LIFE / FIT FOR REACH

Snapshot: Enforcement of and support action on REACH at Member State level /

Summary of discussions from the Seminar on enforcement practices with regard to the REACH Regulation held within the LIFE Fit for REACH project (LIFE14 ENV/LV/000174)

March 7, 2017

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1 Introduction

In the beginning of February 2017, app. 60 persons from 10 Member States met in Tallinn, Estonia, to exchange experience and discuss several issues in relation to the enforcement of specific provisions of the EU chemicals regulation REACH. The seminar was organised by the Baltic Environment Forum in the context of the ongoing project LIFE Fit for REACH (LIFE14 ENV/LV/000174) that aims to facilitate the implementation of substitution activities and improvements of general chemicals management in companies in the Baltic States.

The workshop participants represented national enforcement authorities, helpdesks, competent authorities and ministries. In addition, industry and NGO representatives, consultants and ECHA staff took part in the seminar.

The current report starts with an introduction on the enforcement challenges (Section 2) and on the intended information flow under REACH (Section 3). The following sections reflect the enforcement practices, as identified from the seminar discussions organised according to the areas 'registration' (Section 4) 'communication' (Section 5) and 'restrictions' (Section 6). The last section of this report summarises the overall state of play as observed at the seminar and draws conclusions with regard to open issues and further work.

2 Implications of REACH for enforcement

The chemicals legislation REACH implements a risk-based system for chemicals control. All risk management measures are based on conclusions from risk/safety assessments. This is true e.g. for the recommendations on safe use in form of exposure scenarios (ES), which companies derive from their chemical safety assessments (CSA) as well as for restriction proposals, which authorities need to derive, among others, based on a demonstration of unacceptable risks. The risk approach of REACH requires combining information on a substance's hazards and its uses, drawing conclusions on the level of risk and the appropriateness of responses identified.

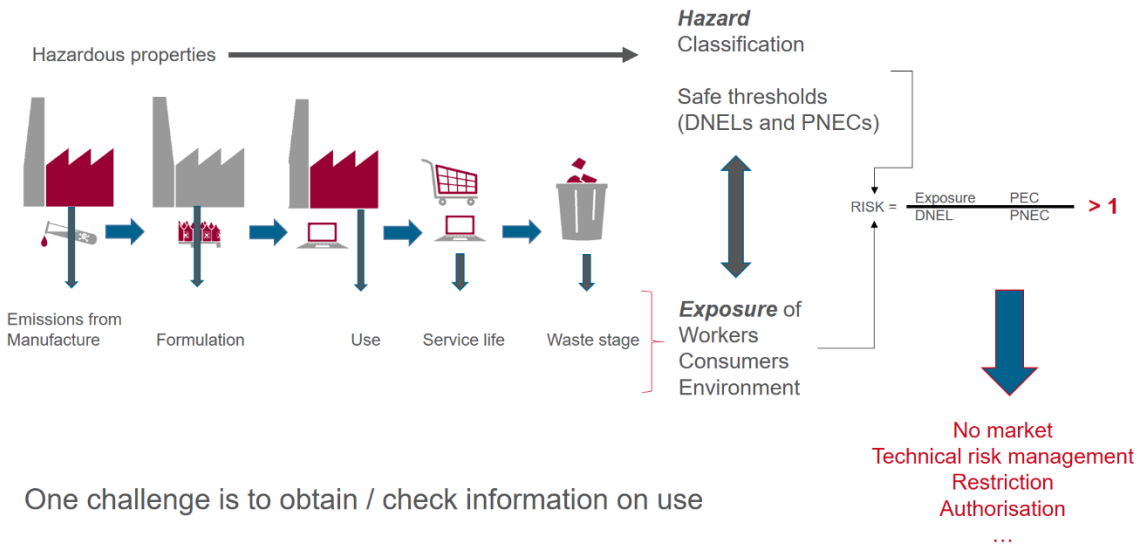


Figure 1: Under REACH, chemicals control bases on risk/safety assessment by industry or authorities

The application of a risk based approach for granting market access is new to the industry, while (most) Member States implemented the approach before REACH in the 'existing substances programme'[1]. The shift of responsibility for demonstrating the safe use of chemicals is new to all actors. Due to the novelty of the approach, in particular communication routines, (standardised) instruments and related competences and capacities are (still) missing. Furthermore, it takes time to build trust in the system and for all actors to take on their role.

Although REACH has been in force for almost 10 years (and had a long discussion and legislation development phase before its adoption), all actors are still learning how to implement it. It appears that not everyone has understood all implications of the system yet, in particular with regard to the changes in the burden of proof and the shared responsibility for the safe handling of chemicals in the supply chain.

Enforcement has to strike a balance between

- taking into account the fact that REACH is a 'learning system' and that awareness and understanding in industry still needs to be supported and
- providing the necessary incentives and creating sufficient pressure so that the actual risk reduction REACH should lead starts to realize.

Meanwhile, the actual control relates to documents and activities by industry that are also new to the inspectors. Inspectors struggle with decreasing resources, the need to build up capacity to cover the new topics and control tasks as well as to coordinate and cooperate with colleagues from workplace control or environmental permitting.

Consequently, there are several questions that inspection strategies need to answer in order to be able to enforce efficiently and effectively the implementation of REACH. These are, among others:

- Which requirements can inspectors enforce with full vigour, because the industry can be expected to have to implement it and which requirements should be treated as still 'under development'?
- What are appropriate sanctions that motivate industry actors to improve their work rather than to pay fines or go out of business?
- How can the market forces be utilized to increase pressure on the chemicals supply chains to implement REACH as intended?
- How can those actors be identified and reached, which hinder the functioning of the entire system?

ECHA ensure quality and control the content of registration dossiers and chemical safety assessments. In the context of substance evaluations, also Member State Competent Authorities are involved in checking the quality of registration information and may, if necessary request additional information to improve it. Among the most prominent national enforcement tasks under REACH are to check whether:

- substances placed on the market are registered or pre-registered (or are exempted from registration);
- compliant safety datasheets (SDSs), including ESs, are provided with hazardous

[1] Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances

chemicals placed on the market;
- conditions of safe use communicated with SDSs are implemented by the downstream users and forwarded along the supply chains;
- any applicable marketing and use restrictions of substances in mixtures and/or articles are implemented;
- information on SVHC in articles is communicated along the supply chain and to consumers on request;
- substances on the authorisation list are only manufactured and used according to granted authorisation.[2]

3 Communication in the supply chain

In the following three sections, the communication obligations defined in REACH and the communication that is needed (but voluntary) to support chemical safety assessment are briefly summarised because the understanding of the related mechanisms is crucial for the inspection discussion.

