an analysis of the existing literature on the link and possible synergies between REACH and IED was carried out. The project team identified the following documents:

- German Study "Nutzen der REACH-Informationen für umweltrechtliche Vollzugsaufgaben (mit Schwerpunkt im Anlagenrecht)" [Benefit of REACH-Information for environmental enforcement tasks (with focus on lindustrial installations)"] by Prof. Dr. Martin Führ, Dr. Silke Kleihauer (final report February 2010) [Lit. 2] and documentation on two workshops "REACH in der Praxis – Unterstützung für umweltrechtliche Vollzugsbehörden" [„REACH in Practice – Support for environmental enforcement authorities"] [Lit. 3]
- Commission Staff Working Document for the General Report on REACH COM(2013)49 – Revision of REACH[1]
- "Linking the Water Framework Directive and IPPC Directive", final report of an IMPEL project [Lit. 4]
- Study of the Netherlands "Zeer Zorgwekkend Stoffen in Wabo-vergunningen – Een analyse van recente Wm- en omgevingsvergunningen" (March 2013) [Substances of very high concern in Wabo permits – an analyse of recent Wm in environmental permits] [Lit. 5]

Chapter 2 of this final report summarises the results of the analysis.

As another resource for input a questionnaire (Annex II) with eight questions was used to prepare the first project team meeting that took place on 27 June 2013 in Hamburg.

The input from literature, the content of the presentations made during the meeting, the answers to the questions, the results of the discussions and the expertise of the participants formed the basis for this final report.

# 2 Evaluation of existing studies as input to the project

### 2.1.1 „Nutzen der REACH-Informationen für umweltrechtliche Vollzugs-aufgaben (mit Schwerpunkt im Anlagenrecht)" by Prof. Dr. Martin Führ, Dr. Silke Kleihauer

The final report of the project „Benefit of REACH information for environmental enforcement tasks (with focus on industrial installations)" analyses how the risk information about substances generated under REACH obligations can potentially be used for permit and inspection tasks of authorities regulating industrial installations. Chemical substances are produced in industrial installations and their further use by downstream users may take place in other industrial installations. REACH and IED do not answer the following question: To what extent do the results of the Chemical Safety Assessment performed under the REACH Regulation influence the permit requirements concerning risk management, emissions into water, soil and air etc. for industrial installations? The only reference is made in Article 2, par. 4 of the REACH Regulation, where it is said that the REACH Regulation shall apply without prejudice to Community workplace and environmental legislation. According to the report this means that REACH information will not result in higher emission limit values or less strict requirements for industrial installations as they are defined under

the IED regime. The report describes the main REACH mechanisms, explains the chemical safety assessment in more details and summarises the available information under REACH. It provides recommendations concerning the potential use of REACH information for environmental enforcement tasks. Finally it points out how regional enforcement authorities can get access to REACH information with the purpose to use it for permitting and inspection tasks for industrial installations.

### 2.1.2 „REACH in Practice – Support for environmental authorities“ - documentation on two workshops organised by the Federal Agency for the Environment (UBA Germany)

In different contexts environmental law refers to the properties of chemical substances. Examples are: legal acts on water management, immission control, waste management, Seveso Directive. In these fields the sector-specific environmental law relies on results of classification and labelling according to CLP and on information elaborated in procedures under REACH. The series of workshops under the title “REACH in Practice” provided further information and practical advice for all parties involved and revealed the needs of enforcement authorities responsible for permitting and inspection of industrial installations.

The participants agreed that it is necessary to take into account the connection between legislation on chemical substances and that on permitting and inspection of industrial activities. They identified the need for:

- general supporting guidance explaining how to deal with the interface between the two pieces of legislation,
- an adjustment of the application templates dealing with chemical substances to the new data generated by the REACH mechanisms, e.g.
    - include the derived no effect level (DNEL), the predicted no effect concentration (PNEC) and the registration number of each substance into the application,
    - the integration of the following questions concerning the substances used or generated in the installation:
        - are the predicted environmental concentrations (PECs) in the relevant surrounding area to the planned installation below the PNECs?
        - is the planned processing of the substances included in the exposure scenario / identified uses in the safety data sheet?
        - do specific recommendations exist concerning the minimisation of emissions or risk management measures (RMM)?

The legal relevance of DNEL and PNEC values and their importance for enforcement tasks under IED were discussed intensively. Their role should be clarified in the guidance document to be developed for enforcement authorities.

On top of that the participants stated that the operator should be obliged to report new findings on the substances to the authority. This might become an obligation in the permit.

## 2.2 General Report on REACH - Report from the Commission to the European Parliament, the Council, the European Economic and social Committee and the Committee of the Regions in accordance with Article 117 (4) of REACH and Article 46 (2) of CLP, and a review of certain elements of REACH in line with Articles 75 (2), 138 (3) and 138 (6) of REACH, COM(2013) 49 final and Commission Staff Working Document for the General Report on REACH COM(2013) 25 final – Revision of REACH[1]

### 2.2.1 General Report on REACH COM (2013) 49 final

The REACH Regulation (REACH entered into force on 1 June 2007. It put the Commission under a number of reporting and review obligations. In accordance with these obligations the Commission submitted a general report on REACH including a review of certain elements of REACH to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in February 2013 (COM(2013) 49 final). This included the assessment of the scope of REACH to avoid overlaps with other EU provisions. The accompanying Staff Working Document [SWD (2013)25] provided further details.

One of the conclusions of the REACH report was that under the REACH regime the objective of a high level of protection of human health and the environment is expected to be achieved through

- a better knowledge on the properties and uses of substances resulting in better safety and control measures, reducing exposure and hence, the negative impacts on human health and the environment and
- the use of less dangerous alternative substances.or technologies to substances of very high concern (SVHC).

The Commission reviewed the main operational procedures under REACH: registration, information in the supply chain, evaluation, authorisation and restrictions. An evaluation of the registration process, guidance documents, inspection and enforcement activities was carried out. The main findings were on the one hand:

- Increased information is resulting in changes in classification, with the majority becoming more stringent. The quality of the information available for risk assessment has already improved if compared with the pre-REACH situation.
- Increased information in the supply chain and improved safety data sheets is resulting in more appropriate risk management measures, thus contributing to the observed reduction in nominal risk, and has benefited end-users, such as article producers.
- Increased obligations on substances of very high concern (SVHC) through the candidate listing and authorisation provisions have led to increased moves towards the substitution of those substances through the supply chain.

On the other hand the Commission identified some key shortcomings:

- many registration dossiers have been found to be non-compliant, including with regard to substance identity, as reported by ECHA;
- insufficient assessments by registrants of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vBvP) properties, as reported by ECHA;

- problems with regard to the content and format of the extended safety data sheet, as reported by industry.

As mentioned above the Commission had to assess overlaps between REACH and other pieces of EU legislation. Therefore the links between REACH and 155 legal acts regulating chemicals, products environmental protection, workers' protection and food safety have been analysed. The result was that no major overlaps with other EU legislation have been identified. A few minor overlaps were found in the registration area. Concerning restrictions the situation was similar. As a certain number of pieces of EU legislation contain substannce restrictions the Commission considers to invite ECHA to develop an inventory of all existing restrictions in EU legislation on an individual substance basis.

### 2.2.2 Commission Staff Working Document SWD(2013) 25 final - Chapter 5.3.2 Industrial emissions

The definitions under the IED refer once to REACH and once to CLP: For the definition of "hazardous substances" the IED refers to the definition of hazardous substances and mixtures under Article 3 of Regulation (EC) No 1278/2008 on classification, labelling and packaging of substances and mixtures (CLP). Under Chapter V of the Industrial Emissions Directive that sets special provisions for installations and activities using organic solvents, the IED refers in Article 57 to the definition of "mixture" under REACH.

On the other hand REACH lays down that it applies without prejudice to Directive 96/61/EC, the IPPC Directive that is now followed up by the IED. According to the Commission Staff Working Document SWD(2013) 25 final this means that "the application of REACH requirements should not allow circumventing the requirements of the Industrial Emissions Directive" by the operator.

Additionally the Commission Staff Working Document identified the following points:
Several substances that are subject to emission limit values under the IED (Annex II) are also subject to restrictions under Annex XVII to REACH, some of them are also included in the REACH Candidate List of SVHC. Some substances regulated under the IED are also covered by additional EU legislation, e.g. by legislation regulating pesticides and biocides.
Article 61 (4) of REACH regulates that the authorisation for the use of a substance under REACH may be reviewed if environmental quality standards as referred to in the IED are not met. Article 62(5) of REACH allows the applicant for authorisation to include in its application a justification for not considering risks to human health and the environment arising from emissions of a substance from an installation for which a permit was granted in accordance with the IED.

Concerning the nature of the emission limit values of the substances of Annex II to the IED the Commission Staff Working Document identifies that they are not risk based but based on the application of best available technologies. The permit conditions must include emission limit values for all polluting substances listed under Annex II to the Directive and other polluting substances, which are likely to be emitted from the installation concerned in significant quantities. According to Article 14 (1) IED competent authorities are required to select further substances and subject them to emission limit values taking into account their nature and their potential to transfer pollutants

from one environmental medium to another. The SVHC under REACH – as far as not yet mentioned in Annex II IED – are such other polluting substances.

As an important synergy between REACH and the IED the Commission Staff Working Document identifies finally that information on a substance under the registration and authorisation procedures may be used to support the development of BAT reference documents. The risk assessment of substances under REACH that are manufactured or placed on the market in quantities of 10 tonnes or more per year comprises the complete life-cycle of the substance and therefore includes the use and manufacture of these substances in industrial installations covered by IED and options to avoid and control emissions. In this respect Recitals 14 and 21 of REACH state that the information yielded on substances may also be used in risk management procedures under other EU legislation.

## 2.3 Finalised IMPEL projects

So far there was no IMPEL project with focus on REACH and environmental aspects but the final report of "Linking the Water Framework Directive and IPPC Directive" ([Lit. 4] finalised 2010) provides some information about the interaction of REACH with IPPC (now IED) and WFD (chapter 9). The conclusions of the chapter "Interactions of The REACH Regulation with the IPPC Directive, EQS and WFD" point out that water managers should consider how far action to control specific substances under REACH will contribute to reducing their presence in water bodies and, therefore, whether such action may be sufficient to meet objectives. On top of that IPPC authorities and water managers should identify whether specific assessments undertaken under REACH are available for specific substances of concern and provide information on toxicity, etc., which may help in understanding the behaviour and impact of those substances in water bodies.

## 2.4 Study of the Netherlands "Zeer Zorgwekkend Stoffen in Wabo-vergunningen – Een analyse van recente Wm[2]- en omgevingsvergunningen" (March 2013) - Substances of very high concern in Wabo[3] permits – an analyse of recent Wm in environmental permits (March 2013) [Lit. 5]

The Ministry of Infrastructure and Environment carried out an analysis on dealing with substances of very high concern in environmental permits in the Netherlands. The study is a documentation of how difficult it is for permit writers in their daily work to deal with substances of very high concern in environmental permits, varying from hospitals to waste incineration plants. Chapters 5.1 Conclusions and 5.2 Recommendations of the final report were translated into English and shall serve as input to the IMPEL project. These chapters are presented below.

[2] Environmental Protection Act

[3] Environmental Licensing Bill (General Provisions)

### 2.4.1 Conclusions and recommendations[4]

#### 2.4.1.1 Conclusions

Based on the analysis of 27 recent Environmental Management Act permits (and its successor the Environmental Licensing (General Provisions) Act), it is shown that competent authorities do not deal with substances of very high concern in an equal and unambiguous way. The main conclusions based on the analysis are:

- Not in all cases, substances of very high concern (substances fulfilling Art. 57 criteria) are recognized as such. In three cases this was obvious, while in some other cases it was not clear.
- When substances of very high concern are addressed, there is in most cases a reference to the Dutch guidelines on emissions to air (NeR).
- BAT is often mentioned in relation to IPPC and BREFs; rarely specifically in relation to substances of very high concern.
- Substances that got labelled substances of very high concern after permitting, stay "under the radar", so minimization of those substances is not guaranteed.
- Few permits have a list of substances used/emitted. According to the researchers, this would be recommendable especially in the light of the previous remark.
- Few permits describe in detail how emissions (in case emissions limit values are set) should be determined (measurement frequency, hourly average values etc.)
- An immission survey in relation to substances of very high concern is sometimes done, but not always. In five of the checked permits, a specific immission survey for substances of very high concern was done.

#### 2.4.1.2 Recommendations

The conclusions can be used to further improve the 'Guidance emission prevention substances of very high concern'. Based on the conclusions, the following recommendations were made:

- A good description of substances of very high concern should be in the guidance. Also a simple method to check if a substance is a substance of very high concern is important. An instrument as the NeR database listing the substances is a good example[5].
- With REACH, the pace in which substances are identified as substances of very high concern increases. It is important to secure that substances stay "in the picture". It is important for permit writers to realize this.
- In addition to the previous point, it was considered useful to have a list of substances annexed to every permit. This makes it easier to keep these substances "in the picture".
- The guidance should pay attention to measurement methods and the bases of the set emission limit values.

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[4] This document is a translation of chapter 5 and table 2 (chapter 3) of "Zeer Zorgwekkend Stoffen in Wabo-vergunningen, Een analyse van recente Wm- en omgevingsvergunningen", Survey done on behalf of the Ministry of Infrastructure and the Environment, March 2013.

[5] The researchers note that the new system will be based on criteria instead of a list, yet propose to have a list with a disclaimer. On the internet site http://www.infomil.nl/onderwerpen/klimaat-lucht/ner/bijlagen-digitale/4-5-overzicht/ either the common name or CAS number can be used to get the emission limit value for any substance, as far as this information is available. The Netherlands are working on updating the list using the REACH data. From 2015, this approach should be part of general binding rules.

### 2.5 Other input

#### 2.5.1 ECHA work on Interlinks with other legislation requirements

The aim of this work is to explore and promote the efficient use of information on chemical substances in a multi and cross-legislative context.
The focus of the work is on industrial installations and industrial activity taking place within the installation and the industrial actors addressed are downstream users (DU) as defined in the REACH Regulation.
The interlink analysis presented in chapter 6 of this report is based on this ECHA work.

# 3 Relevant processes under the Directive on industrial emissions (IED) – a short introduction

In order to prevent, reduce and as far as possible eliminate pollution arising from industrial activities the IED provides a general framework for permitting, monitoring and inspection of the main industrial installations. The IED is supported by a wide range of other EU law, such as E-PRTR[6], EQS-Directive[7], Groundwater Directive, Waste Framework Directive, Seveso III Directive etc. The interlink between IED and REACH will be discussed in more detail in chapter 6.

This chapter provides an overview of the IED regulatory cycle and identifies roughly the interaction between IED and other pieces of legislation that are relevant in permitting and inspection.

## 3.1 Permitting: Steps of the permit procedure focused on substances and the relation to REACH

Integrated permitting of industrial installations and activities is a very complex task in which different experts are involved. Figure 1 shall demonstrate this. The scope of IED permitting (and consequently inspection) related to chemical substances is very broad. The criteria for determining best available techniques reflect the integrated approach. In the permit procedure it may require the assessment of

- Emissions to air, water and soil
- Avoidance of hazardous waste
- Effects on flora, fauna, habitats
- Aspects concerning work safety (fire protection, explosion protection, workplace concentrations ….)

