ECHA
EUROPEAN CHEMICALS AGENCY

# Forum

# REF-9 project report on enforcement of compliance with REACH authorisation obligations

Adopted at 13 February 2023

**Disclaimer**

This publication is solely intended for information purposes and does not necessarily represent the official opinion of the European Chemicals Agency. The European Chemicals Agency is not responsible for the use that may be made of the information contained in this document.

This report presents the results of inspections made under the Forum enforcement project. Duty holders and substances selected for checks were those that were relevant for the scope of the project. The project was not designed as a study of the EU-EEA market. The number of inspections for individual countries is varied. Accordingly, the results presented in the report are not necessarily representative of the situation in the EU-EEA market as a whole.

**FORUM REF-9 project report on enforcement of compliance with REACH authorisation obligations**

**Reference:** ECHA-23-R-02-EN
**ISBN:** 978-92-9468-260-4
**Cat. Number:** ED-09-23-032-EN-N
**DOI:** 10.2823/122384
**Publ. date: March 2023**
**Language: EN**

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:
http://echa.europa.eu/contact

**European Chemicals Agency**
Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Telakkakatu 6, Helsinki, Finland

# Table of Contents

## Glossary

| Term | Description |
|---|---|
| **AfA** | Application for authorisation |
| **APF** | Assigned protection factor |
| **BAT** | Best available technique |
| **CLP or CLP Regulation** | Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures |
| **C&L** | Classification and labelling |
| **CSR** | Chemical safety report |
| **COM** | European Commission |
| **S-CIRCABC** | Secure CIRCABC |
| **DU** | Downstream user |
| **ECHA** | European Chemicals Agency |
| **EEA** | European Economic Area |
| **ES** | Exposure scenario |
| **eSDS** | Extended safety data sheet |
| **Forum** | The Forum for exchange of information on enforcement: network of authorities responsible for the enforcement of the REACH, CLP, PIC and BPR regulations in the EU, Norway, Iceland and Liechtenstein |
| **ICSMS** | Information and Communication System for Market Surveillance |
| **IED** | The Industrial Emissions Directive 2010/75/EU of the European Parliament and the Council on industrial emissions |
| **MS** | Member State |
| **NACE** | Nomenclature of economic activities is the European statistical classification of economic activities. |
| **NC** | National coordinator |
| **NEAs** | National enforcement authorities |
| **OC** | Operational conditions |
| **OR** | Only representative |
| **OSH** | Occupational safety and health |
| **PPE** | Personal protective equipment |
| **RCOM** | Response to comments table |
| **REACH or REACH Regulation** | Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals |
| **REACH-IT** | The central IT system that supports industry, Member State competent authorities and the European Chemicals Agency to securely submit, process and manage data and dossiers |
| **REF** | REACH-EN-FORCE, coordinated enforcement project of the Forum |
| **RMM** | Risk management measures |
| **SCCs** | Strictly controlled conditions |
| **SDS** | Safety data sheet |
| **SEVESO** | The Seveso III Directive - 2012/18/EU of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC |
| **SME** | Small and medium-sized enterprise |
| **SVHC** | Substance of very high concern<br>In the context of this report, SVHC means an Annex XIV substance with a sunset date that has expired |
| **WG** | Working group of the Forum |

# Executive summary

The European Chemicals Agency's Enforcement Forum for Exchange of Information on Enforcement (ECHA Forum) has finalised its ninth REACH-EN-FORCE (REF-9) project, where the compliance with REACH authorisation obligations was assessed.

This was an EU-wide enforcement project including EEA countries carried out during 2021 in 28 countries[1].

National enforcement authorities completed 690 inspections on substances suspected to be covered by a substance entry from Annex XIV to the REACH Regulation in 516 companies. 43 different substance entries[2] listed in Annex XIV were addressed as part of these inspections.

In this project report, 502 substance inspections in 404 companies are presented and analysed. In these inspections, inspectors could confirm that the inspected substance is a substance listed in Annex XIV and is placed on the market or is used at the time the inspection was conducted. 31 different Annex XIV substances were actually addressed in these 502 substance inspections with chromium trioxide and strontium chromate the two most frequently inspected substances.

The inspected company had a downstream user role for 90 % of the reported Annex XIV substance inspections while it was the authorisation holder for only 10 % of the reported substance inspections. As a consequence, most of the inspections have focused on uses of substances from Annex XIV and the majority of inspections have addressed such uses that are covered by an upstream authorisation (or by a related application for authorisation).

203 out of the 502 substance inspections reported (40 %) found at least one non-compliance with the REACH obligations checked in the scope of the REF-9 project (see Section II). 162 out of 404 companies inspected (40 %) were non-compliant. The substances from Annex XIV that were most frequently involved in non-compliant cases were (in brackets the rate of non-compliance for each substance): lead sulfochromate yellow (63 %), strontium chromate (51 %) and chromium trioxide (35 %).