3.1 Assessment and communication mechanisms

REACH includes a number of assessment and communication principles to ensure that the use of substances does not cause any unacceptable risks to humans or the environment. These are, among others, the following:

- For all substances placed on the market above 1 t/a, a minimum dataset must be provided to ECHA ('no data, no market') including hazard data and basic exposure information (Annex VI) or, under certain conditions a chemical safety report (CSR).
- Registrants assess, under which conditions of use a substance can be safely used (CSA). They communicate the results of the CSA - the relevant identified conditions of safe use – to their customers (immediate downstream users) in the format of an ES attached to the SDS.
- Formulators must consider the information in ESs they receive and forward the relevant information on the conditions of safe use to their downstream users with the SDS[3].
- Formulators and end-users of chemicals must either
    - implement the conditions of safe use as communicated or
    - demonstrate their use is safe albeit not complying with the suppliers conditions or
    - request reassessment by the supplier or
    - may not use the substance/mixture containing the substance anymore.
- Actors producing, importing or distributing articles must inform their customers of the content and information on safe use of substances of very high concern on the candidate list for authorisation (SVHC) in the articles, including to consumers if they request it.

[2] The enforcement of authorisations was not discussed at the workshop.

[3] There are no requirements defining the format for information provision. Hence, formulators may forward substance ESs, a consolidated ES for the mixture or integrate the information he receives in the main body of the SDS.

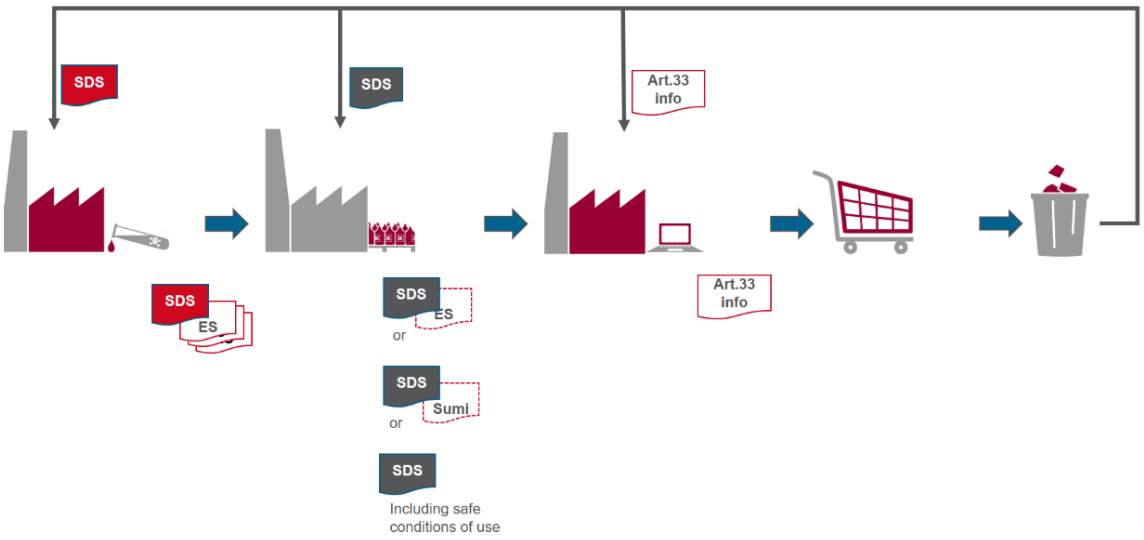


Figure 2: Legally required communication with substances, mixtures and articles

EU-wide legislation defining the system for classification and labelling was first introduced in 1967 (substances) and 1988 (mixtures)[4]. It was amended several times and implemented in accordance with a UN framework in 2008 (CLP Regulation)[5]. The communication on chemicals via SDSs was introduced in 1991 and amended several times[6]. The most recent communication instrument, the 'exposure scenario' was introduced with REACH. The ES describes the use and exposure situation of a substance as such, in mixtures or in articles, which is a fundamentally different approach than that taken by all former communication systems, as they focus on hazard information.

3.2 Communication on (the safe) use

In the CSA, information on a substance's hazards (generated and/or compiled from existing data or testing) is combined with data on the use(s) of a substance along its entire lifecycle. Registrants usually know the function(s) of their substances and may be aware of the mixture types their substances are included into. However, they are normally not aware of the end-uses and even less, the particular conditions under which the substances are used (as such, in mixtures and in articles). Consequently, registrants need to collect this information from their supply chains.

If downstream users' successfully provide information on their conditions of use to the registrants, they are rewarded by receiving ESs that realistically reflect their conditions of use. This means that they have little efforts in complying with the conditions communicated to them.

[4] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

[5] 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

[6] COMMISSION DIRECTIVE of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC (91/155/EEC)

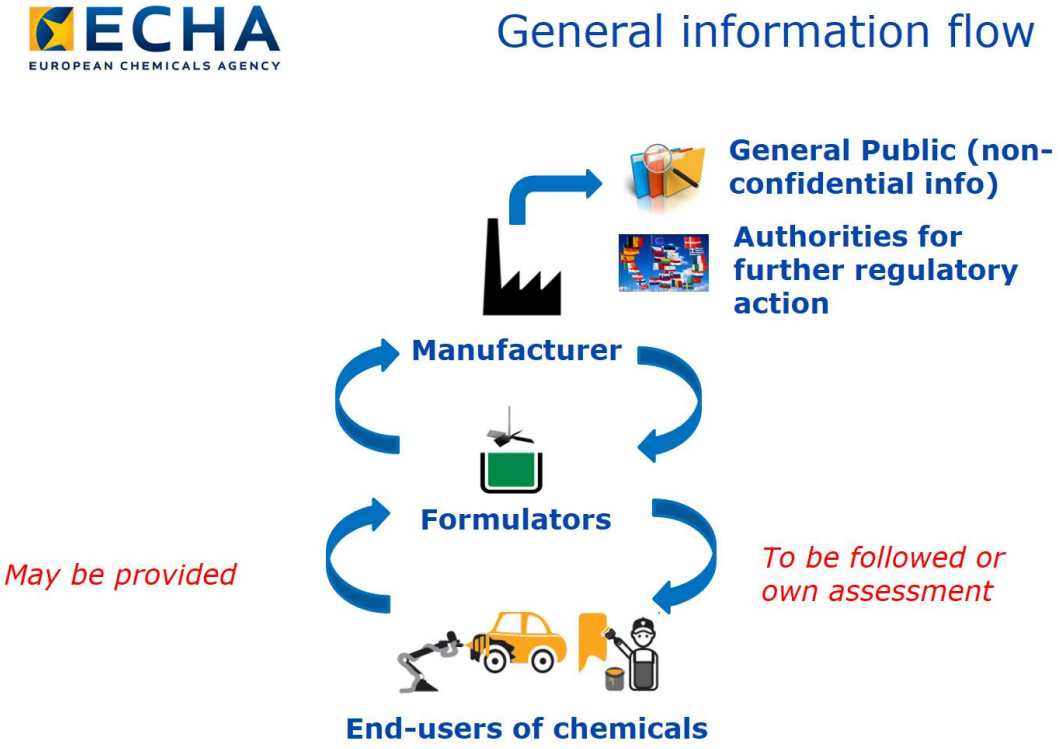


Figure 3: Information flow along the supply chain (source: Presentation Andreas Ahrens; Tallinn February 1, 2017)