[6] Regulation concerning the establishment of a European Pollutant Release and Transfer Register (EC) No 166/2006

[7] Directive on environmental quality standards in the field of water quality (2008/105/EC)

- Protection of national heritage
- Protection of the ozone layer etc.
- Avoidance of hazards (including Seveso II and in future Seveso II requirements)
- Efficient use of energy …

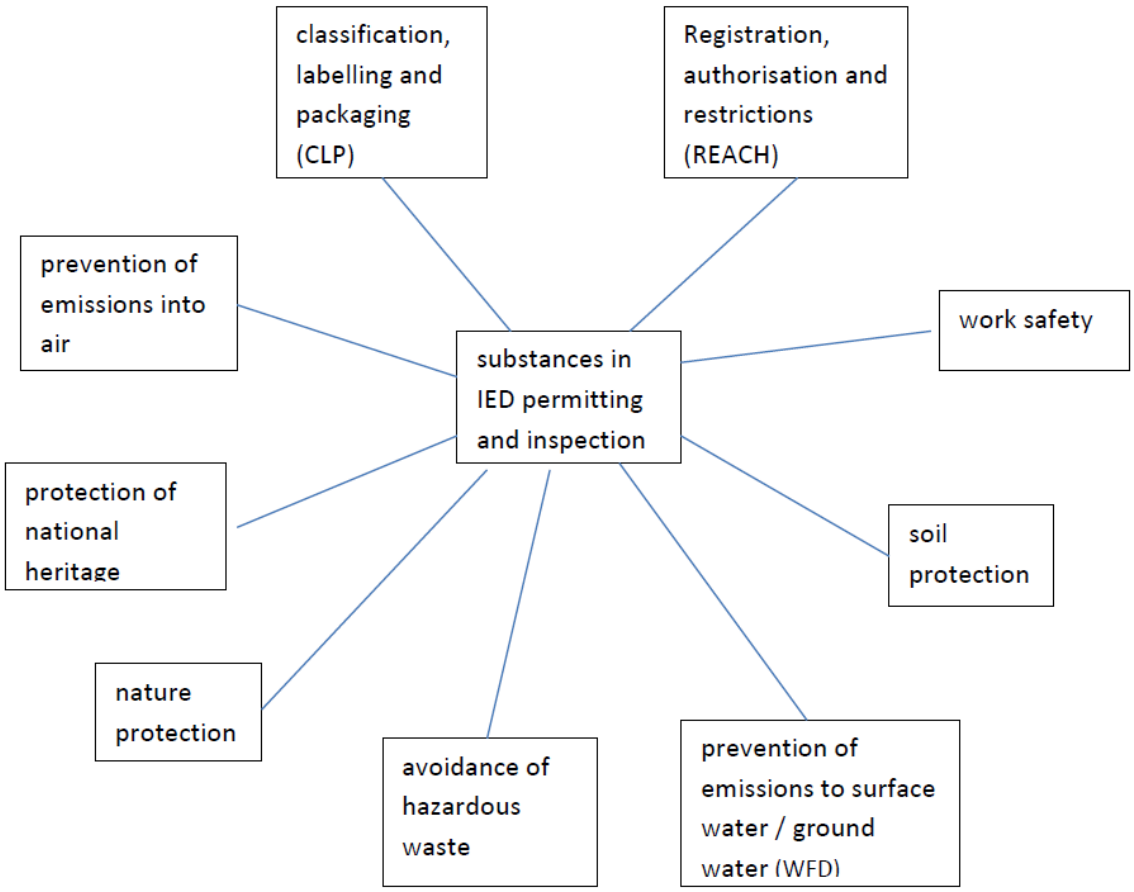



**Figure 1: Substances in permitting and inspection and the relation to different legal acts**

A wide range of legal acts have to be taken into consideration during the process. If there are no requirements concerning the individual chemical substance in the media specific directive or BAT conclusions permit writers can subject them to emission limit values taking into account their nature and their potential to transfer pollutants from one environmental medium to another. For that purpose other sources like REACH data can be used.

## 3. 2 The regulatory cycle of IED

The regulatory cycle of IED permitting and inspection includes the following steps:

1. Determination of the installation
2. Application
3. Assessment of the application documents
4. Involvement of the public
5. Permit decision
6. Monitoring and reporting
7. Inspection
8. Review of the permit.

Figure 2 shows the input to the steps, links between the steps and how they work together.

### 3.2.1 Determination of the installation

First of all the operator has to describe the boundaries of the planned installation. The Industrial Emissions Directive (IED) defines an “installation” as a stationary technical unit within which one or more industrial activities listed in Annex I or in part 1 of Annex VII of the IED are carried out, and any other directly associated activities on the same site which have a technical connection with the activities in those Annexes and which could have an effect on emissions and pollution.

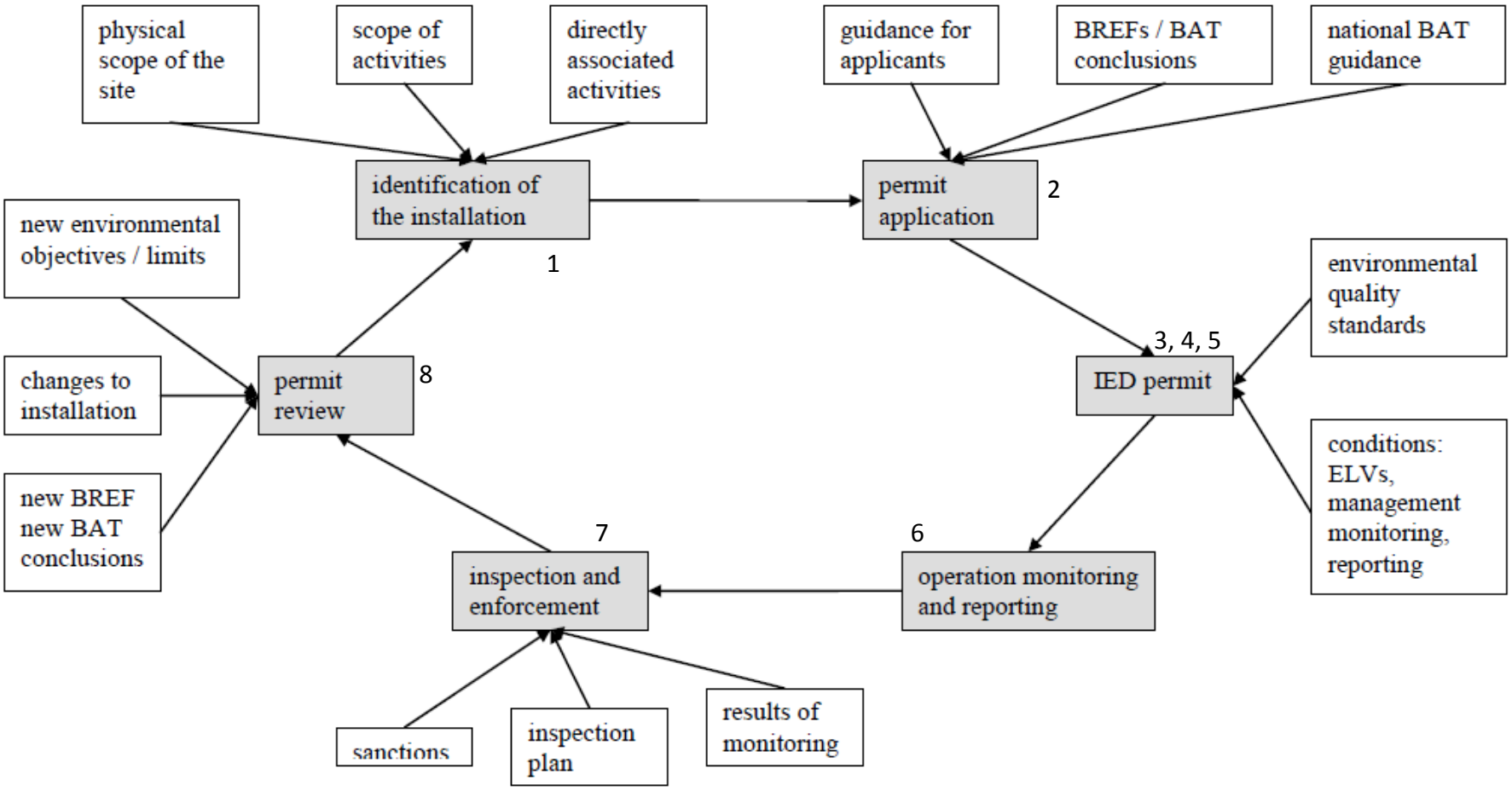
The definition of the boundary of an IED installation has influence on the items (including substances) to be assessed by the authorities involved. For example, although waste water treatment off site might be excluded from the permit, it may be appropriate for the IED permit to set conditions to address the quality of that waste water (e.g. presence of certain priority substances) in order to meet objectives of the EQS Directive.

### 3.2.2 Application for an IED permit

Before starting the preparation of a permit application operators should contact the competent authority and use the available templates and guidance material. Some countries use BREFs and BAT conclusions directly others still transpose it into national law.

According to IED Article 12 the permit application must include a description of the following:
- the installation and its activities,
- the raw and auxiliary materials, other substances and the energy used in or generated by the installation,
- the sources of emissions from the installation,
- the conditions of the site of the installation,
- the nature and quantities of foreseeable emissions from the installation into each medium as well as the identification of significant effects of the emissions on the environment,
- the proposed technology and other techniques for preventing or where this is not possible reducing emissions from the installation,
- measures for the prevention, preparation for re-use, recycling and recovery of waste generated,
- further measures to comply with the general principles of the basic obligations of the operator as provides for in IED Article 11,

**Figure 2: The IED regulatory cycle**



- measures planned to monitor emissions into the environment and
- the main alternatives to the proposed technology, techniques and measures studied by the applicant in outline (for installations regulated under the EIA Directive[8]).

Operators can use information that is supplied or produced in response to other legislation for their application. This includes e.g. information published in the ECHA dissemination portal, information provided in safety data sheets, exposure scenarios or information the operator has generated when complying with REACH obligations. The IED does not address the compliance with the duties under REACH as such.

If the activity involves the use, production or release of relevant hazardous substances and having regards to the possibility of soil and groundwater contamination on the site, the operator shall submit a baseline report before starting operation of the installation and before a permit for an installation is updated. For this purpose he can also use information that is supplied or produced in response to other legislation, e.g. REACH (see chapter 6 for some examples).

### 3.2.3 Assessment of the application documents

In this step the competent authority – in cooperation with other authorities affected by the project - has to assess the environmental performance of the installation. The Directive on Industrial Emissions sets out a broad objective of preventing or reducing emissions to the environment as a whole. Installations should comply with BAT and the BAT conclusions as well as requirements deriving from other sector specific law (e.g. WFD and work safety). However, if environmental quality standards require stricter conditions than those achievable by the use of best available techniques additional measures may be required in the permit to comply with environmental quality standards. For example if a priority substance regulated under WFD (e.g. mercury) would be present in the waste water of an installation, the operator would be required to take measures to reduce emissions and to phase out the emissions, discharges and losses of the substance. On top of that permit writers are required to select further substances and subject them to emission limit values taking into account their nature and their potential to transfer pollutants from one environmental medium to another (Art. 14, par 1 IED)

### 3.2.4 Involvement of the public (Art. 24 IED)

This step belongs to the IED requirements. The public may provide relevant input to the authority concerning the situation and conditions of the site.

### 3.2.5 Permit decision

Based on the assessment of the permit application the permit is drafted. The permit should include requirements to ensure the operators compliance with the general principles governing the basic obligations of the operator. In addition to emission limit values for polluting substances to air, water

[8] Directive on the assessment of the effects of certain public and private projects on the environment (2011/92/EU) codification

and land, it should include suitable emission monitoring requirements (methodology, frequency and evaluation procedure), appropriate requirements ensuring protection of the soil and groundwater and measures concerning the monitoring and management of waste generated by the installation.

BAT conclusions shall be the reference for setting the permit conditions. One criterion for the determination of the Best Available Technique is the use of less hazardous substances. For that purpose, some steps in the Authorisation process of REACH can provide useful information related to possible alternatives of substances subject to authorisation.

### 3.2.6 Monitoring and reporting

Monitoring and reporting will confirm if the installation is operated in compliance with the emission limit values [ELVs] set out in the permit. According to the frequency defined in the permit (at least annually) the operator has to submit the emission report to the competent authority. BAT conclusions are the reference point for setting conditions concerning monitoring.

### 3.2.7 Inspection

Based on the individual inspection plan the competent authority shall regularly draw up programmes for routine environmental inspections, including the frequency of site visits for different types of installations. The determination of the period between two site visits is based on a systematic appraisal of the environmental risks of the installation and lies between 1 year and 3 years for installations posing the lowest risk. For the risk assessment the characteristic data of the chemicals processed or produced in the installation play an important role. If noncompliance with the permit conditions was identified during the inspection, an additional site visit has to be carried out within 6 months of the first inspection.
Non-routine inspections shall be carried out to investigate serious environmental complaints, serious environmental accidents, incidents and occurrences of non-compliance as soon as possible and where appropriate, before the granting, reconsideration or update of the permit.

### 3.2.8 Review of the permit

The IED requires a periodic review of permits. The Directive highlights a number of circumstances when a permit review has to be carried out. These include issues relating to the installation, the processes and the results of monitoring and / or inspection. Within 4 years after the publication of BAT conclusions, the competent authorities have to ensure that all permit conditions are reconsidered and, if necessary, updated to ensure compliance and the operator has to carry out appropriate measures at the installation for returning to compliance.

Under the IED hazardous substances are definded according to in Article 3 of the Regulation on Classification, Labelling and Packaging [EC1272/2008] and competent authorities should regularly check whether substances produced or used in the installation are put on the candidate list or subject to authorisation or restrictions. This may also result in new measures and a permit revision.

## 3.3 Chemical substances relevant for IED permitting and inspection and the instruments / procedures provided by the directive

In the IED there are many references to chemical substances. Table 1 of Chapter 6.4 provides an overview of key articles in the Directive on Industrial Emissions related to substances and their relation to other pieces of legislation on chemicals, especially to REACH. Annex II to the IED "List of polluting substances" (see Annex III to this report) provides a number of polluting substances to air and water. Many of them are sum parameters (bulk parameters), so that they cover a wide range of substances.

Some examples for requirements/obligations under the REACH Regulation and their relevance for permitting and inspection shall be discussed here.

### 3.3.1 To which substances does the IED refer?

Article 3 IED "Definitions" states that "substance" means any chemical element and its compounds with exception of radioactive substances, genetically modified micro-organisms and genetically modified organisms.

In the context of the IED "pollution" means the direct or indirect introduction as a result of human activity, of substances, vibration, heat or noise into air, water or land which may be harmful to human health or the quality of the environment, result in damage to material property, or impair or interfere with amenities and other legitimate uses of the environment.

For the definition of "hazardous substances" the IED refers to the definition of hazardous substances and mixtures under Article 3 of Regulation (EC) No 1278/2008 on classification, labelling and packaging of substances and mixtures (CLP).

### 3.3.2 Information on substances in the permit application

As already described in chapter 3.2.2 the application must contain information about the substances and the mass flows on site (see Article 12 IED). For installations processing dangerous substances the operator has to carry out an assessment on the applicability of Seveso Directive. The criteria to define dangerous substances under Seveso III Directive are aligned with those under CLP regulation. For activities covered by Seveso Directive the application has to provide information on the substances present in the installations and on any reaction products likely to appear in case of a major accident. The establishments are subject to risk management measures with additional requirements depending on the quantity and the hazards of the substances. For establishments[9] with significant quantities of dangerous chemical substances the operator has to submit a safety report. REACH/CLP-data can be used for this purpose. But the operator has to provide additional information

[9] Directive on the control of major-accident hazards involving dangerous substances (96/82/EC) and (2012/18/EU) are related to establishments. An establishment is defined as the whole area under the control of an operator where dangerous substances are present in one or more installations, including common or related infrastructures or activities.

on physical and chemical behaviour of the dangerous substances under normal conditions of use and foreseeable accidental conditions. This may require specific risk assessments not covered by other pieces of legislation.

### 3.3.3 Emission limits in the permit

According to Article 14 IED par.1 the permit has to include all measures necessary for compliance with the general principles governing the obligations of the operator and the environmental quality standards. The measures shall include at least the emission limit values for polluting substances listed in Annex II to the IED, and for other polluting substances which are likely to be emitted from the installation concerned in significant quantities, having regard to their nature and their potential to transfer pollution from one medium to another.