The main non-compliances of the 203 substance inspections for the detailed REACH requirements checked within the scope of the project are related to downstream user duties and are as follows:

- 26 % of substance inspections were not in compliance with Article 56(2) (using the substance in accordance with the conditions of a granted authorisation to an actor upstream in the supply chain for that use);
- 26 % of substance inspections were not in compliance with Article 37(5) (downstream user identifies, applies and, where suitable, recommends appropriate measures to adequately control identified risks); and
- 20 % of substance inspections were not in compliance with Article 66(1) (notification of downstream users using the substance in accordance with Article 56 (2)).

[1] In this report, all references to EU market include also Iceland, Liechtenstein, and Norway.

[2] In the REF-9 project substances were inspected in chemical products (substances or mixtures). The chemical products checked and the substances subject to the inspection in these chemical products were selected once a substance listed in the Authorisation List in a concentration above 0.1 % w/w was identified as a constituent. The REF-9 project focused only on substances listed in Annex XIV to the REACH Regulation with sunset dates that have passed by the project start date (January 2021)

Some cases could be identified in which the inspected companies completely failed to observe REACH authorisation duties as the substance placed on the market or used did not have a valid authorisation, an application for authorisation had not been submitted or was still ongoing and there was no exemption from authorisation for the specific use. The rate of substance inspections that identified such "free riders (supply and use)", i.e. either users or duty holders placing on the market, was 3 %, which is a small proportion of the overall non-compliance rate of 40 %.

At the time of reporting the inspection, 254 enforcement measures were imposed by the enforcement authorities for the 203 substance inspections where non-compliances were identified. The most frequent enforcement actions were written advice in 111 inspections and administrative orders in 62 inspections.

Key conclusions

In general, the project shows an overall non-compliance rate of 40 %, both in terms of substance inspections and of companies. This is higher than the usual average level of non-compliance found by inspectors for provisions of EU chemicals legislation. This can be, in part, related to the situation that both placing authorised substances on the market and using authorised substances in accordance with the conditions of the authorisation decision are new and complex duties for the duty holders affected.

Currently, there is no comprehensive ECHA guidance document available for suppliers and users of authorised substances, which would clearly set out the details of the duties and requirements in terms of placing on the market and using authorised substances. Duty holders have just started to find answers and solutions for new requirements in relation to their obligations under Title VII of the REACH Regulation.

Non-compliance can also be related to the presence of very complex supply chains that present serious challenges in relation to the communication of information in a clear and concise form to the downstream users using the authorised substance.

In general, the highest non-compliance rates observed in this project were for duties related to downstream users (e.g. Article 56(2) or Article 37(5) of REACH).

*Inspection results related to the supply chain*

For downstream users, the very low level of communication of information by their supply chain both in terms of quantity and quality continues to be a serious impediment. The key obstacles are:

- In 35 % of inspections at downstream users, inspectors found that relevant information in relation to uses/OC/RMM/PPE[3] or monitoring arrangements from the authorisation decision had not been communicated down the supply chain to the downstream users in the extended safety data sheet. Since Article 31(9) of REACH requires suppliers to update a safety data sheet "without delay" once an authorisation is granted, this finding is alarming. This non-functioning of obligatory supply chain communication puts the risk management instrument covering downstream users by upstream authorisations (Article 56(2) of REACH) in question.
- The extended safety data sheet shows significant quality deficits and poor quality information (even information gaps) as identified in the inspections (see the analysis

[3] Uses/operational conditions/risk management measures/personal protective equipment

in Section 3.5). Downstream users often lack the experience and expertise to understand that they need to ask their suppliers for better quality information.

*Inspection results related to the use of authorised substances*

The inspections revealed that the majority of downstream users observe the basic authorisation requirements in relation to the use of an Annex XIV substance (e.g. the substance is authorised for the use or at least an application for this authorisation is submitted, or the use is exempted from authorisation requirements). There are only 2 % of use-related substance inspections that could establish that authorisation requirements have been ignored, that is, the Annex XIV substance was in a use requiring an authorisation – "free riders (use only)".

*Inspections focusing on authorised substances*

Authorisation conditions include measures which are also addressed by national workplace safety legislation or by national environmental legislation and the resulting overlapping obligations of the duty holders are not clearly clarified in the authorisation decisions or in related guidance. In general, REACH inspectors in many cases do not have the full knowledge to check environmental and workplace safety requirements. It, therefore, remains difficult to conduct inspections for these overlapping obligations.