In order to streamline, standardise and simplify the communication on uses and conditions of use, industry associations developed several instruments. At the core of these are the so called 'sector use maps', which structure the descriptions of a sector's uses and processes of substances and mixtures. The use maps connect each use with emission and exposure models for workers health and the environment, as well as standard parameters for the consumer exposure assessment, if available. For their CSRs and supply chain communication, registrants can identify the uses of their substances in the sector use maps, 'copy' the related specifications and describe the conditions of use as provided in the exposure assessment tools if safe use can be demonstrated. When using ECHA's tool for developing a chemical safety report (CHESAR), they can implement these steps almost automatically. Only if they cannot demonstrate safe use of the substance, registrants need to collect additional information to refine the assessment and communicate these with the ES. Downstream users may apply the sector use maps if they want to identify a use to the registrant.

At the time of writing the report, downstream user (formulator) associations were still developing the sector use maps. They should be ready for the 2018 registration deadline. It is not clear if all sectors will establish sector use maps.

3.3 Communication on SVHC in articles

The communication on SVHC on the candidate list in articles is a completely new legal requirement to article producers, importers and distributors. Before REACH entered into force, only in exceptional cases, e.g. for batteries, actors handling articles were required to communicate the substance content of their products. However, restrictions of substances in articles already existed before REACH in chemicals legislation as well as in product-related

legislation.[7] Consequently, actors handling articles are familiar with mechanisms preventing that particular substances are contained in particular products or used upstream. However, they are inexperienced in identifying the content of substances in all input materials from their upstream supply chain and providing related information for all their products to their customers.

4 Enforcing Registration

4.1 Background

REACH requires that all substances manufactured in or imported into the EU in amounts exceeding 1t/a to be registered, with some exemptions as defined in the provisions on the scope of REACH. The registration deadline for high volume substances (above 1000 t/a) and substances known to be carcinogenic, mutagenic or reprotoxic (CMRs) above 1t/a was in 2010 and that for substances in amounts between 100 and 1000 t/a in 2013. The last deadline expires 31st of May 2018.

The principle 'no data no market' implies that inspectors, via their market surveillance, identify if substances are placed on the market as such or in mixtures which should have been registered and punish identified infringements. Hence, inspectors need to know the substance amounts that an actor manufactures or imports and if a substance is classified as CMR to check the registration deadline.

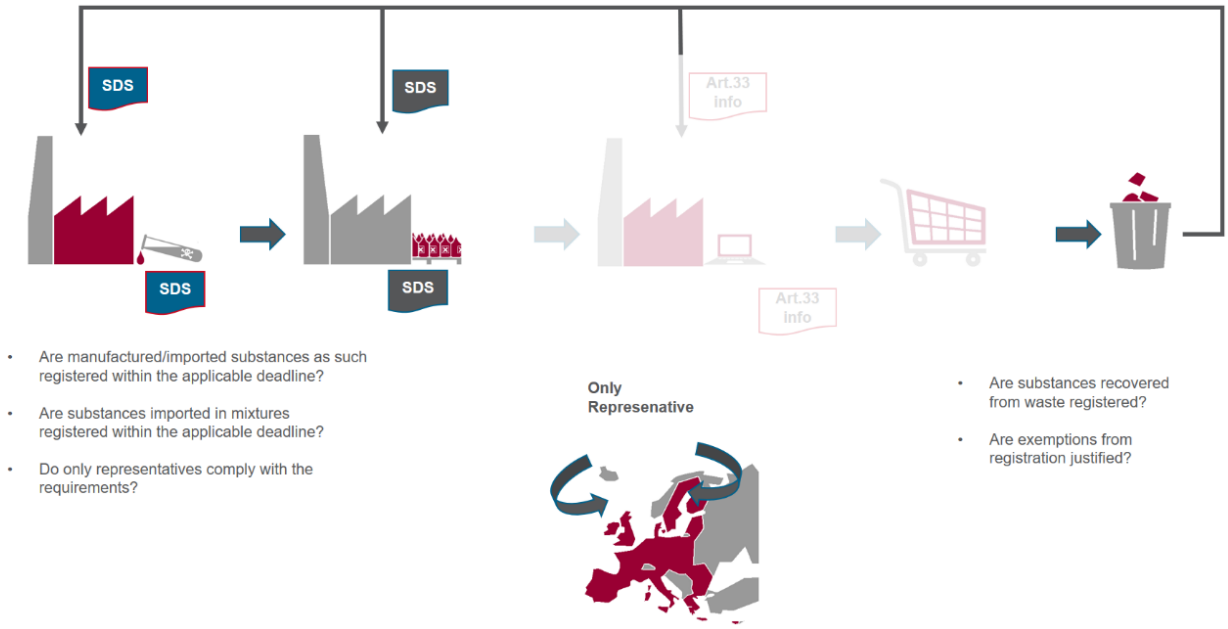


Figure 4: Registration cases to be controlled

[7] REACH Annex XVII includes all marketing and use restrictions formerly defined in a related Directive. In addition, some legislation which also existed before REACH (and still in place) includes substance restrictions in particular articles, such as vehicles, electrical and electronic devices or toys.

Non-EU chemicals producers may organise their export to the EU only via representatives (ORs), who take the responsibility for registration and the provision of SDSs to the downstream users, while the actual physical import may be practically managed by importers[8] all over Europe. The ORs are required to keep track of and document the imports in order to ensure registrations are up to data and amended, if registration thresholds are exceeded.

Enforcing compliance of ORs on the one hand involves controlling that the registered substance amount covers all imported amounts and that the registration and the SDS they supply are compliant. On the other hand, inspectors need to control that the uses supported by importers relying on an OR are covered in the OR's registration and that they report the amounts they import to the OR.

Recovery of substances from waste is a 'substance manufacture' under REACH. Consequently, companies recovering substances from waste are to register them. REACH Article 2.7(d) exempts recovered substances from registration, if it can be demonstrated that the substance is already registered and an SDS is available. Enforcing these requirements involves checking if during the recovery process the waste ceases to be waste in the legal meaning and evaluating if exemptions are justified. The latter entails assessing sameness of the recovered substance with a registered substance and the presence of an SDS.

4.2 Current experience from enforcing registration

According to the participants at the workshop, controlling if a substance should be registered (and is not) does not pose any major problems. Manufactured amounts are checked in the companies' production and sales statistics. For importers of substances as such or in mixtures, information is normally obtained from the customs, which registers all related trade flows and can extract specific data. As regards mixtures, amounts can be calculated either based on the SDSs (concentration ranges) or based on company information on the mixture composition. This information may be confidential and is therefore partly encrypted for the inspectors' use. No differences were observed between the Baltic States, 'old Member States' and Poland.