The emission limit values shall be based on the best available techniques as laid down in the decisions on BAT conclusions. When the application proposes a best available technique that is not described in the BAT conclusions the authority shall ensure that the technique is determined by giving special consideration to the BAT criteria of Annex III to the IED.

Where an environmental qualitiy standard requires stricter conditions than those achievable by the use of best available techniques, additional measures shall be included in the permit.

The obligations of the IED are not limited to the substances listed in Annex II of the IED. As "pollution" is defined as "direct or indirect introduction as a result of human activity, of substances ... into air, water and land which may be harmful to human health or the quality of the environment, ..." the meaning of "other polluting substances" is worth considering. There is no special list of substances concerning soil and the operator has to prepare a baseline report on "the relevant hazardous substances" with regard to the possibility of soil and groundwater contamination (Article 22 par. 2 IED). The baseline report is a new instrument and there is a need for guidance on its content and for criteria concerning "the relevant hazardous substances" and "the relevant amounts". Additionally the IED only refers to relevant hazardous substances, not to hazardous waste which may contaminate soil and groundwater in the same way. Here seems to be a gap.

The project team agreed that the substances of very high concern (SVHC[10]) and hazardous substances according to Article 3 (18) IED used / produced during the industrial activity should be assessed with specific care in environmental permits.

The result of the consideration of these references to chemical substances in the IED is that a wide range of chemical substances is subject to permitting and inspection activities. For a certain number

[10] SVHC are those with the following properties: carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Regulation (EC) No 1272/2008 (CMR substances); persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII. Other substances of equivalent concern to the above can be identified as SVHC on a case-by-case basis

of substances BAT conclusions provide emission limit values. For “other polluting substances” than mentioned in Annex II the IED does not provide an extra procedure for the determination of ELVs.

It is not known which Member States and how many Member States have developed supporting guidance material for dealing with the item. Chapters 4.8 “Determination without Established Immission Values and in Special Cases” and 5.2.7 “Carcenogenic, Mutagenic or Reproduction Toxic Substances and Slowly Degradable, Highly accumulative and Highly Toxic Organic Substances” of the German “First General Administrative Regulation Pertaining to the Federal Immission control Act (Technical Instructions on Air Quality Control – TA Luft)” of 30 July 2002 (GMBl. P. 511) provide such guidance.

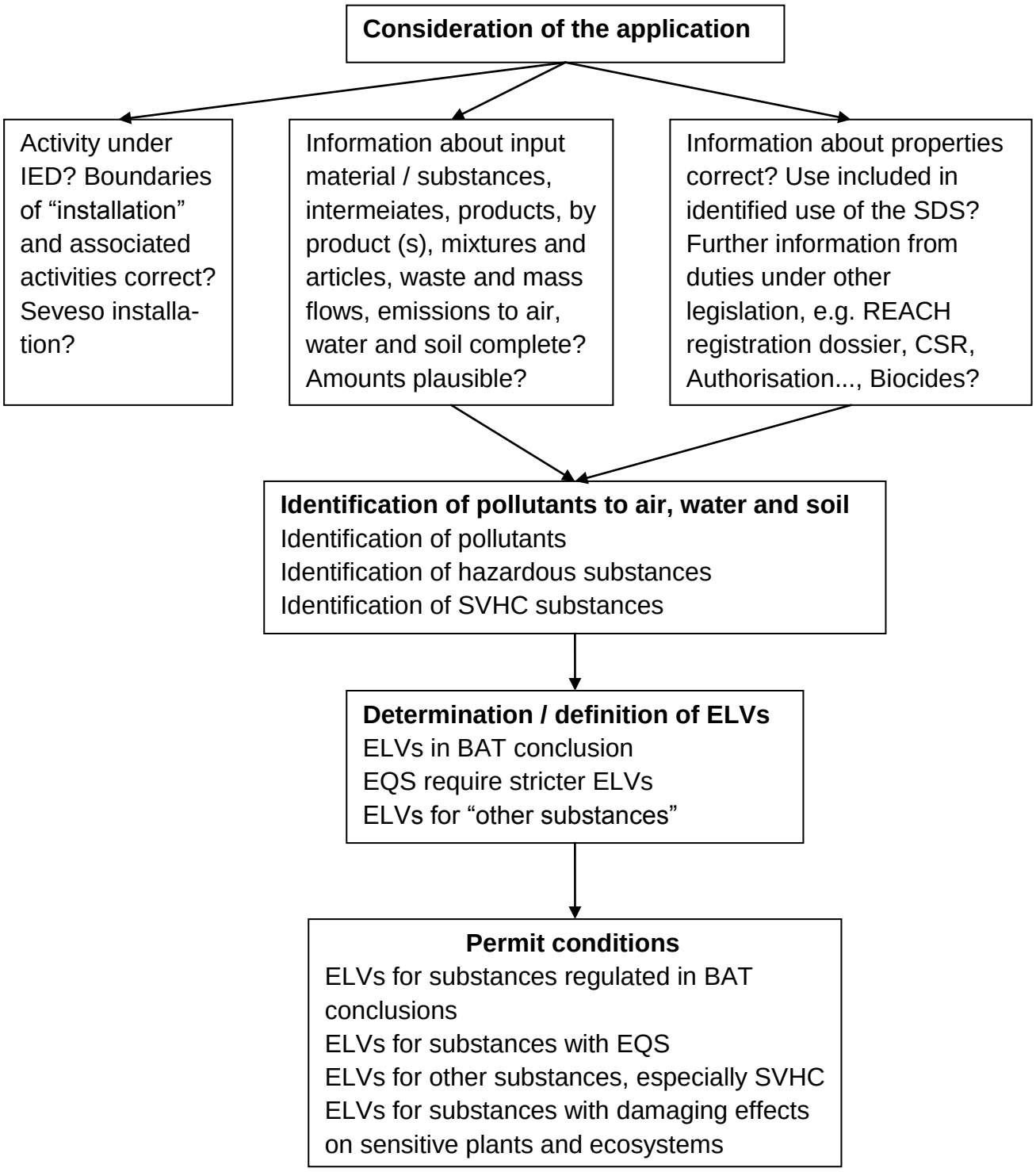
### 3.3.4 Substances in IED inspection tasks

As described in chapter 3.2.7 the competent authority shall carry out routine inspections of IED installations including site visits. Article 3 IED defines “environmental inspections” as all actions, including site visits, monitoring of emissions and checks of internal reports and follow-up documents, verification of self-monitoring, checking of the techniques used and adequacy of the environment management of the installation. The inspection covers the check and promotion of compliance of the installations with its permit conditions.

As chemical substances used, produced or occurring on site in significant amounts have direct impact on potential risks and emissions the check of the inventory of chemical substances should always be one item of environmental inspections. If there are new substances on site their properties and classification have to be checked and the authority has to determine whether a review of the permit is necessary. For substances newly identified as SVHC this might be the consequence. Possibly for the next considerable change of the installation (and consequently the new permit) a baseline report on soil and groundwater contamination might be necessary. Art. 22 IED requires the submission of the baseline report before starting operation of an installation or before a permit for an installation is updated.

For the check of the inventory of chemical substances and the assessment of the risk management measures on site, IED inspectors can refer to the safety data sheets. As there is still a need for improvement of the quality and consistency of information provided in SDS, inspectors generally use additional literature and other expertise to prepare inspections and do the follow-up work. It is not the task of IED inspectors to check the quality of the SDS systematically. If they find inconsistencies they should inform the competent REACH authority about their findings. Sometimes the inspectors face the challenge of high numbers of different substances on site. Cases with more than 250 are known. Close cooperation of competent REACH and IED authorities would be valuable and should be established.

**Figure 3: Steps in the permit procedure with relation to substances – tasks of the authority (application for a new installation)**



### 3.4 Conclusions

IED permitting and inspection tasks are closely related to chemical substances and their properties. Permit writers and inspectors should have access to good and reliable information. They may use the information generated by the REACH actors (manufacturer/down stream user/importer) for compliance with duties under REACH Regulation, e.g. the SDS. Doing this they have to be aware of the fact that for substances (and mixtures) that are not listed in the Annex VI to the CLP-Regulation the manufacturers carry out a self-classification.

# 4 Relevant REACH processes and REACH generated information

The REACH Regulation aims at a high level of the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals as well as the free circulation of substances on the internal market.

REACH establishes procedures for collecting and assessing information on the properties and hazards of substances and for defining the measures needed to manage the risks. Under REACH the authorities can impose further risk management requirements where that is needed, including restrictions or authorisation requirements. The authorisation process aims, in addition to a high level of risk control, at the progressive substitution of substances of very high concern where economically and technically viable alternatives are available.

We will first describe the REACH processes most relevant for this project and then have a look at the information generated by REACH and its availability to different stakeholders.

## 4. 1 REACH registration

Companies have the responsibility for collecting information on the properties and uses of substances that they manufacture or import at or above 1 tonne per year. They also have to make an assessment of the hazards and potential risks presented by the substance and identify, communicate and implement the appropriate risk management measures.

This information is communicated to ECHA through a registration dossier containing the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled. The information on the properties of the substances and required operational conditions and risk management measures is communicated also to downstream users in the supply chain through an (extended) safety data sheet (ext-SDS) with exposure scenarios in an annex.

Registration applies to substances on their own, in mixtures and in certain (limited) cases in articles. Substances that are already regulated by other legislations such as medicines, radioactive substances etc., are partially or completely exempted from REACH requirements.

Registration is based on the "one substance, one registration" principle, i.e. manufacturers and importers of the same substance have to submit their registration jointly. Unambiguous substance identification is a pre-requisite to most of the REACH processes. Actors in the supply chain must have sufficient information on the identity of their substance.

### 4.1.1 Phase-in substances

There is a special **transitional regime** for substances which, under certain conditions, were already manufactured or placed on the market before REACH's entry into force. Companies can benefit from the transitional regime if they pre-registered their substances by 1 December 2008.

Substances fulfilling at least one of the following criteria may be considered as **phase-in substances** in accordance with REACH (Article 3(20)):

* Substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)
* Substances that have been manufactured in the EU (including the countries that joined on 1 January 2007) but have not been placed on the EU market after 1 June 1992
* Substances that qualify as "no-longer polymers''.

### 4.1.2 Registration deadlines

Registration is an on-going process but for pre-registered substances the first two registration deadlines (30 November 2010 and 31 May 2013) are already over. Pre-registered substances manufactured or imported at 1000 tonnes or more per year, carcinogenic, mutagenic or toxic to reproduction substances above 1 tonne per year, and substances dangerous to aquatic organisms or the environment above 100 tonnes per year were to be registered by the first registration deadline while pre-registered substances manufactured or imported at 100 tonnes or more per year by the second deadline. The next and last registration deadline is set on **31 May 2018** and will cover pre-registered substances manufactured or imported at 1 tonne or more per year.

All substances that do not fulfil any of the criteria for phase-in substances are considered as **non-phase-in substances.** Potential manufacturers and importers of **non-phase-in substances** have to submit an inquiry to ECHA and subsequently register the substance in accordance with REACH **before** the substance is manufactured or imported.

### 4.1.3 Registration documents

The **registration dossier** is an information package prepared by registrants for a particular substance. For that purpose, registrants must use a software application that fixes the format of the dossier. This application is called IUCLID 5 and it implements the Harmonised Templates developed by the

OECD. It is compatible with other chemical legislations around the world. Once complete, the dossier is submitted electronically to ECHA via REACH IT.

The registration dossier consists of two main components:

- a **technical dossier** (the IUCLID file) is required for all substances subject to the registration obligations
- a **chemical safety report** (CSR) is required if the substance is manufactured or imported by a manufacturer or importer in quantities of 10 tonnes or more per year.

The chemical safety report documents the chemical safety assessment and is the key source from which the registrant provides information to all users of chemicals through the exposure scenarios. It also forms a basis for other REACH processes including substance evaluation, authorisation and restriction.

The chemical safety assessment is carried out to demonstrate that the risks from the exposure to a substance, during its manufacture and use, are controlled when specific **operational conditions** (OC) and **risk management measures** (RMM) are applied. These conditions of use of a substance constitute the exposure scenario, which is an essential component of the chemical safety report.

For more details on the registration process, please refer to the ECHA's website: http://echa.europa.eu/regulations/reach/registration

### 4.1.4 Relevance for the interactions between IED and REACH

In terms of relevance for the interactions between IED and REACH, registration is the process where most of the REACH information is generated. The registrants generate this information, submit it to ECHA and communicate part of it to downstream users along the supply chain via the safety data sheet and the exposure scenario. Registration data is available for the REACH competent authorities and relevant parts of it also for the national REACH enforcement authorities (see chapter 4.4.3 and 4.4.4). ECHA also publishes information from the registration dossiers on its website.

Registrants (chemical industry installation) can benefit from the full registration information and other industrial installations information communicated in the REACH supply-chains for their IED permit application and monitoring purposes. National permitting and enforcement authorities can use the information as well. Furthermore, this information can be used for more general IED purposes (e.g. BAT).

It is important to understand that not all registrations include the same data set because information requirement for registration is dependent on the tonnage band of the registration.

## 4.2 REACH Authorisation

**Substances of Very High Concern** (SVHCs) are substances that may have serious and often irreversible effects on human health and the environment. The authorisation process aims to ensure that the risks resulting from the use of SVHCs are properly controlled and that they are progressively

replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available.

Substances with the following hazard properties may be identified as SVHC:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Regulation (EC) No 1272/2008 (CMR substances)
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII)
- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMRs or PBT/vPvB substances

The authorisation process involves three steps:

1. Identification of SVHCs and their inclusion in the **Candidate List**[11] for authorisation.
   A Member State or ECHA at the request of the European Commission can propose a substance to be identified as a Substance of Very High Concern (SVHC). The intention to propose a substance to be identified as an SVHC is made public in the registry of intentions before the proposal is submitted so as to give advanced information to industry and other stakeholders.
   Consequences: The inclusion of a substance in the Candidate List creates legal obligations to companies manufacturing, importing or using such substances, whether on their own, in preparations or in articles. It also is a signal to stakeholders that industry using the substance should start considering substitution.
2. Recommendation for and inclusion in the **Authorisation List** (Annex XIV)
   ECHA prioritises the substances from the Candidate List to determine which ones should be included in the Authorisation List as a priority and therefore, subject to authorisation.
   Consequences: When on the Authorisation List, substances are subject to authorisation requirement. They cannot be placed on the market or used after a given date (the sunset date), unless an authorisation is granted for their specific use, or the use is exempted from authorisation. The signal given to stakeholders is clear, the use of the substance is no longer approved of unless under certain circumstances.
3. **Applications for authorisation** and subsequent decision making process.
   Manufacturers, importers or downstream users can apply for an authorisation for the placing on the market or the use of a substance on the Authorisation List.
   Authorisations will be granted by the European Commission if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. If not, an authorisation may still be granted when it is proven that the socio-economic benefits of using the substance outweigh the risks and there are no suitable alternative substances or technologies.

[11] The full name of the list is "Candidate List of Substances of Very High Concern for Authorisation"

For more details on the process, please refer to the ECHA's website:
http://echa.europa.eu/regulations/reach/authorisation

### 4.2.1 Relevance for the interactions between IED and REACH

The registry of intentions provides early information of substances which may become subject to authorisation. The lists included in the authorisation process (Candidate List, Authorisation List) as well as the authorisation decisions are probably the most relevant elements of the process for the interactions between IED and REACH. They give clear signals and regulate which substances are to be substituted as soon as technically and economically feasible alternatives are available or require an authorisation. This information can be used for IED purposes (e.g. BAT). Additionally the process generates information about possible alternatives that can also be interesting for IED purposes.

## 4.3 REACH Restrictions

Restrictions are a tool to protect human health and the environment from unacceptable risks posed by chemicals (safety net). Restrictions may limit or ban the manufacture, placing on the market or use of a substance. A restriction may apply to any substance on its own, in a mixture or in an article, including those that do not require registration.

A Member State or ECHA, upon request of the European Commission, can propose restrictions if they find that the risks need to be addressed on a Community wide basis. The final decision on restriction is taken by the Commission.