Key recommendations[4]

To industry

1. *Suppliers* to improve the quality and completeness of the extended safety data sheets in relation to the conditions of use of the authorised substances to ensure compliance as an actor in the supply chain and to ensure that all relevant information is communicated down the supply chain in clear and concise language, which can be easily understood by the downstream users. In particular, the prompt update of safety data sheets according to Article 31(9) of REACH and according to the deadlines specified in the authorisation decisions is critical. It is important that the safety data sheets are in the languages of the Member States.
2. *Suppliers* to actively communicate by all possible means to downstream users in relation to their obligations when using the authorised substance. This shall also include the procedures to follow in relation to requests for further clarification of information in relation to authorisation conditions and particularly to the operating conditions/risk management measures required in relation to the specific uses of the downstream user.
3. *Downstream users* to ensure that if they use a substance subject to authorisation that they use it in accordance with the conditions of use and particularly in accordance with the operational conditions and risk management measures set out in the authorisation decision for their specific use. If it is unclear from the extended safety data sheet which operational conditions or risk management measures are required for their specific use, then they should seek clarification from their supplier of the substance. In addition, downstream users also have to ensure that the Article 66 notification is kept up-to-date including an update if they cease to use the authorised substance.

[4] The full set of recommendations is listed in Section 4.2

To ECHA Secretariat

The ECHA Secretariat to develop a comprehensive and consistent guidance to suppliers and users of authorised substances. Also the two previous Forum pilot projects on authorisation identified the need for a comprehensive ECHA guidance document which provides clarification and guidance to suppliers and users of authorised substances in relation to their duties and provides answers and solutions for them to enhance compliance. Results of the REF-9 project clearly confirm the lack of such comprehensive and consistent guidance.

To the European Commission

Authorisation decisions should be clear enough to be implemented by duty holders and to enable effective enforcement:

- The authorisation decision should always clearly identify who is the responsible actor when it comes to the authorisation conditions. This allows the relevant actor in the enforcement to be addressed.
- Authorisation decisions should be published in the language of all relevant Member States (i.e. for upstream authorisations also in the languages of the Member States in which downstream users are using the authorised substances).
- Duties for providing information in the supply chain between the authorisation holder and downstream users using authorised substances should be regulated explicitly and detailed in the authorisation decision for all suppliers. This will improve communication in the supply chain.
- In general, overlap with other existing relevant legislation should be considered and clarified in the conditions of the authorisation decision (e.g. monitoring requirements in workplace safety or in environmental legislation or hierarchy of control of occupational safety and health (OSH)).
- For monitoring requirements, details on the measuring method (sampling and laboratory analysis) need to be regulated in the authorisation decision to ensure a harmonised approach for this authorisation condition.

This report sets out the scope of the REF-9 project on authorisation (Section I and II), and it reviews and analyses the results of the inspections completed as part of the project (Section III). Based on analysis of the results of the project, conclusions and recommendations are drawn (Section IV).

# I. Content and key findings

### 1. Project overview

An enforcement project was carried out in EU and EEA countries with the aim to check compliance with REACH authorisation requirements regarding placing on the market and use of all substances from Annex XIV to the REACH Regulation (the Authorisation List) with sunset dates that had passed by the project start date (January 2021).

In general, for a relevant substance from Annex XIV, the project checked whether:

- the relevant authorisation was granted for placing that substance on the market and for its use(s) or whether the application submitted for authorisation of use(s) was still under assessment by authorities or whether a specific exemption from authorisation was applied for the use(s); and
- obligations of the authorisation provision for suppliers related to information in the supply chain are observed; and
- downstream users using an Annex XIV substance were supplied with this substance by a valid supply chain covered by an authorisation or by a still ongoing application for authorisation; and
- timely Article 66 downstream user notifications have been submitted; and
- the substance was used in accordance with the conditions set out in the authorisation decision; and
- once applicable, the review provisions specified in the authorisation decision have been observed in time.

In this way, the checks addressed the provisions from Title VII of REACH on the specific authorisation requirement (i.e. Articles 56, 60, 61, 65 and 66 of the REACH Regulation) but also the provisions of REACH on safety data sheets (Article 31) and on the requirement for downstream users to take action to adequately control identified risks (Article 37(5)).

### 2. Companies and substances inspected

In 2021, national enforcement authorities in 28 European countries reported a total of 690 inspections in 516 companies on substances suspected to be covered by one of 43 different substance entries listed in the Authorisation List (Annex XIV to the REACH Regulation)[5].

In this project report, 502 substance inspections in 404 companies are presented and analysed. In these inspections, inspectors could confirm that the inspected substance is a substance listed in Annex XIV and is placed on the market or is used at the time the inspection was conducted.