Controlling the compliance of the ORs' registration requirements was stated to be easily manageable by making random checks on the list of importers and the amounts they import that the ORs need to maintain. However, the Baltic States and Poland reported that only few ORs exist in the countries. It was stated to be more difficult to control compliance of importers/downstream user relying on an OR, because these actors would frequently not be able to provide the contact details of their ORs. Furthermore, if the ORs are located in another country, the respective competent authority or inspection in the Member State of the OR would have to be contacted to obtain further information.

In all cases, the participants confirmed that a good cooperation with the customs services is essential. Some participants, e.g. from Poland and Lithuania, mentioned that their cooperation with customs could be improved and that customs services sometimes lack full understanding of the issue or are involved in other activities with higher priority.

With a view to the upcoming registration deadline, all seminar participants regarded it challenging to make all potential registrants aware of their obligations under REACH. In all

[8] Due to the existence of the OR, these 'importers' are considered downstream users under REACH, although physically managing the import of substances and mixtures.

Member States awareness raising campaigns are ongoing to reach particularly small and medium sized (SME) manufacturers and importers. These campaigns include information provision from the helpdesks and on their websites, sending postcards to pre-registrants, motivating industry associations and related organisations to raise awareness via their networks, campaigns in social media and the press as well as regional 'information days'. In addition, national guidance documents are developed and other support offers are made. Latvia and the Nordic countries operate databases with contact details of potential registrants while other countries like Poland, Lithuania or Germany have to identify them e.g. via associations and other company networks.

It is observed that a large number of companies is still considering whether or not to register and evaluates, if registration can be avoided (e.g. by sourcing from EU companies).

4.3 Registration of substances recovered from waste

All actors commenting on this issue saw the enforcement of registering substances recovered from waste as very difficult or even impossible. The main challenges mentioned concern the definition of (end-of) waste and demonstrating the sameness of recovered substances in case exemptions are claimed.

Different situations exist with regard to the recovery of substances 'from waste', which carry different legal implications. A systematic differentiation of cases presented at the seminar includes the following examples:

- 'closed loop' - solvents are recovered from a process; they never become waste in the sense of the legal definition and are hence rather 'internally recycled', than recovered (which may also happen in a managed supply chain model scheme);
- 'cycling in the same application' - lubricants are collected after use, refined and placed onto the market; it is challenging for companies to agree on the sameness, in particular because the companies recovering lubricants are competing in the same markets as the primary producers;
- 'cycling in the same application, with mixing of material streams' - primary and secondary metals always (slightly) different with regard to their content of metals; usually metals producers use both, metal ores and scrap metals as input materials for their production. While the waste status does not appear to be a problem, also here the definition of a substance and the identification of sameness can be challenging;
- 'cycling into new, simple applications' - fuels produced from waste materials, for example 'biofuels' from food oils, are usually complex in composition and have changing composition characteristics. It is questionable with which type(s) of fuels sameness could be established, if at all;
- 'cycling into new, complex uses' - recovery of plastics usually results in a mixture of polymers and additives, which could be considered a mixture or a substance. If it were a mixture, the additives (and monomers) might have to be registered, while if it is a substance, no sameness could be claimed.

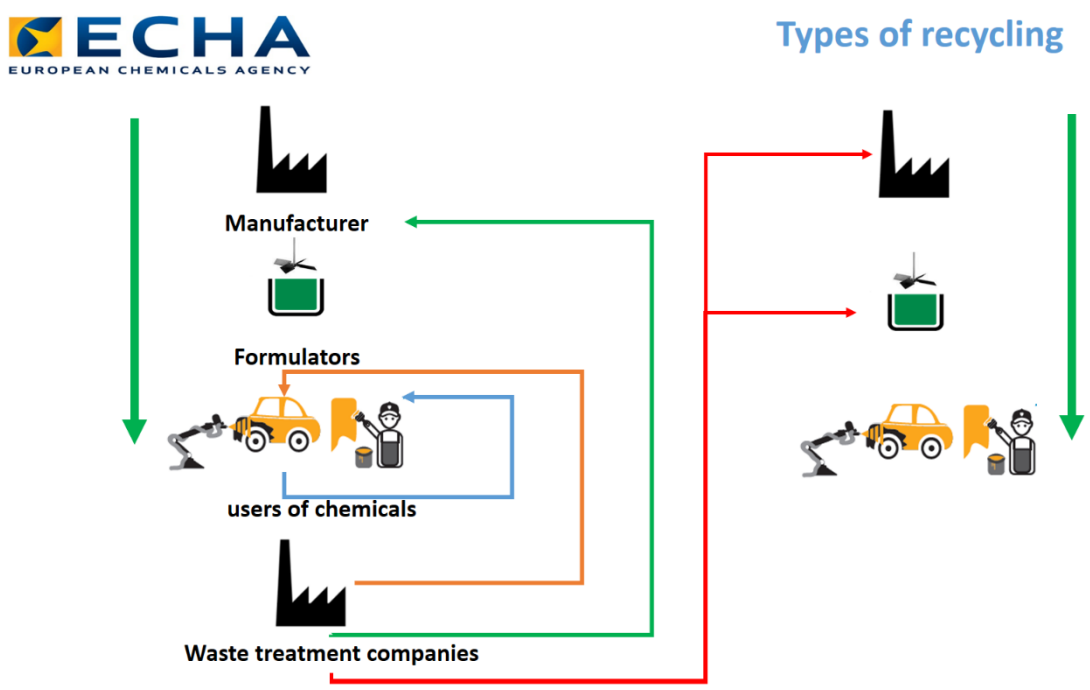


Figure 5: Overview of cases – recovery of substances (from waste) (source: Modified presentation Andreas Ahrens; Tallinn February 1, 2017)

This list of cases illustrates the two core problems in the implementation and enforcement of the registration requirements for substances recovered from waste.

No clear, EU-wide definition for the end-of-waste exists for all types of waste streams[9], hence, it is the Member States who frequently need to decide if a substance is recovered from a waste or not (and hence a registration is required or not). Three cases or options could be distinguished:

- Waste treatment results in a material that can be sold on the market but is still considered a waste. Consequently, no registration is needed but the customers need a waste permit to handle the material;
- One or more substances are recovered from waste, which are the same as already registered substances. Consequently, no registration is needed, if the sameness can be demonstrated;
- One or more substances are recovered from waste but it cannot be demonstrated that they are the same as already registered ones. Hence, the substance(s) must be registered.