The intention to prepare a restriction proposal is made public in the registry of intentions before the proposal document itself is prepared so as to give advance warning to stakeholders.

Consequences: Once the substance restriction has been adopted by the European Commission, industry (manufacturers, importers, distributors, downstream users and retailers) must comply.

For more details on the process, please refer to the ECHA's website:
http://echa.europa.eu/regulations/reach/restriction

### 4.3.1 Relevance for the interactions between IED and REACH

The registry of intentions provides early information of substances which may be subject to restriction. Restriction list resulting from the restriction process is probably the most relevant elements of the process for the interactions between IED and REACH. Similarly to the Authorisation List, the Restriction List regulates which substances or uses are not allowed or allowed under specific conditions and this information can be used for IED purposes (e.g. BAT).

## 4.4 REACH generated information

One of the consequences of the registration process and downstream user obligations and other REACH processes, is that a greater quantity of substance-related information is generated, circulated and used.

The REACH recital 14 states "....Available information, including information generated by this Regulation, should eb used by the relevant actors in the application and implementation of appropriate Community legislation..." The use of the generated data is one of the main areas where interactions between the REACH and IED legal frameworks can be identified.

In order to identify and better understand these interactions it is first useful to describe what information is available and to whom it is available. The description is divided in the following sections:

1. Information generated by and therefore available to registrants (table 1)
2. Information provided to or generated by downstream users (tables 2 – 5)
3. Information available to REACH competent authorities
4. Information available to REACH enforcement authorities
5. Information available to all (table 6)

### 4.4.1 Information generated by and therefore available to registrants

**Table 1: Registration dossier**

| Information | Content | When is it required? | How/by who is it generated |
|---|---|---|---|
| Registration dossier | Technical dossier (the IUCLID file):<br>• Identity of the manufacturer/importer<br>• Identity of the substance<br>• Information on the manufacture and use(s) of the substance and if relevant use and exposure categories<br>• Classification and labelling of the substance<br>• Guidance on safe use<br>• Exposure information for substances in quantities of 1 to 10 tonnes<br>• Study summaries of the information on the intrinsic properties of the substance;<br>• Robust study summaries of the information on the intrinsic properties of the substance, if required;<br>• Proposals for further testing, if relevant | Upon registration of substance<br><br>Information requirements varies for different tonnage bands | Upon registration, generated by registrants, members of SIEF[12] |

[12] SIEF: Substance Information Exchange Forum

| | | | |
|---|---|---|---|
| | Chemical safety report:<br>• Summary of risk management measures<br>• Declarations that risk management measures are implemented and communicated<br>• Identity of the substance and physical and chemical properties<br>• Manufacture and uses<br>• Classification and labelling<br>• Environmental fate properties<br>• Human health hazard assessment<br>• Human health hazard assessment of physicochemical properties<br>• Environmental hazard assessment<br>• PBT and vPvB assessment<br><br>• Exposure assessment<br>• Risk characterisation | CSR, if registration tonnage above 10 t/a<br><br>Additionally for substances that<br>1. meet the criteria for classification as hazardous or<br>2. are PBT or vPvB | Upon registration, SIEF work |

As said before, it is important to understand that not all registrants have access to the same data set because the information requirements for registration are dependent on the tonnage band of the registration.

### 4.4.2 Information provided to or generated by downstream users

Downstream users are provided with information on substances via the two main tools for communication in the supply chain: the safety data sheet and the exposure scenario.

**Table 2 Safety Data Sheet**

| **Information provided** | **Content** (REACH Annex II) | **When is it required?** | **How is it supplied?** |
|---|---|---|---|
| Safety data sheet (SDS) | 1. Identification of the substance/mixture and of the company/undertaking<br>2. Hazards identification<br>3. Composition/information on ingredients<br>4. First-aid measures<br>5. Fire-fighting measures<br>6. Accidental release measures<br>7. Handling and storage<br>8. Exposure controls/personal protection<br>9. Physical and chemical properties<br>10. Stability and reactivity<br>11. Toxicological information<br>12. Ecological information<br>13. Disposal considerations<br>14. Transport information<br>15. Regulatory information<br>16. Other information | Substance or mixture that<br>1. meets the criteria for classification as hazardous or<br>2. is PBT or vPvB or<br>3. is included in the Candidate List for reasons other than 1. or 2.<br><br>Updates should be provided to all former recipients to whom the substance or mixture has been supplied within the preceding 12 months | Provided by the supplier of the substance |

**Table 3: Exposure Scenario**

| Information provided | Content | When is it required? | How is it supplied? |
|---|---|---|---|
| Exposure Scenarios – (ES) | Exposure scenario:<br>• Title section (the short title gives a short description of the scope of the ES The title includes a full list of all the uses covered by the ES. The tasks/activities covered by the ES can be listed as sub-headings called "Contributing Scenarios")<br>• Conditions of use affecting exposure (this section is the core of the ES as it includes the Operational Conditions (OCs) and Risk Management Measures (RMMs) for each contributing scenario. It is usually structured into sub-headings for each activity/contributing scenario)<br>• Exposure assessment (this section is relevant to end users if they are undertaking a more detailed review of the ES. It includes information and key values from the exposure estimates such as release factors)<br>• Additional advice (This section includes advice to the downstream users on how can they verify that their use is covered by the ES, if their conditions of use don't match exactly the ES) | Substance for which the manufacturer/importer has registered for over 10 tonnes per year and that is classified as hazardous or is PBT or vPvB.<br><br>Updates should be provided to all former recipients to whom the substance or mixture has been supplied within the preceding 12 months | Provided by the supplier of the substance |

Communication in the supply chain is sometimes required even in situations where an SDS is not required and in some other specific situations.

**Table 4: Other information**

| Information | Content | When is it required? | How is it supplied? |
|---|---|---|---|
| Communication in the supply chain when no SDS is required | • Registration number if available<br>If substance is subject to authorisation:<br>• Statement about authorisation obligation<br>• Details of any granted or denied authorisation<br><br>If substance is subject to restriction:<br>• Details of any restriction imposed<br>• Any other information available and relevant for the safe use of the substance or mixture. | Substance or mixture for which a SDS is not required (Article 31)<br><br>Updates should be provided to all former recipients to whom the substance or mixture has been supplied within the preceding 12 months | Provided by the supplier of the substance |
| Substance in article (SiA) information communicated | Sufficient information, available to the supplier to allow safe use of the article, as a minimum the name of the substance | When article contains a concentration above 0,1 % w/w of a substance identified as an SVHC | Provided by the supplier of the article |

In specific cases, downstream users may have to perform their own chemical safety assessment and compile a chemical safety report. The content of this CSR will not be submitted to ECHA but may be used in further communication in the supply chain.

**Table 5: Information generated by DU**

| Information | Content | When is it required? | How is it generated? |
|---|---|---|---|
| DU CSR<br>(if DU performs a DU CSA) | DU CSA:<br>• Exposure scenario for uses not covered<br>• If necessary, refinement of the hazard assessment by the supplier<br>• Risk characterisation for each new exposure scenario<br>The process is documented in a CSR | When own (or customer) use is not covered, or is advised against, in the supplier's exposure scenario and the DU decides to carry out their own CSA because other options (see Article 37.4) are not suitable or exemptions do not apply | DU own chemical safety assessment |

### 4.4.3 Information available to REACH competent authorities

The REACH competent authorities in all countries of the European Union and the EEA countries have access to the **full REACH database** via a REACH-IT portal for evaluation and regulatory risk management activities.

### 4.4.4 Information available to REACH enforcement authorities

In addition to the information publicly available, REACH and CLP enforcement authorities have access to **RIPE**, the **REACH Information Portal for Enforcement**.

"RIPE" is a web-based application intended to give the enforcement authorities in the EU Member States, Norway, Iceland and Liechtenstein access to the information submitted to the European Chemicals Agency (ECHA). The enforcement authorities need access to this information to be able to effectively enforce the REACH and CLP Regulations.

RIPE has been developed as a separate application from REACH-IT to accommodate the need for easy and secure access by numerous users from many locations in Europe. It was made available to the Member States on 27 June 2011.

Who uses RIPE?

RIPE is intended for REACH and CLP enforcement authorities in the EU Member States, Norway, Iceland and Liechtenstein. It may also be used by other Member State Authorities, if needed for the purposes of enforcing REACH and CLP Regulations. Based on Member State estimates, RIPE is expected to be used by around 2 500 inspectors in the European countries. RIPE will not be available to the general public and the access to it is strictly controlled by the Member States and ECHA.

What information is available in RIPE?

RIPE holds information on submissions (registration, notifications of substances in articles, C&L notifications etc.) to ECHA made by industry. It allows inspectors to easily check all the information, relevant to their Member State, needed for enforcement activities that are performed on a daily basis. This includes information such as whether a dossier was submitted, by whom and when. Furthermore, it contains much of the key data from the dossier such as tonnages, production and use sites, intended uses, information on classification and labelling, guidance on safe use and key information on physicochemical, toxicological and eco-toxicological properties indicated in the dossier.

In comparison to the information on registration dossiers which is published on the ECHA website and where the information is first filtered and aggregated (see chapter 4.4.5), RIPE shows detailed information from specific dossiers. RIPE also always shows who submitted a dossier regardless of confidentiality claims.

Why is it important?

RIPE is a tool that makes the work of enforcement authorities significantly easier, more effective and allows for much stronger control of REACH and CLP compliance. The inspectors will be able to directly and easily check if the companies have complied with their submission obligations. They will

also have access to data from the dossiers so that they can make qualitative assessments of important documents, such as the Safety Data Sheets, or assess whether claims about the use of intermediates under strictly controlled conditions are justified. Moreover, access to this data will make it easier for inspectors to plan and target their enforcement activities.

Who benefits?

The direct beneficiaries of RIPE are its users – the inspectors. However, stronger and more effective enforcement and control will also improve the competitiveness of the compliant chemical industry. Ultimately, by allowing better control of the REACH and CLP provisions, the tool will contribute to improving the protection of the environment and the health of European citizens.

### 4.4.5 Information available to all

The REACH Regulation stipulates that ECHA shall publish certain information it holds on substances free of charge over the internet. This dissemination of information is realised via the ECHA website, in the section **"Information on Chemicals"** http://echa.europa.eu/en/information-on-chemicals.

The information from registration dossiers is filtered and aggregated before publication. This means that first confidential and not meant for publication information is removed and then the separate dossiers of a joint submission are combined into a single document for publication. Other information such as notifications to the Classification and Labelling Inventory is also published. ECHA does not verify the information before dissemination.

**Table 6: Information published on ECHA's website from registration dossiers and C&L notifications**

| Information available | Content | When is it published? |
|---|---|---|
| Information on registered substances | Public part of registration dossiers (Article 119) such as:<br>• General Information<br>• Classification and Labelling<br>• Manufacture, Use & Exposure<br>• PBT assessment<br>• Physical and chemical properties<br>• Environmental fate and pathways<br>• Eco-toxicological Information<br>• Toxicological information<br>• Guidance on safe use | Included in the database as soon as the compulsory data submission steps are completed |
| Classification & Labelling Inventory | • Article 42 CLP and 119(1) REACH<br>• Harmonised classification<br>• Notified classification<br>• IUPAC name for some hazardous substances, EINECS name of substance, numerical identifiers, C&L of substance | Substances that are either in the EC inventory or have been notified as hazardous (according to Article 119(1) of REACH) by at least one notifier are added to the database |

In addition to registration and C&L Inventory data, ECHA also publishes information on the **REACH regulatory risk management processes** that substances undergo as well as the different public consultations accompanying these processes.

The **lists** resulting from these processes contain the most relevant information considering the context of this project. Some of the supporting documents or results from consultation procedure can contain interesting information (for example in terms of potential substitution options or technological alternative to a process) but this interest will be relevant to only a very few substances and/or uses.

The Candidate List

The list and supporting documents can be accessed from http://echa.europa.eu/candidate-list-table. At the time of writing the Candidate List contained 144 substances.

The Authorisation List

The list and supporting documents can be accessed from http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list. At the time of writing the Authorisation List contained 22 substances. One application for authorisation was received but no authorisation has been granted yet.

The Restriction List

The list and supporting documents can be accessed from http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions/list-of-restrictions-table. At the time of writing the Restriction List contained 105 substances or group of substances.

## 5. Objectives of REACH and IED – how do they complement each other?

The aim of the Directive 2010/75/EU on industrial emissions (**IED**) is, by taking an integrated approach, to prevent pollution and where that is not practicable to reduce emissions from installations and industrial activities into air, water and land in order to achieve a high level of protection of the environment as a whole. In order to achieve this aim the Directive sets the regulatory framework for permitting, monitoring and inspection.
All industrial activities listed in Annex I of the IED are - in one way or the other -associated with possible releases or emissions of chemical substances. A number of typical substances are listed Annex II of the IED. They can be emitted via different pathways to the environment. Therefore it takes an integrated approach with the aim of achieving overall reductions in the amounts and impacts of polluting emissions to air, water and land. Energy consumption is also addressed. The emission limit values are part of the IED permit. For their determination permit writers refer to the "best available techniques" (BAT) described in the BAT reference documents (BREFs) and the BAT conclusions. The BAT conclusions summarise inter alia the emission levels associated with the best available techniques. Thus the IED regulates the emissions of certain polluting substances from industrial installations and activities. For other/new substances not yet regulated in BAT conclusions permit writers have to make assessments and may - with reference to similar substances and taking into account their properties – determine emission limit values. For example, in the Netherlands the Ministry for Infrastructure and the Environment determines ELVs in such cases.

The aim of **the REACH Regulation** is to ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It includes the promotion of alternative methods for the assessment of hazards of substances, as well as the free circulation of substances on the EU market.
In principle, REACH applies to all chemical substances and mixtures; not only those used in industrial processes but also in our day-to-day lives, for example in cleaning products, paints as well as in articles containing substances such as clothes, furniture and electrical appliances. Therefore, the Regulation has an impact on most companies across the EU.
In detail it applies to the manufacture, placing on the market or use of substances on their own, in mixtures or in articles.

**Conclusion:** While REACH applies to all substances, the IED regulates the emissions of certain polluting substances – a subgroup of the substances regulated under REACH.
Under REACH companies have to collect and assess information on the substances as well as identify, communicate and implement operational conditions and risk management measures which are needed to control risks to the environment and human health.
IED permit writers and inspectors have to assess chemical substances processed in industrial installations and activities. On top of that they have to identify those substances that are unintentionally generated during the industrial process (e.g. dioxins, $SO_2$ etc.) and to assess their impacts. For Seveso III installations any reaction products likely to appear in case of a major accident have to be included. For their work permit writers need reliable and consistent information on chemicals. The substances they deal with are a subgroup of those regulated under REACH. That is

why the use of information elaborated for REACH purposes may be a relief for IED tasks. (Seveso III, recital 4 addresses the quality of the information submitted, especially in cases of self-classification of substances)

# 6 Interlinks of the REACH Regulation with IED

## 6.1 Introduction

Although REACH and the IED have different aims and different ways of action, it is recognised that there is a clear interlink in the use of data between the two legislations.
Operators of industrial installations manufacturing and or using chemical substances in their activities have obligations under both IED and REACH and are therefore key actors in making sure chemical substances are used safely and that their release to the environment is avoided or at least minimised.

### 6.2 Method

The analysis of interlinks in the use of data between the two pieces of legislations was conducted by

- taking into account the input of other relevant projects
- making an inventory of the downstream user (DU)/operator obligations under IED legislation
- identifying REACH generated information helping with compliance of identified obligations
- building “synergy” tables

The information interaction considered goes from REACH to the IED but a reciprocal interaction can be envisaged in most cases. Where specific “one-way” information interactions were identified they have been listed separately.

### 6.3 Scope

The legal obligations under consideration are related to the industrial installation and industrial activity taking place within the installation. The industrial actors addressed are downstream users (DU) as defined in the REACH Regulation.
Only the provisions applying to all activities covered by the IED (i.e. chapter II) have been considered in this analysis. Special provisions for specific installations (chapter III to VI) were not addressed.