In some of the remaining 188 cases not presented and analysed in this project report, replacement and substitution of substances from Annex XIV has been observed by inspectors. In some cases, inspectors were aware that the company had substituted the Annex XIV substance before commencing the REF-9 inspections and, in many instances, the company was not inspected as part of the REF-9 project. However, in other situations the substitution of the substance from Annex XIV only became apparent during the course

[5] In the REF-9 project, substances were inspected in chemical products (substances or mixtures). The chemical products checked and the substances subject to the inspection in these chemical products were selected once a substance listed in the Authorisation List in a concentration above 0.1 % w/w was identified as a constituent. The REF-9 project focused only on substances listed in Annex XIV to the REACH Regulation with sunset dates that have passed by the project start date (January 2021)

of the REF-9 inspection and some participating countries have sent inspection results covering the new situation in the company after the substitution.

In the 502 inspections of substances from Annex XIV, inspectors focused on duty holders that have used the inspected substance but duties when placing the inspected substance on the market have also been checked.

The 502 substance inspections covered:

- 261 (65 %) companies that were small and medium-sized enterprises.
- The company had a downstream user role in 90 % of the substances inspections.
- The company was the authorisation holder for 10 % of substance inspections reported.
- 31 different Annex XIV substances were actually addressed in the substance inspection, with chromium trioxide and strontium chromate the two most frequently inspected substances.
- 73 different identified uses of the substances from Annex XIV defined either in the application for authorisation or in the authorisation decision were checked and these uses were most often related to plating, coating or surface treatment.
- 63 different uses related to exemptions from the authorisation requirement were also checked (most often related to use as intermediates or use in scientific research and development).

**Compliance with authorisation duties when placing substances from Annex XIV on the market.**

In 98 of the 502 inspections, the inspected substance was placed on the market for a specified use after its sunset date as defined in Annex XIV. The inspected substances were placed on the market for specified uses as follows:

- 64 (65 %) based on an authorised use:
  - 16 based on own authorisations;
  - 48 under an upstream authorisation.
- 5 (5 %) based on an application for authorisation that had been submitted.
- 23 (24 %) based on a legitimate exemption (most often use in scientific research and development).

A total of 6 (6%) supply-related inspections found that the substances from Annex XIV have been placed on the market in breach of REACH authorisation obligations (Article 56(1) of REACH) - "free riders (supply only)":

- They did not have a valid authorisation.
- There was no ongoing/pending application for authorisation.
- There was no exemption from authorisation for their specific use.

For the substances with a granted authorisation, the supplier failed to include the required authorisation number on the label and in the safety data sheet (SDS) in 27 % of the inspections. In 19 % of cases with missing authorisation numbers a non-compliance of authorisation holders or downstream users (formulators) was identified by inspectors based on Article 65 of REACH, which requires these two duty holders to ensure proper labelling.

**Compliance with authorisation duties when using substances from Annex XIV.**

In 463 out of 502 inspections, the inspected substance was used after its sunset date defined in Annex XIV. Substances subject to inspection were used by companies as follows:

- 368 (80 %) based on an authorised use:
  - 44 based on own authorisation;
  - 324 based on an upstream authorisation.
- 29 (6 %) based on an application for authorisation that had been submitted.
- 55 (12 %) based on a legitimate exemption (most often use in scientific research and development).

A total of 11 (2 %) use-related inspections of substances from Annex XIV found that the substances have been used in breach of REACH authorisation obligations (Article 56(1) or Article 56(2) of REACH) - "free riders (use only)":

- They did not have a valid authorisation.
- There was no ongoing/pending application for authorisation.
- There was no exemption from authorisation for their specific use.

### 3. Enforceability of authorisation conditions/chemical safety report/succinct summary

For the 399 substance inspections with a granted substance authorisation in place, the inspectors also reported their experience in relation to the application of the authorisation decisions (with the chemical safety report (CSR)), the succinct summaries, the (extended) safety data sheets and the enforceability of these formal documents during their inspections of authorisation conditions.

In general, inspectors indicated that for 63 % of completed inspections of authorised substances, the safety data sheet was the easiest source of information followed by the succinct summary (49 %) and the CSR (26 %). This feedback indicates that inspectors are familiar with the information in the safety data sheet (SDS) and that the operating conditions/risk management measures (OCs/RMMs) are covered in the SDS in a form that can be easily used for inspections in about two-thirds of cases. The succinct summary does not provide much added value in half of the cases. The low rate of use of the CSR shows that there is clearly a need to transfer the information in relation to the OCs and RMMs into a suitable format for use on inspections. Given that the succinct summary has been established to assist inspectors to inspect OCs/RMMs applied when using authorised substances, there is a need to improve this information instrument.

### 4. Practical check of the conditions of the authorisation decision

Practical checks for compliance with the conditions of the CSR/authorisation decision/succinct summary were carried out during the 369 inspections of authorised substances which were either:

- placed on the market (19 cases); or
- used by the authorisation holder itself (38 cases); or
- used by a downstream user in the supply chain of an authorisation holder (324 cases).