Estonia has implemented national definitions of the end of waste criteria on some waste streams in their legislation[10], but the borderline between REACH and waste are mainly discussed case-by-case during the permitting process and on deciding if the waste recovery operation is recycling or not. In Estonia, recycling operation means that waste ceases to be waste and it is not the decision of a company but rather that of a permitting authority. However,

[9] End-of-waste criteria only exist for copper, steel and glass cullet

10 Estonian end-of-waste criteria exist for composting and anaerobic digestion of biodegradable wastes, and for producing fuel additives from oil shale mining and enrichment wastes

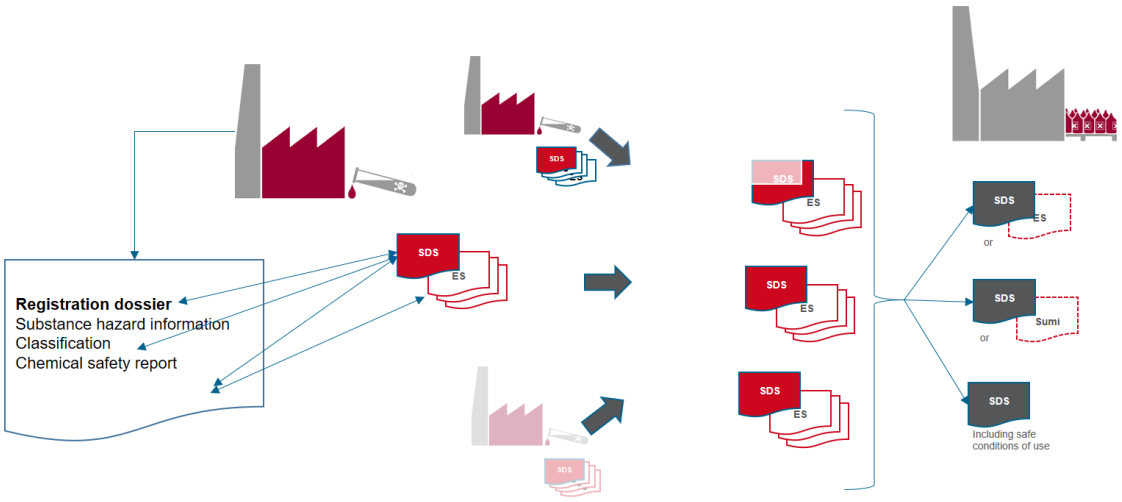
a lack of a harmonised definition for the end of waste may result in different statuses of a recovered substance in different Member States with the related differences in legal obligations which are applicable to them.

It is **difficult to define the identity of a substance recovered from waste and to evaluate the sameness** with registered substances. Problems arise, among others, from the definition of a substance (REACH Article 3.1): A substance may include 'impurities' that result from its production method according to the definition of REACH Art. 3(1). Challenges stem from the need to decide on a substance type (mono- or multi constituent, UVCB), allocating impurities of the recovered substance(s) if more than one is recovered from waste and changes in the composition that my result from changes in the input material (waste). In addition, recovered substances may have a different hazard profile than the registered ones, due to their impurities, which could lead to the conclusion of non-sameness.

It was felt that further, potentially EU-wide discussions are necessary to develop consistent solutions to these problems. The ongoing debate on the circular economy and the accommodation of concerns related to hazardous chemicals in material cycles may be one option for discussion. Any debates and questions to the EU Commission should be accompanied with specific examples of an unclear end-of-waste status or problems in substance identification/demonstrating sameness, if available.

5 Supporting and enforcing communication in the supply chain

Section 3.2 describes a potentially standardised, necessary but voluntary 'bottom up' communication, which should happen prior to registration. The legally defined 'top-down' communication on chemicals' hazards and safe use is obligatory. Consequently, this part of the information flow can, should be and is subject to enforcement actions. Enforcement may relate to the SDS's main body, the ES or the information flow on SVHC in articles. It could control the mere existence, the consistency, the clarity and/or the correctness of information provided by the supply chain actors. An overview of enforcement aspects is provided in the following figure.



Section 1: uses clear, concise, consistent with CSR
Section 2/3: hazard/classification correct
Section 8: consistent with CSR/ES
Section 11/12: consistent with CSR
ES: consistent with CSR

Section 1: uses covered by received ESs
Section 2/3: hazard/classification correct
Section 8: consistent with information in received ESs
Section 11/12: consistent with information received
If ES/Sumi: consistent with received information

Figure 6: Enforcement of SDSs and information on safe use

5.1 Safety data sheets: Main body

5.1.1 Background

REACH Article 31.1 specifies that an SDS must be provided if:

- a substance or mixture is classified as hazardous according to the CLP-regulation,
- a substances fulfils the PBT/vPvB criteria according to REACH Annex XIII,
- a substance is included on the candidate list for reasons other than listed above,
- one is requested for a mixture that is not classified as hazardous but contains at least one substance that is either hazardous to human health or the environment, or is included on the REACH candidate list or for which workplace exposure limit values exist.

The structure of the SDS is defined in REACH Art. 31.6 and in Annex II. A guidance document is available by ECHA.

5.1.2 Experience from enforcement of the SDS main body

The inputs from the participants indicate an overall improvement both with regard to the availability of SDSs and the quality of their content.

The main deficits in inspected SDSs were found in the sections 1 – 3[11] and in Section 8[12]. In addition, representatives from all Baltic Member States and Poland reported that safety data sheets are not available in the national language or are of very low quality. This problem seems to be less relevant in the 'old' Member States represented at the seminar.

According to the participants, SDSs are not updated and contact details of suppliers are

[11] identification of substance/mixture and of the company; hazards identification; composition/information on ingredients;

[12] exposure controls/personal protection

missing or incorrect (Section 1), in particular in SDSs provided by importers or retailers. The classification and labelling information would be incorrect (Section 2), because placers on the market do not consider all available information, wrongly apply classification rules and/or copy mistakes from their suppliers. Incompliance of Section 3 was not further specified but it was commented that discussions in the 'Forum'[13] revealed broad differences in understanding which information should be provided here. The main deficits reported for Section 8 of the SDS relate to inconsistent information, i.e. hazard classification does not match the exposure pathways described and/or the protection measures recommended.

The reasons for the SDSs' incompliance were seen in a lack of competences and resources, in particular in SME companies placing mixtures on the market, and a high reliance on the outcomes of SDS software (or the use of none). In particular, importers from non-EU companies were stated to struggle with the compilation of SDSs, because their suppliers were not willing to provide them with the necessary data or an EU-compliant SDS. This problem appeared to be more pronounced in the 'new' Member States, than in the 'old' ones.

Some participants reminded that SDSs are complex and require information from different areas, such as toxicology and ecotoxicology, transport and storage. The implementation of REACH Annex II was found challenging for companies. For the inspectors at the meeting the interpretation of Annex II is clear and there is no need for further clarification or guidance to control SDSs.