## 6.4 Interlink analysis

The analysis presented here considers the way industrial operators under IED that also have a downstream user (not registrant) role under REACH can use the REACH information available to them in order to support compliance with their IED obligations.
It is important to note that the extent of REACH information available to industrial operators varies according to their role under REACH (see chapter 4.4). For instance, chemical industry installations (manufacturers of chemical substances) are usually registrants under REACH and have therefore access to full registration dossiers which contain a lot more information than a safety data sheet or an exposure scenario.

The analysis should not be seen as a "tool for compliance" for operators/downstream users but it is meant to provide hints on where they can find relevant information for compliance purposes and therefore promoting a more efficient use of information.
Although the work has been conducted from an industry perspective, the identified synergies can be looked at from the authorities' point of view and provide environmental inspectors with tools to verify compliance.

Table 1: REACH - IED synergies for operators/downstream users

| IED ref. | Obligation | Information source in REACH |
|---|---|---|
| Article 11 General obligations | Preventive measures against pollution | • Exposure Scenario (ES) to help/support:<br>✓ identify possible release route<br>✓ quantify release<br>✓ identify risk management measures (RMM) required to achieve adequate control of risks |
| | Application of BAT | • ES: to identify RMM required to achieve in adequate control of risks (cf. criteria 10 of Annex III of IED) |
| | Reducing waste and waste impact | • SDS: section 13 |
| | Accident prevention | • SDS: section 2 and 7 |
| | Accident mitigation | • SDS: sections 4, 5 and 6 |
| Article 12 Application for permit | Description of installation and activities | • ext-SDS[13]: identified uses of substance, OC and RMM to contribute to description of activities |
| | Description of substances | • SDS: classification and hazard information on substances<br>• ECHA dissemination site: search for extra/missing info, data source |
| | Baseline report | • SDS: to identify relevant hazardous substances<br>• ES: to identify possible release route (what substance for what environmental compartment) |
| | Foreseeable emissions and significant effects | • SDS: to identify relevant hazardous substances<br>• ES: to identify possible release route (what substance for what environmental compartment and what effect) |
| | Waste management plan | • ES: waste stage of the substance<br>• SDS: section 13 |
| | Monitoring plan of the emissions to the environment | • SDS: to identify relevant hazardous substances for monitoring<br>• ES: to identify possible release route (what substance for what environmental compartment) |
| | If SEVESO compliance also needed | • SDS: section 15 lists other legislations relevant to the substance<br>• ext-SDS: altogether to identify relevant hazardous substances for the preparation of the safety report |
| Article 13 BAT | Info exchange on installation performance and emissions | • ES: to support the identification of release routes relevant for the industrial sector |
| | BAT identification | • ES: to identify RMM resulting in adequate control of risks |
| | BAT - criteria 2 (use of less hazardous substance) | • Registry of intentions (early information of substances which may be subject to harmonised classification, authorisation or restriction) |

[13] ext-SDS: extended safety data sheet

| | | |
|---|---|---|
| | | • Candidate List and Authorisation List (substances which should be replaced as soon as technically and economically feasible alternatives are available)<br>• Analysis of alternatives section of the application for authorisation dossier: can provide information on potential alternative substance and or technology<br>• Information on alternatives from SVHC or restriction dossier: can provide information on potential alternative substance and or technology |
| Article 20<br>Change by operator | Substantial change | • ext-SDS: to help identify whether change of substance is relevant to qualify as "substantial change" |
| Article 22<br>Site closure | Potential contamination of soil and groundwater at the site | • ext-SDS: to help identify relevant hazardous substances and their possible release route for site evaluation planning upon closure of the site (what substance to what compartment and what fate) |
| Article 23<br>Inspection | Environmental risk appraisal for inspection planning | • ext-SDS: to help identify relevant hazardous substances and their possible release route for input in environmental risk assessments |

In addition to the above synergies, some specific information feed from IED to REACH have been identified.

Table 2: Specific IED to REACH feed

| **Information provided by IED at DU level** | **Potential use for REACH compliance** |
|---|---|
| Environmental permit application information such as<br>• inventory of chemicals needed and their use | • DU obligations<br>✓ checking own use against ext-SDS<br>✓ communication in the supply chain if relevant<br>✓ communication to ECHA if relevant |
| Monitoring data such as<br>• environmental monitoring<br>• emission monitoring<br>• waste production and management<br>• raw material - chemicals and energy consumption<br>• industrial activity | "Real life" data can be useful if performing own DU CSR[14] |
| Environmental risk assessment | DU CSR |
| Emerging techniques described in BREF (can provide information on potential alternatives in terms of techniques and/or substances to be used) | Support for substitution of hazardous substances with less hazardous or with alternative techniques. In particular substances included in the Candidate List and Annex XIV |
| Permit granted under IED | In the case of a DU applying for a REACH authorisation, according to REACH Art 62(5) the applicant can consider to use an IED permit granted to the installation as a justification for not considering the risks to human health and the environment arising from emissions of a substance from the installation |

[14] DU CSR: downstream user's chemical safety report

There is need for further work to clarify how to ensure that both risk management measures (RMMs) and organisational conditions (OCs) identified for a substance at registrants' level under REACH and the emission limit values set out in permits based on BREFs under the IED are complied with.

## 6.5 Conclusions

As illustrated by Tables 1 and 2, downstream users/operators can benefit from the information generated under REACH and IED for cross-legislation compliance in many different situations. Again it is important to stress that the role that operators have under REACH will determine the amount of REACH information that they will have access to.

The analysis presented above is only part of the interlinks that the REACH Regulation has with other legislations.
It is a benefit for all parties if the information generated under one legislative regime can be used by industrial operators/downstream users to facilitate compliance under a second regime. Additionally it is a powerful tool to achieve the aims of both REACH and the IED. This should be emphasised both to competent authorities and the industry.

Last but not least there is a need to raise awareness and provide all the actors having a role in cross-legislation issues with guidance and tools on how to deal with and use the synergies identified.

# 7 Best practice examples for supporting templates / databases / tools related to chemical substances for permitting and inspection work

## 7.1 Templates and guidance documents

Operators do not produce permit applications in isolation. In many Member States templates and guidance on national (or regional) level is available. For example in the Netherlands the operators use an internet tool for the submission of their application. This tool provides general indications what kind of information is needed.

## 7.2 Content of the permit application – data concerning chemical substances required

The answers of the project team members to the questionnaire concerning data on chemical substances required in the application (see Annex II) can be summarised as follows:

- Name of chemical substance
- Quantity
- Concentration
- Identifiers, CAS-no, EC-no
- Physical / chemical / toxic / ecotoxic properties, chemical fate,
- Characterisation / description of use (input material, solvent, product, intermediate, by-product ..)
- Details of use / details about the process
- In case of storage, use, production - hazard classification and safety measures (SDS)
- Risk assessment
- Assessment of alternatives – use of less hazardous substances
- Information about possible emissions or possible reactions of substances in case of an incident or accident in the production process
- Kind and amount of emissions

As part of the application safety data sheets have to be submitted. Authorities provide supporting templates or electronic tools for the preparation of permit application documents. An example from northern Germany is shown in the next chapter.

### 7.2.1 Lower Saxony, Schleswig-Holstein, Mecklenburg-West Pomerania, Brandenburg (DE)

In the north of Germany an electronic tool for writing the permit applications has been developed by the Länder Niedersachsen, Schleswig-Holstein, Mecklenburg-Vorpommern and Brandenburg. Currently the first applicants are testing it. Concerning substances applicants have to fill in the template 3.5 “Information about substances including waste water, waste material and the mass flows” (see Figure 4). On top of that Template 16.1 “REACH duties” covers the annual amount of production, information about registration, substance of Annex XIV or XVII REACH, candidate list, substance of nanoscale and identified use. Template 16.2 “Ozone layer depleting substances and substances with climate impact” complement the information (see Figure 5).

**Figure 4: Information concerning substances in the permit application (DE)**

**Template 3.5**

**3.5 Information about substances including waste water and waste material their flows**

| Name of chemical substance / mixture / article | total amount (t) | Composition, content (weight %) | | | | Calorific value (MJ/kg) | EWC code | input material reactant raw material |
|---|---|---|---|---|---|---|---|---|
| | | Name of component | CAS-no | content (weight %) | | | | |
| | | | | Min. | Max. | | | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

| Name of chemical substance / mixture / article | Inter-mediate | Product / article | bypro-duct | waste | Waste water | Relevant concer-ning emissions to air | Regulated under Seveso | Hazardous substance | REACH relevant | climate impact / ozone layer depleting | hazar-dous to waters | ordinance on industrial safety and health | comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |

**Figure 5: Information concerning REACH duties in permit applications (DE)**

**Template 16.1**

**16.1 REACH duties**

| SU no | Name of chemical substance / mixture / article | Role under REACH | Total annual amount (t/y) | composition | | | | | | | | | | | | | comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Name of component | Number | | | Substance with registration | | Substance regulated? | | | content (weight %) | | nano-scaled | Identified use acc. to SDS / registration | |
| | | | | | CAS | EG | Index | Yes? | Reg-no | under annex | | Candidate list | min | max | | | |
| | | | | | | | | | | XIV | XVII | | | | | | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 |
| | | | | | | | | ☐ | | ☐ | ☐ | ☐ | | | ☐ | ☐ | |

SU = subunit of installation on site

**Template 16.2**

**16.2 Ozone layer depleting and substances with climate impact**

| SU | kind of installation | name of filling substance / refrigerant | amount of refrigerant / filling substance per unit? | number of installations | leakage detection system in place? | interval of leak tests |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| | | | | | ☐ | |

## 7. 3 Procedures and tools for the assessment of substances in permit procedures – some examples

Several countries have developed guidance and tools for the assessment of substances in permit procedures. Others have started to produce it. The examples from Region Marche (IT), Norway and the Netherlands shall demonstrate this.

### 7.3.1 Region Marche (IT)

#### a) Introduction to the assessment of the overall performance of the installation

The main principles of the IED Directive in the context of permitting is prevention of pollution by using optimized production procedures with low-waste technology, use of less hazardous substances etc. rather than use of end-of-pipe techniques for minimisation. Installations must comply with requirements of BREF conclusions. Therefore operators have to use Best Available Techniques (BAT). The IED provides criteria for determining BAT. In the region of Marche (IT) the permit procedure is divided into the steps investigation, evaluation and defining the permit conditions. The permit writer first carries out an investigation on the basis of the criteria defined in the IED. For the assessment standardized parameters for eight macro-fields have been defined. They are divided into two subgroups: a) raw materials, production cycles, waste and energy and b) pollution to air and water, noise emissions and transport impact. Each of them found in the application is then compared with a set of characteristics and a weighted index attributed. For example raw materials are examined on the basis of their toxicity. 5 subgroups have been defined:

I. Inert or not naturally reactive raw materials
II. Low hazardous raw materials (on the basis of national standards)
III. Medium hazardous raw materials
IV. Heavy metals or medium explosive substances or substances which have to be handled with safety devices
V. Carcinogenic substances and/or teratogenic and/or mutagenic ones, PCDD (polychlorinated-dibenzo-dioxins), PCDF (polychlorinated-dibenzo-furans), PAH (polycyclic aromatic hydrocarbons) or high explosive substances, or substances containing toxic-noxious waste or phytotoxic substances

The evaluation of raw materials is difficult when many substances (belonging to different classes) have to be considered together (as it usually happens): in such situation, it is necessary to attribute a unique index to calculate a weighted average of the dangerousness of all the used substances. In the same way the average calculation for riskiness is carried out for all the other parameters e.g. for pollution to air and water. For the assessment of the overall performance of the installation a database is used. The REACH enforcement authority is not involved in the procedure.

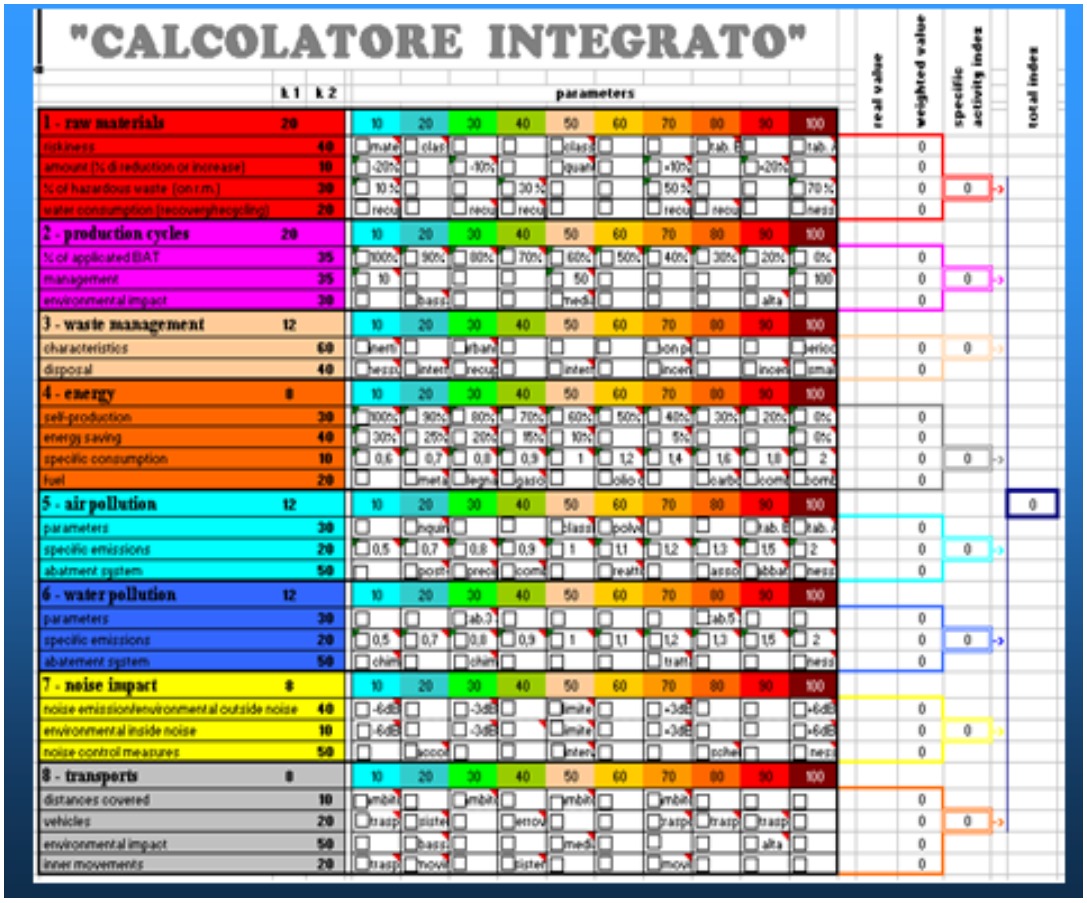



**Figure 6: Assessment of the overall performance of the installation, Region Marche (IT)**

### a) Assessment of Safety Data Sheets (SDS)

For tasks deriving from the REACH Regulation and purposes of the IED Region Marche (IT) uses an electronic database for the assessment of Safety Data Sheets provided by the manufacturer / downstream user / importer or the operator of an industrial installation. For a brief explanation of the use see Annex IV.