The checks focused on the extent to which the following conditions of the authorisation decision have been observed:

- intended or actual use matching the prescribed authorised use;
- the required OCs/RMMs;
- the required PPE;
- additional conditions according to the authorisation decision; and
- monitoring arrangements.

The statistical sample for the inspections of **authorised substances placed on the market** is rather small (19 cases only) to draw any detailed conclusions on the investigations targeting authorisation conditions. However, there seems to be a general trend that for obligations to observe and for obligations to communicate complex information on OCs/RMMs and on monitoring arrangements, the compliance rate by the suppliers is low and can drop to a level of only 53 %.

This finding is a general indicator that the quality of information flow in the supply chain on authorisation conditions is one of the major problems for the functioning of the authorisation instrument as one of the risk management pillars of the REACH Regulation.

In general it can be concluded that for the **use of authorised substances by authorisation holders** compliance with conditions in their own authorisation decisions is in the general range of 80-90 % except for the additional conditions in the authorisation decisions for which the compliance rate drops to around 70 %. This level of compliance needs to be assessed against the fact that the authorisation holders know the conditions of their authorisation decisions exactly as they have also been involved in the detailed assessment of their application for authorisation which was conducted by ECHA before the authorisation was granted to them in the decision of the European Commission.

For checks carried out at **downstream users receiving information** from the supply chain in relation to authorisation conditions in the extended safety data sheet, the following findings were identified:

- Critical information from the authorisation decision in relation to OCs/RMMs and requirements in relation to personal protective equipment (PPE) was missing in about 10 % of cases.
- Approximately 20 % of safety data sheets (SDSs) did not contain relevant information with respect to additional conditions and to monitoring arrangements specified in the authorisation decision.

One reason for the latter information being missing in SDSs could be that new obligations for SDSs as defined in Annex II to REACH are only required from 2023 onwards. Only these new provisions explicitly require upstream suppliers to communicate information in relation to additional conditions and monitoring requirements in Section 15 of the SDS. As such, the inspection findings in relation to information missing in the SDSs prove the importance of these new explicit requirements for SDSs.

However, in general it needs to be noted that the non-compliance rate of suppliers with SDS obligations as observed in the SDSs received by downstream users has to be seen in light of the obligation of Article 31(9) of REACH requiring all suppliers to update the SDS "without delay" and to provide it to all former recipients once an authorisation is granted. This important communication mechanism of REACH to ensure a functioning supply chain communication is obviously not operating as intended.

A general comparison of inspection results on completeness of information about different authorisation conditions in the SDS at the level of suppliers (supplier's SDS) and of downstream users (received SDS) shows that the completeness of information on authorisation conditions in the SDS is, in general, lower when checked with the supplier compared to the check of the SDS received by the downstream user (however, the statistical sample of inspections at suppliers in general is low). In addition, completeness of information on additional conditions and on monitoring arrangements of the authorisation decision shows the lowest rate and can be missing in a quarter of the SDSs of authorised substances.

For checks on **downstream user's use**, the following findings could be identified:

When using authorised substances up to 20 % of downstream users failed to comply with the obligation to implement risk reduction measures that are required in the extended SDS and in the authorisation decision in relation to:

- applying the required OCs/RMMs (20 % non-compliance rate);
- using the required PPE (17 % non-compliance rate); or
- applying the required additional conditions of the authorisation (17 % non-compliance rate).

The obligatory monitoring arrangements are even more often not implemented (30 %).

When summarising the findings in order to establish the overall non-compliance related to the Article 37(5) duties of REACH (duty to identify and apply risk reduction measures), inspectors identified a non-compliance rate of 26 % for the inspected authorised substances.

19 % of the inspected substances were missing Article 66 notifications, and 40 % of the inspections found that the notified substance use had not yet the monitoring data included as required by many authorisation decisions. However, this more broad absence of monitoring data in the notifications might be triggered by the related notification deadline defined in the most relevant authorisation decisions. This deadline was in December 2021 which was the last month of the one-year period of field inspections in this project and the majority of inspections have been finalised before.

When summarising the findings in order to establish the overall non-compliance related to the Article 66 duties of REACH, inspectors identified a non-compliance rate of 20 % for the inspected authorised substances.

In 35 % of the inspections of authorised substances, information in relation to uses, OCs, RMMs, PPE or monitoring arrangements only became available to the company after an initial intervention from an inspector. This indicates that in about one-third of the supply chains, communication about authorisation requirements along the supply chain does not function at all.

A general comparison of inspection results between duty holders (suppliers, authorisation holders, downstream users) and their duties to adhere to different elements of the authorisation conditions shows that authorisation holders themselves when using the authorised substance are somewhat more compliant in adhering to the authorisation conditions than downstream users.