5.1.3 Sanctions and inspection strategies

It was observed that the ranges of fees and sanctions for infringements against the SDS provisions differ to a large extent (from 300 up to 50,000 Euro) between the present Member States. Baltic inspectors expressed some uncertainty as to which severity of sanctions would be appropriate for a particular type of infringement. All inspection strategies introduced at the seminar include an escalation of reactions, starting with awareness raising of an incompliance and requesting improvement up to imposing penalties, if the cause of incompliance is not removed.

All Member States confirmed that they inspect

- on a routine basis, a random selection of companies or products as well as reactions to complaints, and
- in form of campaigns, which may target specific groups of actors (e.g. formulators), products or sectors.

The REACH EN-force (REF) projects by the Forum were mentioned as important incentive and idea-giver for such campaigns.

5.2 Safety data sheets: Exposure scenarios

5.2.1 Background

REACH Article 31.7 specifies that actors conducting a CSA for a substance in the scope of registration or of a downstream user chemical safety report are to provide the relevant ESs with the SDS. In addition, it specifies that downstream users receiving ESs must consider these when compiling the SDSs for their mixtures and forward the relevant conditions of safe

[13] The Forum is an organisation managed by ECHA. All Member State enforcement authorities are represented in the Forum. The aim of the Forum is to facilitate experience exchange and enhance harmonisation of enforcement of the REACH provisions.

use to their customers. REACH Article 31.2 requires that information in the SDS must be consistent with the ES.

REACH Article 37 defines the requirements of downstream users with a view to ESs they receive. It specifies that the downstream users must

- either implement the safe conditions of use in the received ESs or SDSs, or
- prove that the use is safe under the conditions they apply via a downstream user chemical safety report or
- change their supplier/the chemical they use.

The Forum will implement a project to enforce the provisions on communicating the safe conditions of use down the supply chain (REF 5). The enforcement actions take place in 2017 and the publication of results is expected in 2018.

5.2.2 Experience from enforcement of the exposure scenarios

Representatives from all Member States unanimously stated that hardly any ESs are communicated in the supply chains and hence few are present in the inspected downstream user companies. Those ESs that inspectors, helpdesks or competent authorities have seen were reported to be (still) lengthy and difficult to understand. Many ESs were found to be inconsistent within themselves and/or with the main body of the SDS. Another deficit stated was that ESs are not specific, e.g. the conditions of use would not be relevant to the use or not concrete and therefore difficult to understand. Similarly as for the SDSs, ESs are not available in national languages.

Checking the consistency between the ES for communication with the SDS and the CSR submitted to ECHA with the registration dossier may pose challenges to inspectors, as access to the central database is needed. Furthermore, CSRs are not generally searchable and may be complex.

The participants stated that up to now, they implement little to no enforcement actions on ESs. All present enforcement authorities plan to participate in the REF 5.

It was stressed that the implementation gap on top-down supply chain communication is largely due to the switch from the hazard-based chemicals legislation to the risk-based system under REACH. All actors, including industry, national competent authorities and inspectors, would need time to learn how to make a safety assessment and which of the conditions assumed in that assessment to communicate (at which level of detail) in the ES along the supply chain. The sharing of responsibilities between industry actors and the reversed burden of proof would (still) create uncertainties about the ‘who does what’.

Another reason for the partly low quality of ESs was seen in the fact that they still originate from the registration dossiers submitted for 2010, which was done under high time pressure. According to ECHA, the industry updated only a small share of these dossiers.

With regard to their organisation, chemicals inspections and authorities indicated that they teamed up or plan to do so with the workers protection inspectorate, the organisations working on environmental permitting and control and partly also the consumer protection/sanitary services. Some inspectorates have already organised capacity building and emphasised this as important element for the success of future control measures.

5.2.3 Inspection strategies

ECHA stated that their work focuses on checking the consistency of the ESs with the registration information and the CSRs. They observed several types of inconsistencies:

- Member registrants' ESs concerning specific uses are not included in the lead registrant's CSR (e.g. if not assessed as safe) but are communicated along the supply chain.
- The use descriptions in the CSRs are vague and it is unclear which specific downstream uses they cover (broad use descriptions, unspecific conditions of (safe) use).
- Basic assumptions on the (safe) use in the CSRs are not communicated in the ESs (e.g. it is assumed that during use of a substance no water contact occurs but this is not stated in the ES or the SDS).
- Specific risk management measures are included in only one of the documents, either the ES or the CSR. In the latter case, the ES would not reflect the full set of conditions of safe use assumed in the registration and in the former case it would be unclear on which basis these measures are recommended.

There was consensus among the participants that awareness raising and capacity building would be necessary on all sides to increase the flow of ESs along the supply chain and improve their quality substantially. The communication tools industry is developing with the aim of simplifying and standardising communication would be an important support and their use should be promoted, in particular by the trade associations and larger companies.

It was pointed out that industry's interest in communicating ESs down the supply chain is currently limited, because they trigger (additional) requirements for the downstream users (checking and implementing the conditions of safe use) and (additional) communication efforts by the registrants and formulators (streamlining information in ESs for communication and integrating it into the SDS). Therefore, enforcement could provide an important incentive for pushing ESs into the market.

Regarding the enforcement of ESs and the related, upcoming REF project, it was mentioned that it might be wise not to aim at full implementation of all tasks but to target inspections. For example, targeting could consist of primarily checking the presence, consistency and clarity of information. Focusing could also include:

- checking only substance ESs rather than also looking for safe use information for mixtures or
- checking only one use per substance/SDS and not all of them (assuming one use description is compliant then also the other described uses should be compliant).

ECHA announced it would provide summaries from registration dossiers to support enforcement campaigns and facilitate checking consistency between information in the registration dossiers/CSRs and information on safe use communicated in the supply chain.

5.2.4 The use of exposure scenarios in other legal contexts

From the inputs and discussions at the workshop it can be concluded that ESs do not significantly contribute (new information) to the employers' risk assessment at workplaces, partly because few are communicated with the SDSs.

Likewise, it was stated that neither the ESs nor the emission estimation tools developed at EU

level[14] are regarded as helpful to support the permitting process according to the Industrial Emissions Directive. While information on the maximum use amount of a particular substance at a site would be interesting information for the permitting authorities, this type of information would not reach the installations. Similarly, the predicted no effect concentrations (PNECs) are currently not used for deriving emission limit values or permit conditions. It was commented that the current permitting procedures, based on the Best Available Techniques Reference Documents (BREFs) follow a different logics than REACH, i.e. is not based on risk but determining technically feasible emission limit values. These would be frequently set as sum parameters, rather than substance specific values. It was concluded that synergies from REACH and the environmental or installation related legislation cannot be observed, yet.

5.3 SVHC in articles

5.3.1 Legal background

Article 33 sets out the legal requirements related to the communication on substances of very high concern (SVHC) which are included in the candidate list for authorisation. The communication obligation is triggered if an SVHC is contained in an article in concentrations above 0.1%. According to the ruling of the EU Court of Justice the threshold of 0.1% applies to the 'smallest unit being an article' regardless of whether or not this is included into another (complex) article; i.e. an article does not cease to be an article unless it becomes waste.[15] If an SVHC is contained above 0.1%, related information must be provided within the supply chain automatically and to consumers within 45 days and free of charge, if these pose a respective request.