**Table 1: Example for systematic assessment Safety Data Sheets (IT)**

| Field | Description | | Evaluation |
|---|---|---|---|
| SUPPLIER | **supplier of the SDS (if it does not correspond with the manufacturer, the manufacturer is indicated in the database in parenthesis below the name of the supplier** | | |
| FROM OUTSIDE EU? | **yes / no** | | |
| PRODUCT NAME (SUBSTANCE/MIXTURE) | **name of the product** | | |
| USE | **use of the product (for example lubrificant)** | | |
| DEPARTMENT | **department of use of the product (for example foundry)** | | |
| | **if the product is a substance:** | | |

| | | | |
|---|---|---|---|
| SUBSTANCE/COMPONENT OF THE MIXTURE | **name of the substance; if the product is a mixture: name of all the components (substances) present in the SDS** | | |
| CAS NUMBER | **CAS number of the substance** | | |
| EC NUMBER | **EC number of the substance** | | |
| REGISTRATI ON NUMBER | **REACH registration number of the substance** | | |
| CONC. % | **concentration of the substance** | | |
| SUBSTANCE CLASSIFICATION | **classification of the substance (for example corrosive) according to new CLP Regulation n. 1272/2008 and old Directive 67/548*** | | |
| PHRASES H/R | **Hazard statements (H) and risk phrase (R)* according to new CLP Regulation n. 1272/2008 and old Directive 67/548*** | ***old Directive 67/548 until 01/06/2015** | |
| subject to AUTHORIZATION? | **yes / no (see REACH Annex XIV)** | | |
| SVHC? | **yes / no (see latest version of Candidate List published by ECHA)** | | |
| possible SVHC? | **yes / no (see Registry of Intentions)** | | |
| MIXTURE or substance CLASSIFICATION | **if the product is a substance: the classification could be the same of the B12 cell; if the product is a mixture: classification of the mixture according to Directive 1999/45* and new CLP Regulation n. 1272/2008**** | ***Directive 1999/545 mandatory until 01/06/2015 **Regulation n. 1272/2008 optional until 01/06/2015 and mandatory after 01/06/2015 (01/06/2017)** | |
| PHRASES R/H | **if the product is a substance: phrases R/H could be the same of the B13 cell; if the product is a mixture: Risk phrase (R)* and hazard statements (H)** of the mixture according to Directive 1999/45* and new CLP Regulation n. 1272/2008**** | ***Directive 1999/545 mandatory until 01/06/2015 **Regulation n. 1272/2008 optional until 01/06/2015 and mandatory after 01/06/2015 (01/06/2017)** | |
| PHRASES S/P | **Precautionary statements P (new Regulation) or safety advice S (old directive)** | | |
| LABEL HAZARD PICTOGRAM | **if the product is a substance: hazard pictogram of the label according to new CLP Regulation n. 1272/2008 if the product is a mixture: hazard pictogram of the label according to Directive 1999/45* or new CLP Regulation n. 1272/2008** | ***Directive 1999/545 is possible only until 01/06/2015 (01/06/2017)** | |
| SDS NUMBER | **number of the SDS in the list of SDS owned by the company (SDS attached and numbered)** | | |
| SDS DATE | **date of the latest revision of the SDS** | | |
| SDS COMPLIANT? | **yes / no** | | |
| NOTES | **reason for the negative judgment of the SDS (see technical report)** | | |
| ACTIONS TO BE TAKEN | **actions to be taken to ensure compliance with REACH, for example "request an updated SDS"** | | |

### 7.3.2 Norway

In Norway the Norwegian Environment Agency grants permits according to the legislation implementing IED and is at the same time the competent authority for REACH. This agency is also responsible for the enforcement of the permits and the environmental part of REACH. The responsibility for permitting and for inspection is divided into two separate departments. Other agencies are involved in the enforcement of other parts of REACH, e.g. the Norwegian Labour Inspection Authority.
For the time being the authorities use a national priority list of substances where some of the substances are covered by REACH. The normal procedure is to check whether the application for an IED permit covers emissions of these substances. Then it is considered if the emissions are environmentally significant and need to be regulated. In such cases Emission Limit Values (ELV) for the substances are set according to BAT.

An internal study is underway in the agency investigating common issues between IED, REACH and CLP. It is considered to establishing a work tool for checking the status of the substances according to REACH, CLP and other existing chemical regulations.

By now a preliminary flow sheet (see Figure 7) has been produced, which identifies consequences related to different chemicals regulations. The flow-sheet will be further developed.

A database has been published on the authorities' web-site http://www.miljodirectorated.no/kjemikaliesok/. The users can fill in the name of the substance in question and the CAS- and EC-numbers. The database gives an answer to which chemical regulations the substance is covered by; the national priority list, REACH candidate list, REACH authorisation list, REACH restricted substance list, CLP and possible other regulations like for biocides.

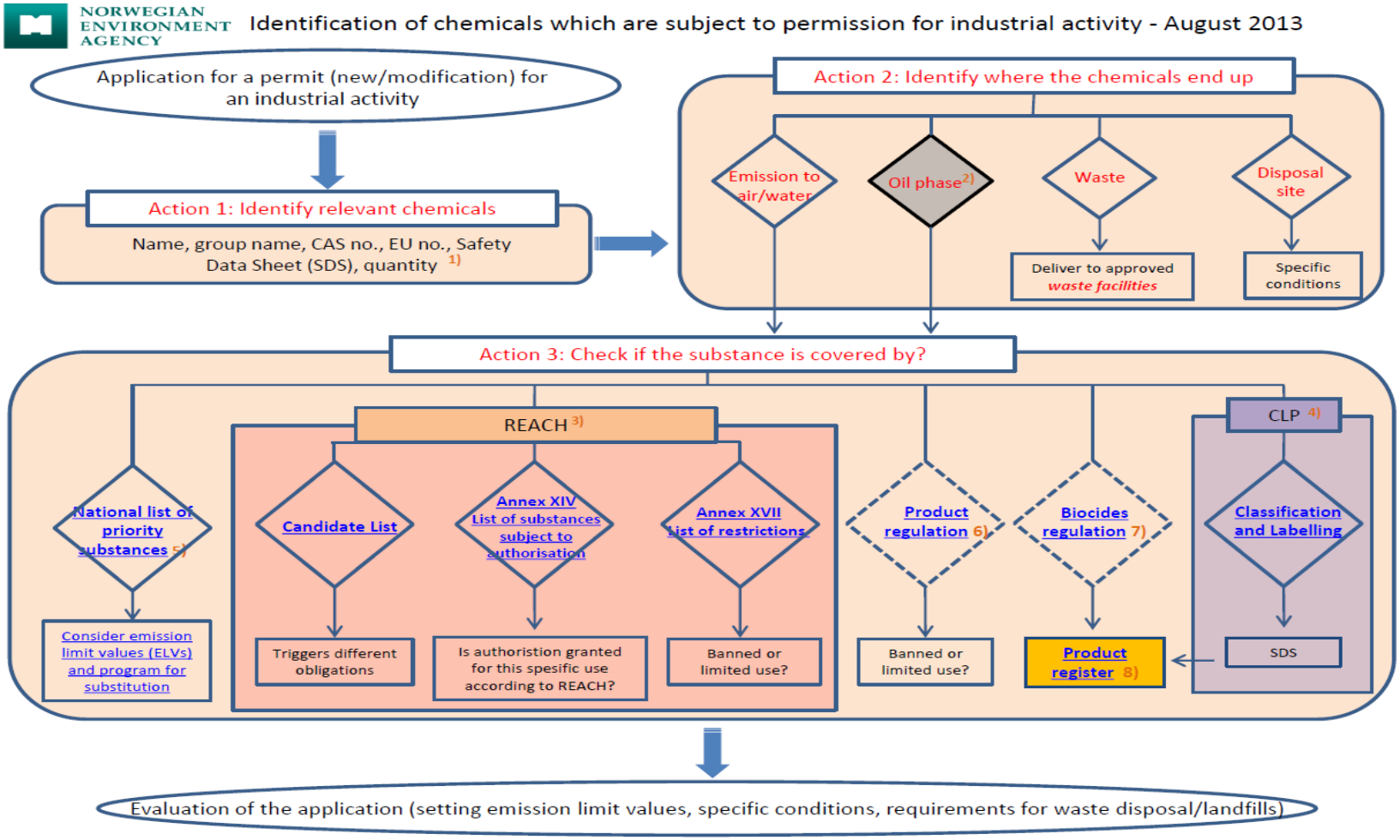



**Figure 7: Preliminary flow sheet for the identification of chemicals which are subject to permission for industrial activities**
(notes, glossary and comment see next page)

## Notes, glossary and comment to the flow-sheet (Figure 7)

**Notes:**

1) «small and large» is described in a guidance relating to emission of substances to air or water (a special report in Norwegian)
2) Oil phase means the part that is sent from offshore to land-based processing and it may contain residual chemicals. Normally no requirements are given for this fraction.
3) Substances manufactured or imported in quantities more than 1 tonn shall be registered in REACH.
4) For inspection activities

**Glossary:**

**5) National list of priority substances**: the substances of highest concern for the health and the environment in Norway. About 30 substances /groups of substances are prioritized and listed on a national list of priority substances. The goal is to stop or reduce significantly the emissions of these substances within 2020.

**6) Product regulation**: Norwegian legislation regulating chemical substances, mixtures and products – the regulation implements several EU regulations including e.g. fluorinated greenhouse gases, substances that deplete the ozone layer, persistent organic substances (POPs) and EE-products

**7) Biocides regulation**: implements EU biocidal products directive (98/8/EC) – Revised by Regulation (EU) nr. 528/2012

**8) Product register**: a governmental central register of chemical substances and mixtures produced in or imported to Norway.

**Comment:**

The flow sheet is only meant for substances used in the production at the production site and not for substances used internally such as in the canteen or in cleaning activities

**NB. Different questions and issues such as intermediates and exposure scenarios have been discussed during development of this flow sheet and some of these will be discussed further. The flow sheet will be revised accordingly.**

### 7.3.3 Flow sheet for dealing with substances of very high concern (SVHC) (NL)

The Netherlands is developing supporting documents on how to deal with substances of very high concern as defined in REACH Article 57 in IED permitting. It is still under development. A flow sheet (see Figure 8) has been developed for the assessment.

Concerning the steps the following general description can be made:

Step 1: the approach is for substances of high risk only. Other substances have less obligations to meet a maximum acceptable quality standard, except for those set on European level, such as $NO_x$ and dust.

High risk substances are <u>at least</u> the following:

- Mentioned in annex VI of regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and

1999/45/EC, and amending Regulation (EC) No 1907/2006 and considered carcinogenic, mutagenic or toxic for the reproduction;
- The inventarisation of classified substances as mentioned in Article 43 sub 1 of regulation (EC) No 1272/2008 and considered carcinogenic, mutagenic or toxic for the reproduction, category 1a or 1 b;
- The candidate list as mentioned in article 59 of REACH;
- Annex XIV of REACH;
- Annex A, B or C of the Stockholm Treaty of persistent organic pollutants;
- Annex I, II, III or IV of Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC;
- List of substances of possible concern OSPAR
- Annex X to the Water Frame work Directive
- Substances with endocrine-disrupting properties as mentioned in article 5 sub 3 of regulation (EU) 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market and use of biocidal products;
- Annex II, section 3.6.5 of regulation (EC) 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Step 2: the expected emission in g/hour has to be determined.

Step 3: Each substance is classified, being 3 subgroups for substances of very high concern. If the amount of emissions expected is less than the threshold value of the group, the emission is considered not significant.

| subgroup | Threshold value | ELV |
|---|---|---|
| Substances with an extreme risk | 20 mg TEQ/year[15] | 0.1 ng TEQ/$Nm^3$ |
| Minimizing obligation 1 | 0.15 g/hour | 0.05 mg/$Nm^3$ |
| Minimizing obligation 2 | 2.5 g/hour | 1 mg/$Nm^3$ |

Step 4: BAT should be applied in all those cases where the emission is considered relevant

Step 5: the immission should be determined, based on actual measurements or using a standardized model. (Immissions are air pollutants affecting humans, animals, plants, soil, water, the atmosphere, cultural assets and any other property.)

[15] TEQ : toxicity equivalent, the toxic equivalency factor (TEF) expresses the toxicity of dioxins, furans and PCBs in terms of the most toxic form of dioxin, 2,3,7,8-TCDD

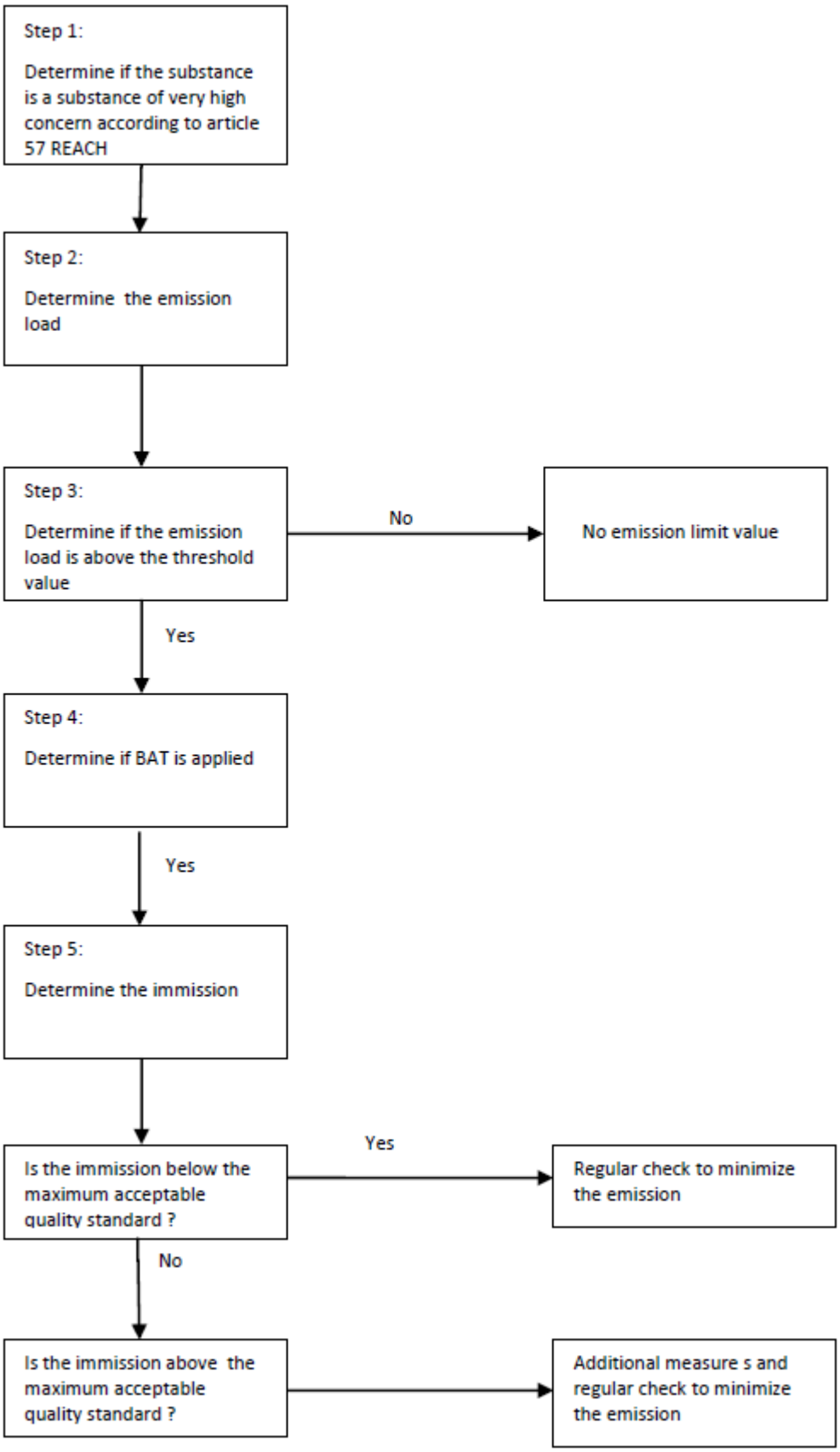



**Figure 8: Flow sheet for dealing with substances of high risk (NL) in the permit procedure**

If the immission is below the maximum acceptable quality standard, there is still an obligation to check regularly, but at least every 5 years, if the maximum acceptable quality standard is not breached.

If the maximum acceptable quality standard is breached, additional measures have to be taken to reduce the emissions.

The system for other emissions is similar, but has less obligations to comply to a maximum EQS (only for a limited amount of European set standards, which are part of national law).