Inspections of suppliers of authorised substances in general (authorisation holders and other suppliers) reveal that the suppliers' own uses seem to be particularly often non-compliant with the authorisation conditions (however, the statistical sample of inspections at different kind of suppliers is low).

When using authorised substances, compliance with the required monitoring arrangements is particularly low and can be absent in one-third of inspected substance uses. Only authorisation holders themselves seem to have less problems implementing the correct monitoring arrangements which are well known to them from the application phase when they have been involved in the corresponding assessment work of ECHA.

**5. Infringements and enforcement measures**

At least one non-compliance with the REACH obligations checked in the scope of the REF-9 project was found in 203 of 502 reported inspections on substances from Annex XIV,

resulting in a 40 % non-compliance rate for inspected substances. 162 of the 404 companies inspected were non-compliant (40 %).

In general, the highest infringement rates can be seen for downstream user-related duties.

The main non-compliances of the 203 substance inspections for the detailed REACH requirements checked within the scope of the project are related to downstream user duties and are as follows:

- 26 % of substance inspections were not in compliance with Article 56(2) (using the substance in accordance with the conditions of a granted authorisation to an actor upstream in the supply chain for that use);
- 26 % of substance inspections were not in compliance with Article 37(5) (downstream user identifies, applies and, where suitable, recommends appropriate measures to adequately control identified risks); and
- 20 % of substance inspections were not in compliance with Article 66(1) (notification of downstream users using the substance in accordance with Article 56 (2).

Some cases could be identified, in which the inspected companies completely failed to observe REACH authorisation duties as the substance placed on the market or used did not have a valid authorisation, an application for authorisation had not been submitted or was still ongoing and there was no exemption from authorisation for the specific use. The rate of substance inspections that identified such "free riders (supply and use)", i.e. either users or duty holders placing on the market, was 3 %, which is a small proportion of the overall non-compliance rate of 40 %.

The three substances from Annex XIV that were most frequently involved in non-compliant cases were (in brackets the rate of non-compliance for each substance): lead sulfochromate yellow (63 %), strontium chromate (51 %) and chromium trioxide (35 %).

At the time of reporting the inspection, 254 enforcement measures were imposed by the enforcement authorities for the 203 substance inspections where non-compliances were identified. They are broken down as follows:

- 22 verbal advices;
- 111 written advices;
- 62 administrative orders;
- 17 fines;
- 10 criminal complaints/handing over to public prosecutor's office; and
- 32 other.

For those 203 inspections where non-compliant substances were reported, 147 (72 %) follow-up activities (e.g. further investigations) were still ongoing and 56 were completed (when the inspections were finished).

Regarding all 502 inspections carried out, the inspections were reported as completed for 302 inspections, while follow-up activities were still ongoing for 200 inspections at the time of reporting.

The high numbers of inspections in which not all follow-up activities were concluded by the time the project questionnaire for the inspection was submitted (up to 72 %, 147 out of 203 cases) indicates the high complexity of at least some of the details of the relevant investigations (supply chain communication which can involve several actors, assessment of the conditions for the substance uses at the borderline of REACH authorisation requirements and general national workplace safety or environmental legislation).

## 6. Conclusions and recommendations

### Key conclusions

The majority of substance inspections reported during the REF-9 project intentionally related to the role of downstream user duty holders (90 %). With this in mind, the most relevant conclusions of this project can be drawn concerning the use of the authorised substances by downstream users.

In general, the project shows an overall non-compliance rate of 40 %, both in terms of substance inspections and of companies. This is higher than the usual average level of non-compliance found by inspectors for provisions of EU chemicals legislation. This can be, in part, related to the situation that both placing authorised substances on the market and using of authorised substances in accordance with the conditions of the authorisation decision are new and complex duties for affected duty holders. The REF-9 inspections took place in 2021. This was only a few months after several upstream authorisation decisions for chromium trioxide came into force in December 2020.

Currently, there is no comprehensive ECHA guidance document available for suppliers and users of authorised substances which would clearly set out the details of the duties and requirements in terms of placing on the market and using authorised substances. Duty holders have just started to find answers and solutions for new requirements in relation to their obligations under Title VII of the REACH Regulation.

Non-compliance can also be related to the presence of very complex supply chains that present serious challenges in relation to the communication of information in a clear and concise form to the downstream users using the authorised substance.

In general, the highest non-compliance rates observed in this project were for duties related to downstream users (e.g. Article 56(2) or Article 37(5) of REACH).