The Forum plans to implement a pilot project on the enforcement of Article 33. The overall aim is to raise awareness among the duty holders. The project should last for 6 months and starts in October 2017.

5.3.2 Experience from enforcement of communication on SVHC in articles

The participating inspectors stated that they have implemented only few enforcement actions on SVHC in articles. However, some checked how the communication obligations towards the consumers are implemented (c.f. below). According to helpdesk representatives, the number of questions from companies on Article 33 is increasing. Questions focus on the understanding of the 0.1% concentration threshold (after the ruling of the European Court of Justice) and if and which information needs to be provided to consumers.

In general, the implementation of Article 33(2) was checked by:

- testing articles to identify if SVHC are contained
- making an Article 33(2) request to the article supplier and
- comparing the response by the article supplier with own analytical results.

Overall, the results were comparatively consistent across products and countries, although it should be noted that the samples were very small and therefore not representative. According to the presented results, approximately 1/3 of the article suppliers provide incompliant

[14] The ECHA guidance documents include so called Environmental Release Categories (ERCs) and industry develops specific Environmental Release Categories (spERCs) to facilitate (standardised) emission estimation for the chemical safety report and communication in the supply chain.

[15] This is commonly known as the O5A – principle: 'Once an article always an article'

answers[16].

All participants stated that many companies are still unaware of the Article 33 obligations and that very few consumers know that they have a right to ask for information on SVHC in articles. Consequently, an extensive need for awareness raising and information provision was seen and is already satisfied by all stakeholders, e.g. via websites, conferences or information brochures and campaigns, including during enforcement actions.

The consumer smartphone App 'Tjek Kemien' developed by the Danish Consumer Council in cooperation with the Danish Environmental Protection Agency was introduced to the seminar audience. It supports consumers in making SVHC requests through a functionality to scan an article's bar code. If information on the article is included in a connected database, the consumer receives the answer directly. Otherwise, the system automatically sends an e-mail to the article supplier in the name of the consumer. A similar App by Friends of the Earth exists in Germany that was started to inquire endocrine disrupting chemicals in cosmetics and has now been extended to also cover SVHC in articles. A project application was submitted to develop a respective App that should be useable in all Europe.

5.3.3 Inspection strategies and challenges

In most Member States commenting on the issue, inspections campaigns are targeted towards those articles, where high risks are expected. This means they chose articles with a high likelihood that SVHC are contained and where a high consumer exposure level exists and/or vulnerable consumer groups, like children, are exposed.

The inspection of Article 33.2 is challenging, because inspectors need to identify themselves to the article suppliers which is likely to falsify response rates and the quality of responses. A 'shadow enforcement' approach was excluded for public authorities and, likewise but not as strictly, cooperation with consumer organisations to obtain less biased responses were seen as problematic.

Some participants reported an uncertainty on the side of companies and inspectors, what actions companies are to implement (and document) to show due diligence in ensuring compliance with Article 33. No clear answer was found, because it was seen as case specific and dependant on the type of article and trustworthiness of the supplier. However, it appeared to be common understanding that obtaining a general statement from suppliers that an 'article is REACH compliant' is not sufficient.

Generally, the national helpdesks tend to advise that suppliers must provide SVHC information with the articles they provide in the respective supply contracts or to prohibit their use and make communication superfluous. It was stressed that the responsibility for providing information remains with the placer on the market at each supply chain step.

[16] No answer was sent or the suppliers responded that no SVHC is contained although analyses showed that at least one was present.

6 Enforcing Annex XVII

6.1 Background

REACH Annex XVII sets out marketing and use restrictions for substances as such, in mixtures and in articles. These restrictions may be subject to conditions, such as concentration thresholds in mixtures or articles. Some restrictions are very specific, whereas others concern a broader range of materials or articles. The use of substances with a CMR classification is generally restricted in consumer mixtures.

Enforcement of restrictions generally requires a good understanding of the legal text. The documentations of mixtures and articles may be checked but chemical analyses of the composition are usually conducted.

Restrictions had already existed before REACH entered into force. Some restrictions are also included in product legislation and are applicable, albeit with a few substances being restricted under both pieces of legislation.

6.2 Enforcement strategies and approaches

All Member States present at the seminar enforce restrictions on a routine basis, i.e. making random checks and controlling based on complaints or particular suspicions, as well as targeted campaigns for particular substances or products. Similarly to the enforcement of Article 33, campaigns are focused on products with a high risk potential. In addition, criteria to select mixtures or articles for compliance checking include national priorities, synergies with other enforcement campaigns, participation in Forum projects or the expected impact of inspection campaigns.

The selection of particular products or companies for inspection campaigns may be based on different considerations, such as:

- Restricted substances are identified and reported in a particular product, e.g. in RAPEX or the ICSMS, study reports, product advertisements or social media;
- Companies are known for being incompliant, do not cooperate with enforcement or have provided incomplete documentation of their products in the past;
- Complaints are received on a particular problem from consumers or competitors.

Likewise, if a particular product type is selected for inspection, the substances may be selected apart from the existence of a restriction in REACH XVII considering the following aspects:

- available information on the likelihood that a particular substance is present in that product;
- an XRF screening of compounds that might be contained;
- the possibilities of laboratories to analyse substances;
- national priorities on particular substances.

As can be seen, not only scientific reasons influence the selection of substances and products for which restrictions are checked, but practical and political arguments also play a role.

Inspectors either purchase product samples in shops or directly request them from the companies. Based on the analytical results, they identify infringements against restrictions and impose related penalties. It is observed that companies are frequently not aware of the content of a restricted substance in their product. With a view to that, some inspectors were doubtful

of the adequacy of penalties. It appears that sanctions for infringements against restrictions are penalised differently across the member states.

There are several challenges with regard to the conduction of chemical analyses of product samples. First, standardized test methods are missing and for some products, in particular complex articles, the sample preparation may be challenging and difficult to compare if conducted by different actors. This difficulty may be (partly) remedied by the compendium of analytical methods[17] prepared by the Forum members, which describes testing methods in relation to a restriction and for the particular matrices a substance is expected to be found in. However, for many substances and matrices respective methods do not exist. Even if methods are available, the possibilities to conduct tests may be limited by the number and capacities of laboratories able to conduct the test.

Testing may give different results on the content of included substances. This means that inspectors testing the same product as the manufacturing company could analyse a different concentration of a restricted substance than the companies. Resolving these cases requires considerable effort and may involve additional testing, when the company identifies no infringement but the inspectors do.