### 7.3.4 Guidance on the baseline report concerning the state of soil and groundwater (DE)

Where the activity involves the use, production or release of relevant hazardous substances and having regard to the possibility of soil and groundwater contamination at the site of the installation the operator shall prepare and submit a baseline report before starting operation of the installation or before a permit for the installation is updated for the first time after 7 January 2013. An interdisciplinary project team has developed a guidance document[16] including criteria for determining the "relevant hazardous substances".

## 7.4 Example of existing permit conditions concerning chemical substances

In Norway the permit authority integrates a general standard condition into permits regulating industrial activities according to the Norwegian Environmental Act:

*6. Chemicals*
*Chemicals mean chemical substances and mixtures used in industrial activities, both as raw materials in processes and as auxiliary chemicals, such as antifouling agents, detergents, hydraulic fluids and fire extinguishant.*
*For chemicals used in such a way that it could endanger pollution the enterprise shall prove that it has made an assessment of the chemical's health and environmental characteristics on the basis of testing or other relevant documentation.*
*The enterprises shall establish a documented system for substitution of chemicals. It will be a continuous assessment of the risk of harmful effects on health and the environment caused by the chemicals used, and whether alternatives exist. Adverse effects associated with the production, use and final disposal of the products, shall be considered. Where better options are available, the enterprise shall use these as far as this can be done without unreasonable costs or inconvenience. Substances alone, in mixtures and / or products should not be produced, placed on the market or used unless they comply with the REACH regulations and other rules applicable to chemicals.*

[16] The guidance document for the baseline report concerning the state of soil and groundwater (Vollzugshilfe zum Ausgangszustandsbericht für Boden und Grundwasser) is published on the homepage of the German Bund/Länder-Arbeitsgemeinschaft Bodenschutz: https://www.labo-deutschland.de/documents/LABO_Arbeitshilfe_AZB_Stand_2013-08-07_finalisiert.pdf ,

# 8 Main findings / conclusions, recommendations and proposals for future work

According to the Terms of Reference for the IMPEL project "Linking the Directive on Industrial Emissions (IED) and the REACH Regulation" the project team was asked to explore a set of core questions and to identify whether there is a need for follow-up projects on the item. The questions were:

1. How do obligations from the REACH Regulation interact with IED statutory duties concerning permitting and inspection?

2. Which information required for compliance with the REACH Regulation can be used for IED permitting and inspection activities?

3. Which information required for IED permitting and inspection can be used for purposes of the REACH Regulation?

4. Does an overlap between IED and REACH inspection tasks exist and how can it be used best for all parties (meaning that the same or similar tasks have to be fulfilled under both).

In this context several other questions occurred: Do IED and REACH inspectors ask the same questions and check the same things under the different pieces of legislation? Do they do double work? How can this be avoided and how can the collected information be used best by all parties?

Before looking for answers to the questions the project team carried out an evaluation of the existing literature on the item. The result was that there are only a few studies. None of them covers a complete assessment of the interaction between the REACH Regulation and the IED. For a common understanding of the relevant issues a summary of relevant procedures under the IED (with focus on chemical substances and pollutants) and the relevant REACH processes (with focus on the REACH generated information and its availability) was made. This should provide an easy and simple access for representatives of competent REACH and IED authorities to the two pieces of legislation.

## 8.1 Main findings concerning the core questions:

IED permitting and inspection tasks are closely related to properties of chemical substances. Therefore permit writers and inspectors must have reliable and good information. Access to information generated by the operator for compliance with the requirements of the REACH Regulation would be an advantage. Competent IED permitting and inspection authorities have access to the "Information on Chemicals" available to all on the ECHA website as well as to the filtered and aggregated information from registration dossiers and the notifications to the Classification and Labelling Inventory. Users must be aware of the fact that ECHA does not verify the information before dissemination.

The REACH competent authorities in all countries of the European Union and the EEA countries have access to the full REACH database via a REACH-IT portal for evaluation and regulatory risk management activities. In addition to the information publicly available, REACH and CLP enforcement authorities have access to RIPE, the REACH Information Portal for Enforcement. "RIPE" is a web-based application intended to give the enforcement authorities access to the information submitted

to the European Chemicals Agency (ECHA). The enforcement authorities need access to this information to be able to effectively enforce the REACH and CLP Regulations.

A close cooperation of REACH and IED competent authorities is highly recommended. If one of them identifies noncompliance concerning the manufactured or used substances the other authority should be informed.

The systematic analysis of the interlinks and synergies of the REACH Regulation with the IED showed how downstream users / operators can benefit from the information generated under REACH and IED for cross-legislation compliance. Table 1 and 2 of chapter 6.4 provide an overview of REACH and IED sysergies and the identified feed from IED to REACH (answers to questions 1, 2 and 3).

Inspections: Both, REACH and IED inspectors control the chemical substances manufactured / used on site. As chemical substances used, produced or occurring on site have direct impact on potential risks and emissions, the check of the inventory of chemical substances (kind, amount, produced/imported/used etc. on site) should always be one item of environmental inspections. For the check and the assessment of the risk management measures on site, IED inspectors can refer to the safety data sheets and the exposure scenarios, if available. If they find inconsistencies, they should inform the competent REACH authority about their findings. It is the task of REACH inspectors to check the quality of the SDS systematically. From the legal background the authorities do not do the same work, but they both work with the same information from the operator / manufacturer / downstream user. Close cooperation of competent REACH and IED authorities should be established.

## 8.2 Recommendations

During the work on the item of “Linking the Directive on Industrial Emissions (IED) and the REACH Regulation” some recommendations concerning the daily work of REACH and IED authorities were identified.

### 8.2.1 General points for the reduction of workload

#### a) Installation level

- The operator should have an inventory / database of all chemical substances, their classification, properties and information on legal requirements concerning his duties on site. This includes all substances occurring in the whole production cycle (raw material, intermediates, products, by-products, solvents, waste ...).
- The operator has to have all SDS on hazardous substances on site.
- For Seveso installations:
    - the assessment of major-accident hazards for the dangerous substance
    - major-accident prevention policy,
    - safety reports for upper-tier establishments (with higher amounts of dangerous substances).
- The operator should make sure that his supplier has fullfilled his duties under REACH.
- The operator should inform the authority about other substances on site, their classification (official / self-classification) and necessary measures.

**b) Authority level**

- The IED authority should provide guidance for permit writers on how to deal with substances during the procedure. This means the development of guidance with templates, check lists, flow-sheets and lists of priority substances. Guidance on assessment procedures for defining ELVs should complement it. This seems to be necessary as long as it is not part of BREF documents.
- The authority should oblige the operator to notify any relevant changes of chemical substances on site.
- The IED authority should provide information for inspectors on how to deal with the chemical substances during inspections.
- Authorities should have well qualified staff to deal with the item of chemical substances in permitting and inspection.

### 8.2.2 Further Recommendations:

1. The inquiry of data on REACH requirements concerning the individual IED activity should be integrated into the Guidance document on data collection for the development of BREF documents and consequently.
2. A chapter on relevant chemical substances and REACH information should become part of the BREF documents. This would take away burdens from authorities.
3. One criterion for the determination of the Best Available Technique is the use of less hazardous substances. For that purpose, some steps in the Authorisation process of REACH (see chapter 3.2.5) may provide useful information to be exchanged in the process under Article 13 IED.
4. The extension of the project to waste legislation was recommended (reason: end of waste legislation → shift between waste and not waste is not covered by REACH and IED)
5. If permit authorities provide check lists, templates or electronic tools to the operator for writing the permit application, requirements concerning REACH obligations should be part of them.
6. Raising awareness of the issue and make it easier for permit writers and inspectors (especially by the measures mentioned under 1 and 2, by carrying out workshops and integrating information into guidance material for permit applications and putting information on COM homepage under IED permitting and on national pages)
7. Exchange of experience in workshops and via internet and learn from best practice examples.

### 8.2.3 Cooperation of authorities

The competent authority for IED permitting and inspection should have in place at least one person with good knowledge in both fields IED and REACH / CLP. This would ensure that the requirements concerning chemical substances are investigated and appropriate obligations become part of the permits. In any case the competent authority for the enforcement of the IED should seek the cooperation with and the input of the REACH enforcement authority.

In many Member states REACH enforcement authorities and IED permitting and inspection authorities are separate bodies. Where this is the case both authorities should seek contact to each other.

### 8.2.4 Joint inspections

As described in chapter 3.2.7 the competent authority shall carry out routine inspections of IED installations including site visits. The inspection covers inter alia the check and promotion of compliance of installations with their permit conditions. For IED inspections it would be beneficial for IED and REACH authorities to carry out joint inspections at least for the items related to chemical substances.

## 8.3 Unsolved problems / Open questions:

Some questions concerning IED permitting and inspections came up and could not be answered:

- Is the permit writer obliged to check whether the operator has fulfilled (existing installation – change or update of a permit) or will fulfil (new installation – first permit) all the relevant REACH requirements before issuing the permit? It is not clear whether there is a legal duty to do so. But it is strongly recommended to do so, because it might produce tensions if for example the IED authority grants a permit to an installation using or producing a restricted substance. One reason why the permit authority needs an entire overview of the inventory of substances on site and why it must be informed about the risks is that in case of accidents and serious violation / breaches of ELVs, the prosecutor will also check the work of the competent authority. The responsible regulators may come into the situation that in they are partly blamed for the damages.

- Conditions of authorised or restricted uses under REACH will normally be relevant for the permit writer when formulating the permit conditions. Which influence do they have on permit conditions in IED permits?

- Is the inspector obliged to check regularly whether the operator still is in line with the REACH Regulation (e.g. during IED inspections)?

- Do obligations of downstream users to follow received exposure scenarios have an impact on permits?

- Which relevance do PNEC (and DNEL) values have for issuing permits under IED? Their role should be clarified.

- How do authorities deal with end-of-waste criteria?

- Why does Article 22 IED concerning the baseline report on soil and groundwater only refer to “relevant hazardous substances” and not to hazardous wastes which can contaminate soil and groundwater in the same way. (Here seems to be a gap.)

- BREF documents and BAT conclusions are revised every 8 years. Permit writers and inspectors must be able to react in between on innovation and new developments in industry. They cannot wait on the revisions and are forced to define permit conditions if relevant. The uncertainties with nanomaterials show how difficult and complex the item is. The IED does not provide a procedure for the determination of ELVs based on Art. 14 (1). However some countries have developed one. Chapters 4.8 and 5.2.7 of the German Technical Instructions on Air Quality Control (TA Luft) describe the German approach. The Netherlands have an obligation in the law stating to define ELVs in such cases.

## 8.4 Proposals for future IMPEL work on "Linking the Directive on Industrial Emissions (IED) and the REACH Regulation"

The project was carried out in a small team. The project team recommends carrying out a follow-up project on the item because at the moment only the views and input of 6 IMPEL Member States could be collected. Many questions remain open. The follow-up project could go more into details and find answers. The project should start with a questionnaire to collect more information from the IMPEL member states to explore which kind of instruments for dealing with chemical substances in permitting and inspection exist and to collect best practice examples. The instruments and best practice examples should be discussed in a workshop.

If possible templates and check lists useful for dealing with the item in permitting and inspection should be developed afterwards. The project team recommends keeping it simple and general because experts from both sides - REACH and IED - must understand it.

# 9. Dissemination of results

In session 5 on the IMPEL conference in Malta a presentation on the interactions between IED and REACH was made.

The final report will be published on the IMPEL website as well as on the Forum website.

The results will be used as input for the follow-up project described in chapter 8.4.

An article about the project will be published in the Eurobrief, a newsletter of the Enterprise Europe Network Hamburg and Schleswig-Holstein.

The final report will be sent to the IMPEL contact officer at the Commission.

## 10 Literature

[1] Report from the Commission to the European Parliament, the Council, the European Economic and social Committee and the Committee of the Regions in accordance with Article 117 (4) of REACH and Article 46 (2) of CLP, and a review of certain elements of REACH in line with Articles 75 (2), 138 (3) and 138 (6) of REACH, COM(2013) 49 final

and

Commission Staff Working Document (SWD(2013) 25 final), General Report on REACH accompanying the document: Report from the Commission to the European Parliament, the Council, the European Economic and social Committee and the Committee of the Regions in accordance with Article 117 (4) of REACH and Article 46 (2) of CLP, and a review of certain elements of REACH in line with Articles 75 (2), 138 (3) and 138 (6) of REACH, COM(2013) 49 final

[2] Prof. Dr. Martin Führ, Dr. Silke Kleihauer "Nutzen der REACH-Informationen für umweltrechtliche Vollzugsaufgaben (mit Schwerpunkt im Anlagenrecht)"

[3] Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit und Umweltbundesamt "REACH in der Praxis – Unterstützung für umweltrechtliche Vollzugsbehörden"

[4] Final report of the IMPEL project "Linking the Water Framework Directive and IPPC Directive", www.impel.eu

[5] Royal HaskoningDHV "Zeer Zorgwekkend Stoffen in Wabo-vergunningen – Een analyse van recente Wm- en omgevingsvergunningen" (March 2013) for Ministerie van Infrastruktur en Milieu, the Netherlands

## 11. List of Abbreviations

| | |
|---|---|
| CAD | Chemical Agents Directive |
| CMD | Carcinogens and Mutagens Directive |
| CSR | Chemical Safety Report |
| DNEL | derived no effect level |
| DU CSR | downstream user's chemical safety report |
| ELV | emission limit value |
| E-PRTR | European Pollutant Release and Transfer Register |
| EQS | environmental quality standard |
| ES | exposure scenario |
| ext-SDS | extended safety data sheet |
| IED | Directive on Industrial Emissions |
| NeR | Dutch guidelines on emissions to air |
| OC | operational conditions |
| PEC | predicted environmental concentration |
| PNEC | predicted no effect concentration |
| REACH | REACH Regulation |
| RMM | risk management measures |
| SDS | safety data sheet |
| SVHC | substances of very high concern: carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Regulation (EC) No 1272/2008 (CMR substances); persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII |
| SWD | Supporting Working Document |
| TEQ | toxicity equivalent |
| ToR | Terms of Reference |
| WFD | Water Framework Directive |

**Annex I:** Terms of Reference

# TERMS OF REFERENCE FOR IMPEL PROJECT

2013-04-18

**1. Project details**

| **Name of project** |
|---|
| Linking the Directive on Industrial Emissions (IED) and REACH Regulation |