*Inspection results related to the supply chain*

For downstream users, the very low level of communication of information by their supply chain both in terms of quantity and quality continues to be a serious impediment. The key obstacles are:

- In 35 % of inspections at downstream users, inspectors found that relevant information in relation to uses/OC/RMM/PPE or monitoring arrangements from the authorisation decision has not been communicated down the supply chain to the downstream users in the extended safety data sheet (SDS). Since Article 31(9) of REACH requires suppliers to update an SDS "without delay" once an authorisation is granted, this finding is alarming. This non-functioning of obligatory supply chain communication puts the risk management instrument covering downstream users by upstream authorisations (Article 56(2) of REACH) in question.
- A number of inspections identified, that the information provided in the SDS can be complex and difficult to understand for the downstream users resulting in a poor understanding of safety measures required by the downstream users. The challenge is similar to the one already reported in the 2018 REF-5 project[6].
- The extended SDS shows significant quality deficits and poor quality information (even information gaps) as identified in the inspections (see the analysis in Section 3.5).

[6] REF-5 project on the extended safety data sheets, exposure scenarios, risk management measures and operational conditions, see the report on the ECHA website

Downstream users often lack the experience and expertise to understand that they need to ask their suppliers for better quality information.

*Inspection results related to the use of authorised substances*

The inspections revealed that the majority of downstream users observe the basic authorisation requirements in relation to the use of an Annex XIV substance (e.g. the substance is authorised for the use or at least an application for this authorisation is submitted, or the use is exempted from authorisation requirements). There are only 2 % of use-related substance inspections that could establish that authorisation requirements have been ignored, that is, the Annex XIV substance was in a use requiring an authorisation - "free riders (use only)".

Downstream users are less compliant with the implementation of more complex authorisation requirements such as monitoring arrangements, notification of monitoring data to ECHA or implementation of risk reduction measures (Article 37(5) of REACH). This finding seems to be in line with the results of the assessment of the supply chain duties which have shown that the specific information in relation to the authorisation requirements is, in many instances, not communicated, not completely communicated or communicated with a poor quality to downstream users.

*Inspections focusing on authorised substances*

Authorisation conditions include measures which are also addressed by national workplace safety legislation or by national environmental legislation and the resulting overlapping obligations of the duty holders are not clearly clarified in the authorisation decisions or in related guidance. In general, REACH inspectors in many cases do not have the full knowledge to check environmental and workplace safety requirements. It, therefore, remains difficult to conduct inspections for these overlapping obligations.

**Key recommendations**

**To industry**

1. **Suppliers** to improve the quality and completeness of the extended safety data sheets in relation to the conditions of use of the authorised substances to ensure compliance as an actor in the supply chain and to ensure that all relevant information is communicated down the supply chain in clear and concise language, which can be easily understood by the downstream users. In particular, the prompt update of safety data sheets according to Article 31(9) of REACH and according to the deadlines specified in the authorisation decisions is critical. It is important that the safety data sheets are in the languages of the Member States.
2. **Suppliers** to actively communicate by all possible means to downstream users in relation to their obligations when using the authorised substance. This shall also include the procedures to follow in relation to requests for further clarification of information in relation to authorisation conditions and particularly to the operating conditions/risk management measures required in relation to the specific uses of the downstream user.
3. **Downstream users** to ensure that if they use a substance subject to authorisation that they use it in accordance with the conditions of use and particularly in accordance with the operational conditions and risk management measures set out in the authorisation decision for their specific use. If it is unclear from the extended safety data sheet what operational conditions and risk management measures are required for their specific use, then they should seek

clarification from their supplier of the substance. In addition, downstream users also have to ensure that the Article 66 notification is kept up-to-date including an update if they cease to use the authorised substance.

**To the inspectors**

The general awareness of suppliers and actors in the supply chain including downstream users in relation to authorisation duties needs to be improved.

Inspectors are encouraged to assist in raising awareness with the various duty holders in respect to their specific obligations in relation to authorised substances under REACH as part of their regular contact with these duty holders.

**To ECHA Secretariat**

The ECHA Secretariat to develop a comprehensive and consistent guidance to suppliers and users of authorised substances. Also the two previous Forum pilot projects on authorisation identified the need for a comprehensive ECHA guidance document which provides clarification and guidance to suppliers and users of authorised substances in relation to their duties and provides answers and solutions for them to enhance compliance. Results of the REF-9 project clearly confirm the lack of such comprehensive and consistent guidance.