Activities on checking products traded via the internet were reported as generally low up to now. Apart from a lack of resources, challenges identified include identifying the selling companies, in particular if the internet portals are not located within the borders of the Member State. The possibilities to target inspections based on information available in the internet are seen as limited and a legal basis for inspectors to purchase product samples via the internet is missing. If the selling company is located in another Member State, the enforcement of restrictions is passed on to the responsible authorities in that Member State. No actions are possible if the seller is located outside the EU. The internet is, however, regarded as a good option to identify and initiate company visits.

All participants saw a need to raise awareness and build capacity in the companies. However, as these types of provisions has existed for a longer period of time and product incompliance may have substantial financial and liability consequences, implementation appears to be better established than for other REACH provisions.

7 Conclusions

The implementation of REACH has proved to be a long process, with all actors (still) learning and developing implementation instruments. Not all actors are fully informed about their obligations, with those actors at the end of the supply chain apparently being the least aware (article producers and importers). Although REACH was designed to be a ‘learning system’, the question may be posed when the learning phase ends and full implementation of all requirements can be assumed. Vice versa, there is a need to decide, when the grace period should end and enforcement is tightened up in order to ensure a level playing field, reward those companies that are compliant and incentivise and enhance the implementation of the entire system.

[17] https://echa.europa.eu/documents/10162/13577/compendium_of_analytical_methods_en.pdf/3807683c-5340-4638-b5bc-5554635cdc8a

From the discussions at the workshop it was concluded that in **all Member States**, competent authorities, inspectors and helpdesks **invest considerable amounts of resources in awareness raising and capacity building campaigns** (internally and with regard to the market actors). These focus on preparing for the 2018 registration dossiers and providing good quality information. In the scope of inspections and answering to helpdesk questions, specific advice and information on the interpretation of legal requirements are provided.

Overall, **authorities** in the Member States **understand and enforce the majority of the legal requirements** without difficulties, e.g. on safety data sheets, Article 33 and on restrictions. All participants valued the ECHA **Forum** as an **important institution to** bring up related questions, clarify them and **develop harmonised interpretations**. Likewise, most participants were grateful to learn from REF projects organised by the ECHA Forum and eager to continue participation and experience exchange in this context.

The only **unclear** provision identified from the discussions are those on the **registration of substances recovered from waste** and the related exemption under Art. 2.7(d). Here, problems arise on the interface between chemicals and waste legislation from the lack of an EU-wide, harmonised definition of the end-of-waste criteria for all relevant types of waste. Secondly, there are several challenges in the definition of the substance identification and the demonstration of similarity the of registered substances

Ongoing enforcement activities include market surveillance to check compliance with restrictions and the obligation to register substances, including by ORs. Furthermore, the presence and content of safety data sheet is controlled by national inspectors. This indicates that the provisions, which have been in place for the longest time, are well implemented, also from the side of the inspections. The ‘newer’ requirements, i.e. communication of exposure scenarios and of the SVHC content in articles are not yet implemented at full scale, but some Member States implemented first actions. Here, more information and piloting of inspections appears useful and is on the way, e.g. by the ECHA Forum.

Overall, the statements from the participants indicate that the **companies’ compliance rates are increasing in the areas of ‘traditional chemicals control’ but appear to not yet be fully developed with regard to the supply chain communication**. This regards the informal (bottom-up) but also the legally required top-down communication via safety data sheets, exposure scenarios and on Article 33. The market forces within the supply chains and by the consumers appear insufficient to foster information provision, as of yet. Consequently, enforcement could play an important role in triggering that information flow in the future.

All participants expressed that the seminar was an important source of information and inspiration for their work and underlined the need for this type of experience exchange at an informal level.

8 List of participants

International seminar

"Enforcement practices with regard to the REACH Regulation"

01.-02.02.2016, Tallinn, Estonia

Name	Institution
Austria	
Franz Weinberger	Federal Ministry of Environment
Denmark	
Michael Fagerlund	Environmental Protection Agency
ECHA	
Andreas Ahrens	European Chemicals Agency (ECHA)
Juan Pablo Calvo Toledo	European Chemicals Agency (ECHA)
Estonia	
Aljona Honga	Health Board
Allar Leppind	Estonian Environmental Inspectorate
Anna Amelkina	Health Board
Cairit Eit	Baltic Environmental Forum Estonia
Hallar Meybaum	Federation of Estonian Chemical Industries
Hannela Artus	Ministry of the Environment
Heli Nõmmsalu	Baltic Environmental Forum Estonia
Jekaterina Marjina	Health Board
Juhan Ruut	Hendrikson & Ko
Kai Klein	Baltic Environmental Forum Estonia
Katrin Juhanson	Hendrikson & Ko
Katrin Kaare	Environmental Board
Kristel Lopsik	Estonian Environmental Inspectorate
Kärt Kasak	Federation of Estonian Chemical Industries

Maigi Pääre n	Environmental Board
Margus Korsjukov	Ministry of the Environment
Mari-Liis Ummik	Ministry of the Environment
Marina Karro	Health Board
Natalja Borel	Health Board
Rene Rajasalu	Estonian Environmental Inspectorate
Riina Vaht	Environmental Board
Sandra Oisalu	Baltic Environmental Forum Estonia
Silva Prihodko	Estonian Environmental Inspectorate
Tiiu Müürsepp	Tartu Consumer Advice and Information Centre
Finland	
Jouni Räisänen	Finnish Safety and Chemicals Agency
Germany	
Anja Knietsch	Federal Institute for Occupational Safety and Health
Antonia Reihlen	Ökopol GmbH
Latvia	
Aija Zucika	Ecodesign Competence Center
Heidrun Fammler	Baltic Environmental Forum Latvia
Jekaterina Placko	Health Inspectorate of Latvia
Guna Janoviča	State Environmental Service of the Republic of Latvia
Līga Rubene	Latvian Environment, Geology and Meteorology Centre
Linards Lapčinskis	Health Inspectorate of Latvia
Maija Rumpetere	Health Inspectorate of Latvia
Natālija Jaunkalne	Latvian Environment, Geology and Meteorology Centre
Roberts Berzins	State Environmental Service of the Republic of Latvia
Sarmite Rutina-Rutenberga	State Labour Inspectorate
Valters Toropovs	Baltic Environmental Forum Latvia

Lithuania	
Gražvydas Jegelevičius	Baltic Environmental Forum Lithuania
Ingrida Stulgiene	State consumer rights protection authority
Jolita Kruopienė	Kaunas University of Technology
Justė Kukučionė	Baltic Environmental Forum Lithuania
Lina Dunauskiene	Environmental Protection Agency
Marius Šulga	Vilnius regional environment protection department
Otilija Grincevičiūtė	Environmental Protection Agency
Luxembourg	
Kim Engels	Administration de l'environnement
Poland	
Dominik Pisarek	Chief Sanitary Inspectorate
Sweden	
Lisa Ekstig	Swedish Chemicals Agency