**2. Scope**

| | |
|---|---|
| **2.1. Background** | In the Directive on Industrial Emissions (IED) there are many references to hazardous substances and the risks deriving from them. Consequently it is worthwhile to explore<br>b) whether the requirements/obligations under REACH Regulation can be useful for permitting and inspection work<br>c) what changes in REACH formats for registration, applications for authorisation would be possible in order to be even more compatible and provide added-value for IED permitting and inspection,<br>d) which consequences (including positive effects) REACH requirements have for permitting and inspection activities and<br>e) how to improve the synergies and complementarities between these two pieces of legislation.<br><br>To a) Requirements/obligations under REACH Regulation and their relevance for permitting and inspection:<br><br>Article 12 par. 2 IED clearly determines that where other information is supplied or produced in response to other legislation and it fulfils the requirements concerning the permit application documents, that information may be included in, or attached to the application.<br><br>Example: REACH Chemical Safety Report for Registration and/or Authorisation - relevant parts may be<br><br>- used by the operator for writing the application documents,<br>- relevant for the permit writer for the assessment of the application,<br>- relevant for the permit writer for writing the permit conditions.<br>Conditions of Authorised or restricted uses under REACH may also be relevant for the permit writer when formulating the permit conditions.<br><br>If permit authorities provide check lists, templates or electronic tools to the operator for writing the permit application requirements concerning REACH obligations should be part of them.<br><br>Article 14 par 3 BAT conclusions shall be the reference for writing the |

| | |
|---|---|
| | permit conditions. One criterion for the determination of the Best Available Technique is the use of less hazardous substances. For that purpose, the Analysis of Alternatives and Substitution Plan as provided in an Application for Authorisation under REACH, as well as the conditions and length for the granted authorisation, may be useful information to be exchanged in the process under IED Article 13.<br><br>Article 22 par. 2: Where an activity involves the use, production or release of relevant hazardous substances .... the operator shall submit to the competent authority a baseline report before starting operation. For this purpose he can also use information that is supplied or produced in response to other legislation.<br><br>Article 23 Environmental inspections<br><br>The authority has to develop an inspection plan that covers the general items for all installations. On that basis authorities have to develop an inspection programme for routine environmental inspections. For defining the site visit frequency the IED requires to use a risk based approach. The period between two site visits shall not exceed 1 year for installations posing the highest risk and 3 years for installations posing the lowest risk. For the risk assessment the characteristic data of the chemicals processed or produced in the installation are very important.<br><br>To c) Several questions arise concerning permitting and inspections:<br><br>- Is the permit writer obliged to check whether the operator has fulfilled (existing installation – change or update of a permit) or will fulfil (new installation – first permit) all the relevant REACH requirements before issuing the permit?<br><br>- Is the inspector obliged to check regularly whether the operator still is in line with the REACH Regulation (e.g. during IED inspections)?<br>- Do obligations of downstream users to follow received exposure scenarios have an impact on permits?<br>- Is there an added-value in doing it? |
| **2.2. Directive / Regulation / Decision** | Directive 2010/75/EU on industrial emissions (integrated prevention and control (IED) and Regulation (EC) 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) |
| **2.3. Article and description** | Article 12 par 2 IED: use of other information that is supplied o produced in response to other legislation<br>Article 14 par 3 IED: identification of less hazardous substances for the determination of BAT<br>Article 22 par 2 IED: use, production or release of hazardous substances → baseline report on soil and water to be submitted<br>Article 23 IED: environmental inspections<br>Article 5 REACH: no data no market<br>Article 7 REACH: Registration and notification of substances in articles<br>Articles 10 and 12 REACH (and relevant annexes): information requirements (incl. Chemical Safety Report – Annex I) |

| | |
|---|---|
| | Article 31 REACH: Requirements for Safety Data Sheets (information in the supply chain)<br>Article 37 REACH: downstream user – duty to identify, apply and recommend risk reduction measures<br>REACH Titles VII (+ Annex XIV) and VIII (+ Annex XVII) on Authorisation and Restriction<br>Article 119 REACH: information available electronically (ECHA website and databases) |
| **2.4 Link to the 6th EAP** | The Sixth Community Environment Action Programme calls for the encouragement of more effective implementation and enforcement of Community legislation on the environment, among other things through the promotion of improved standards of permitting, inspection, monitoring and enforcement by Member States and through improved exchange of information on best practice on implementation. Article III, Para. 4 of Recommendation 2001/331/EC providing for Minimum Criteria for Environmental Inspections in the Member States pursues the same objectives. |
| **2.5. Link to MAWP** | Promote more coherent implementation of environmental law,<br>Assisting members to implement new legislation and improve existing implementation,<br>Work with external partners to identify and deliver outcomes. |
| **2.6. Objective (s)** | To explore the following: How do obligations from REACH Regulation interfere with IED statutory duties concerning permitting and inspection?<br>Which information required for compliance with REACH Regulation can be used for IED permitting and inspection activities?<br>Which information required for IED permitting and inspection can be used for purposes of REACH Regulation?<br>Does an overlap between IED and REACH inspection tasks exist and how can it be used best for all parties? |

**3. Structure of the project**

| | |
|---|---|
| **3.1. Activities** | Collection and discussion of core questions concerning the link between Industrial Emissions Directive (IED) and REACH Regulation in a small group (at least answers on items mentioned under 2.6).<br><br>If results show that there are relevant requirements deriving from REACH Regulation that influence IED permitting and inspection tasks and vice versa a ToR for a follow-up project with further steps shall be developed. |
| **3.2. Product(s)** | **Final report** |
| **3.3. Planning (Milestones)** | January 2013: identification of project team members<br>February 2013: collection and dissemination of core items for discussion<br>April 2013: first project team meeting<br>June 2013: second project team meeting<br>September 2013: draft final report for Cluster i<br>November 2013: submission of the draft final report to GA |

**4. Organisation**

| | |
|---|---|
| **4.1. Lead** | Gisela Holzgraefe |
| **4.2. Project team** | Representatives of 5 IMPEL member states dealing with both items<br>1 representative from Forum REACH<br>1 representative from IPPC Bureau |
| **4.3. Participants** | Experts from enforcement |

**5. Quality review**

| |
|---|
| The quality of the project will be reviewed by the project participants and appraised by the Cluster i "Improving implementation of EU environmental Law (Permitting, inspection, enforcement and smarter regulation). It will then be submitted to the IMPEL General Assembly for appraisal and adoption. |

**6. Communications**

| | |
|---|---|
| **6.1. Dissemination of results** | The final report will be made available on the IMPEL website. It will be sent to the national IMPEL coordinators.<br>The report will also be sent to Forum REACH and other target groups (via IMPEL secretariat at the European level, via national coordinators at the national level). The results of the project will be reported in professional and technical journals. On top of that they will be used for discussions on national level, for inspector trainings and presented at conferences. |
| **6.2. Main target groups** | European Commission<br>Competent authorities for enforcement of REACH Regulation and / or IED throughout Europe,<br>Forum REACH, European Chemical Agency ECHA, |
| 6.3. **Planned follow up** | If results show that there are relevant requirements deriving from REACH Regulation that influence permitting and inspection tasks a follow-up project with further steps shall be developed. |

**7. Project costs/Resources required**

| | Estimated costs | Budget requested from IMPEL (€) | Total payments committed by lead authority (€) | Payments by lead authority directly to the project (€) | Payments by lead authority via the IMPEL budget (€) |
|---|---|---|---|---|---|
| • **Project meetings in total** | | | | | |
| *Meeting 1*: project team meeting | | | | | |
| No of Participants: 6* | | | | | |
| Travel: | 1.800 € | | | | |
| Accommodation: | 450 € | | | | |
| Catering: | 300 € | | | | |
| Meeting venue: | | | | | |
| Sub-Total: | 2.550 € | 2.550 € | | | |
| *Meeting 2: project team meeting* | | | | | |
| No of Participants: 6* | | | | | |
| Travel: | 1.800 € | | | | |
| Accommodation: | 450 € | | | | |
| Catering: | 300 € | | | | |
| Meeting venue: | | | | | |
| Sub-Total: | 2.550 € | 2.550 € | | | |
| *Meeting 3:* | | | | | |
| No of participants: | | | | | |
| Travel: | | | | | |
| Accommodation: | | | | | |
| Catering: | | | | | |
| Meeting venue: | | | | | |
| Sub-Total: | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| • **Consultant:** | | | | | |
| • **Translation:** | | | | | |
| • **Dissemination:** | | | | | |
| • **Attendance for Project Manager at Cluster meetings:** | | | | | |
| • **Other (specify):** | | | | | |
| **TOTAL** | **5.100 €** | **5.100 €** | | | |
| **Human Resources** | Meeting preparation: 6<br>Meeting participation: 20 days in 2013 plus 8 days from other organisations<br>Project management incl. draft final report: 20 days | | | | |

* 5 participants from IMPEL member states, 1 from Forum REACH (IPPC Bureau pays for participant)

## Annex II: Evaluation of the questionnaire used to collect input for the project team meeting

1. **Which data concerning chemical substances are required in the IED permit application in your country?**

The answers showed that applicants generally have to submit a set of data on chemical substances: Name of chemical substance, quantity, concentration in case of a mixture, identifiers such as CAS- and/or EC-no, physical /chemical / toxic / ecotoxic properties and chemical fate; characterisation / description of use (input material, solvent, product .. ); details of use / details about the process; risk assessment (possible releases or reactions of substances in case of incidents or accidents), assessment of alternatives – use of less hazardous substances, ....

2. **Do you have the same rules throughout the country or is it only for your authority or your region?**

Generally there are the same rules throughout the member state. This seems to be obvious because the IED and the REACH Regulation have to be enforced throughout the country.

3. **Do you have a template which the operator has to fill in? Does guidance material exist?**

In the participating countries guidance material and templates for applicants is in place (BG, CY, DE, IT, NO). In Norway and northern Germany the templates cover information about REACH obligations (registration number, etc.). The Netherlands use an online tool for permit procedures. They provide an internet site for the submission of permit applications with indications what kind of information is needed. A mixture of templates, expertise documents and assessment tools is used for the examination / assessmant of the application documents.

4. **Which data / information required for compliance with the REACH Regulation is used in your country for IED permitting and inspection activities?**

All participating countries use data and information from Safety Data Sheets (SDS). Some templates (DE, NO) for permit applications cover information concerning REACH obligations (annual amount of production, information about pre-registration and registration, substances of annex XIV, annex XVII, substances on candidate list). The Netherlands are in the process of making the approach as described in section 7.3.3 part of general binding rules. As part of this operation, all substances meeting the criteria as given in step 1 (Figure 8) will be classified as SVHC.

5. **Which data / information required for IED permitting can be used for purposes of the REACH Regulation?**

The answers showed that double use of information is possible. Data on quantities of substances planned to be produced or already produced are used to check whether pre-registration and registration was carried out or when the operator has to register. The presence of substance may indicate that REACH obligations are not fulfilled. IED permitting can provide information on use and exposure to substances that can be used for REACH tasks.

6. **Does the competent authority for the enforcement of the REACH Regulation have access to the documents for the permit application in your country? Is it involved in the permit procedure and is it obliged to provide expertise?**

Environmental authorities, REACH enforcement bodies and health and labour inspectorates cooperate closely and are involved in the IED permitting procedure (BG, Cy, DE). In Italy the national enforcement authority (NEA) for the REACH Regulation can have access to documents – technical and administrative documentation is on the internet. The REACH NEA is not involved in the procedure (IT). In the Netherlands there is a collaboration between the authorities.

7. **Do you think it is possible to develop a checklist / a manual for carrying out inspections and to cover a great deal of relevant requirements concerning the REACH Regulation and IED concerning chemical substances?**

The respondents think that it would be useful but not easey to do. It is difficult and complex material that both sides – the authorities competent for REACH-tasks and those competent for IED-tasks must understand in the same way. Therefore the checklists and the manual for inspection tasks should be kept simple and general. Another proposal was that both could be part of BREF documents.

8. **Do you know any studies that were carried out in this field?**

German Study: “Benefit of REACH information for environmental enforcement tasks”, The Netherlands: “How to deal with substances of very high concern in IED permitting”.

Report from the Commission to the European Parliament, the Council, the European Economic and social Committee and the Committee of the Regions in accordance with Article 117 (4) of REACH and Article 46 (2) of CLP, and a review of certain elements of REACH in line with Articles 75 (2), 138 (3) and 138 (6) of REACH,COM(2013) 49 final and

Commission Staff Working Document (SWD(2013) 25 final), General Report on REACH accompanying the document: Report from the Commission to the European Parliament, the Council, the European Economic and social Committee and the Committee of the Regions in accordance with Article 117 (4) of REACH and Article 46 (2) of CLP, and a review of certain elements of REACH in line with Articles 75 (2), 138 (3) and 138 (6) of

REACH, COM(2013) 49 final

Final report of the IMPEL project “Linking the Water Framework Directive and IPPC Directive”, www.impel.eu

[5] Royal HaskoningDHV “Zeer Zorgwekkend Stoffen in Wabo-vergunningen – Een analyse van recente Wm- en omgevingsvergunningen” (March 2013) for Ministerie van Infrastruktur en Milieu, the Netherlands

## Annex III: ANNEX II to the IED

### List of polluting substances

**AIR**

1. Sulphur dioxide and other sulphur compounds
2. Oxides of nitrogen and other nitrogen compounds
3. Carbon monoxide
4. Volatile organic compounds
5. Metals and their compounds
6. Dust including fine particular matter
7. Asbestos (suspended particulates, fibres)
8. Chlorine and its compounds
9. Fluorine and its compounds
10. Arsenic and its compounds
11. Cyanides
12. Substances and mixtures which have been proved to possess carcinogenic or mutagenic properties which may affect reproduction via air
13. Polychlorinated dioxines and polychlorinated dibenzofurans

**WATER**

1. Organohalogen compounds and substances which may form such compounds in the aquatic environment
2. Organophosphorous compounds
3. Organotin compounds
4. Substances and mixtures which have been proved to possess carcinogenic or mutagenic properties which may affect reproduction in or via the aquatic environment
5. Persistent hydrocarbons and persistent and bioaccummable organic toxic substances
6. Cyanides
7. Metals and their compounds
8. Arsenic and its compounds
9. Biocides and plant protection products
10. Materials in suspension
11. Substances which contribute to eutrophication in particular nitrates and phosphates
12. Substances which have an unfavourable influence on the oxygen balance (and can be measured using parameters such as BOD, COD etc.)
13. Substances listed in Annex X to Directive 2000/60/EC

**Annex IV:** Explanation of the database for the assessment of Safety Data Sheets (Region Marche, IT)

Safety Data Sheets were organized into an electronic database (Appendix 1) in which for each chemical used are available all the information relevant for the purposes of REACH / IED Directive.

In detail, the document lists all the substances or mixtures used, its supplier and its origin (if imported from outside the European Union), the use and the department of use and their hazard classification combined with the corresponding hazard pictogram (orange background with square shape according to Directives 67/548 and 1999/45 and white with red border and rhombus-shape according to new CLP Regulation n. 1272/2008) and the corresponding R-phrases / H and S / P (risk phrases R and safety advice S relating to old directives and hazard statements H and precautionary statements P related to new Regulation).

In the case in which the supplier of the product does not correspond with the manufacturer, it is indicated in the database in parenthesis below the name of the supplier.

For each substance, purchased as single substance or contained in a mixture, is reported CAS number, EC number and the number of registration under REACH (if already available, considering that the last deadline for registration of certain substances is May 31, 2018, and considering that the possession of a registration number is not cause for timely updating of a SDS, although this update is recommended); for each substance it is also reported if it is a substance subject to authorization or a substance of very high concern (SVHC - Substances of Very High Concern - contained in the candidate List, periodically updated by ECHA) or a candidate to enter in the list of SVHC ("Candidate list").

For substances which are ingredients of a mixture, their presence as a percentage in the preparation is indicated in the database as well as and their classification.

Finally, a judgment is expressed regarding the completeness and the correctness of the Safety Data Sheet owned by the company for each substance or mixture purchased, including the possible reason for a negative judgment

In detali it is indicated that the SDS:

- does not comply with Regulation 1907/2006 if it still has the composition at paragraph two and the identification of hazards at paragraph three, or
- does not comply with Regulation 453/2010 if it is not divided into subsections introduced by that regulation and / or missing information specifically required in that legislation, or
- is characterized by the old classification of substances if CLP classification is not present, or
- does not possess numbered subsections if only the number of the subsections are missing but all the information are present in the correct format; in this case any request for an updated SDS is of lower priority than the other cases.

Products containing any hazardous substance

The last definition is also used for Safety Data Sheets that do not comply with the Regulation 453/2010 and that are related to non-hazardous product containing any hazardous substances; even in this case (and for all non-hazardous mixtures containing any hazardous substance) a request for an updated SDS is of lower priority.

In some cases, the Safety Data Sheets of non-hazardous products containing any hazardous substances still show the ingredients at paragraph two and the identification of hazards at paragraph three, so the comment to the Safety Data Sheet states "does not comply with Regulation 1907/2006 and old references to classification and labeling "and, once again, the request for updated SDS has a lower priority.

However, it is always to consider that the hazardous characteristics may vary over the years, as a result of improved knowledge. If necessary actions are to be taken to ensure compliance with REACH Regulation are briefly indicated.

The information present in the database are summarized in a technical report.

In this report there are also all the other considerations necessary to ensure the company's compliance to the Regulation, for example actions to be taken when receiving a registration number and an exposure scenario, compliance to Annex XVII “Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles” and so on.

This information and the technical report are the base of assessment of the permit, the identification of pollution to air, water and soil, the determination /definition of ELV s and Permit conditions.