**To the European Commission**

1. The European Commission to ensure that the most up-to-date succinct summaries/chemical safety reports/authorisation decisions are available on one dedicated website as these are the primary/authoritative sources of information used by enforcing inspectors in the various Member States when enforcing authorisation duties.
2. Authorisation decisions should be clear enough to be implemented by duty holders and to enable effective enforcement:
   - The authorisation decision should always clearly identify who is the responsible actor when it comes to the authorisation conditions. This allows the relevant actor in the enforcement to be addressed.
   - Authorisation decisions should be published in the language of all relevant Member States (i.e. for upstream authorisations also in the languages of the Member States in which downstream users are using the authorised substances).
   - Duties for providing information in the supply chain between the authorisation holder and downstream users using authorised substances should explicitly and in detail be regulated in the authorisation decision for all suppliers. This will improve communication in the supply chain.
   - In general, overlap with other existing relevant legislation should be considered and clarified in the conditions of the authorisation decision (e.g. monitoring requirements in workplace safety or in environmental legislation or hierarchy of control of occupational safety and health (OSH)).
   - For monitoring requirements, details on the measuring method (sampling and laboratory analysis) need to be regulated in the authorisation decision to ensure a harmonised approach for this authorisation condition.
   - Authorisation decisions should follow the general principles of implementability and enforceability, i.e. technical requirements are clarified in the decision with the required details or with a reference to an approved standard setting out the details of the technical requirement included in the decision.

## 7. Summary of key indicators

The result related to the main project indicators are presented in Table 1.

The results from the REF-9 project are compared with the results from the previous Forum pilot projects on authorisation in Table 1. In previous pilot projects on authorisation, a number of different substances from Annex XIV were checked. A smaller number of countries participated in the previous pilot projects. Therefore, the data is not directly comparable and it is displayed primarily for information purposes only.

A major difference between REF-9 and the two previous pilot projects was the nature of the substances from Annex XIV that have been checked. In the pilot projects, the main focus was on substances from Annex XIV for which an application for authorisation had not been submitted and, in this way, the inspections focused on potential illegitimate placing on the market or use of the substance. These pilot project inspections did not require the same level of resources to complete compared to the high level of resources required to complete the checks as part of the REF-9 project. The number of inspections completed in the second pilot project was potentially higher for this reason.

**Table 1**. Main project indicators

| No | Indicator | REF-9 (2021) | 1st pilot project on authorisation[7] (2015) | 2nd pilot project on authorisation[8] (2016) |
|---|---|---|---|---|
| 1 | Number of inspections on substances | 502 | 421 | 802 |
| 2 | Number of participating countries | 28 | 18 | 17 |
| 3 | Number of inspected companies | 404 | 235 | 802 |
| 4 | Number of non-compliant substance inspections | 203 | 3 | 12 |
| 5 | % of non-compliant substances [%] | 40 | 0.7 | 1.6 |
| 6 | Number of different substances checked from Annex XIV | 43 | 2 | 13 |

[7] First Forum pilot project on authorisation: project report

[8] Second Forum pilot project on authorisation: project report

# II. Project overview

An EU-wide enforcement project also including EEA countries was carried out with the aim to check compliance with REACH authorisation requirements regarding placing on the market and use of all substances listed in the Authorisation List (Annex XIV to the REACH Regulation) with sunset dates that had passed by the project start date (January 2021).

A total of 43 substance entries from Annex XIV and 75 individual substances of very high concern with defined substance identity (see Annex I: 'The REF-9 questionnaire') were included within the scope of the project.

In the REF-9 project, substances were inspected in chemical products (substances or mixtures). The chemical products checked and the substances subject to the inspection in these chemical products were selected once a substance listed in the Authorisation List in a concentration above 0.1 % w/w was identified as a constituent.

In general, for a substance for which the sunset date in Annex XIV has passed, the project checked whether:

- the relevant authorisation was granted for placing that substance on the market and for its use(s) or whether the application submitted for authorisation of use(s) was still under assessment by the authorities or whether a specific exemption from authorisation was applied for the use(s); and
- timely Article 66 downstream user notifications have been submitted; and
- the substance was used in accordance with the conditions set out in the authorisation decision; and
- once applicable, the review provisions specified in the authorisation decision have been observed in time.

Accordingly, if an authorisation has not been granted at the time of inspection, companies were checked that either they themselves have submitted an application for authorisation (AfA) for placing the substance on the market and for its uses, or that an actor further up the supply chain had submitted an application for authorisation. Only once a specific exemption from authorisation could be applied for the use checked, was this investigation not necessary.

The project also checked if the downstream users of Annex XIV substances, with sunset dates that have passed, were part of a valid supply chain covered by an authorisation or by an application for authorisation, and if users of Annex XIV substances in general were operating in line with the conditions set out in the authorisation or a specific exemption from authorisation could be applied.

Finally, the project also checked obligations for suppliers related to information in the supply chain in relation to authorisation provisions.

The project targeted manufacturers, importers, only representatives and downstream users (formulators, end users) across the EU.

The results of this project are derived from the answers of the inspectors to the questions in the questionnaire (see Annex I: 'The REF-9 questionnaire').

For each substance inspected (substance suspected to be listed in Annex XIV) in the inspected company, one questionnaire was filled in.

In some companies, the inspector just checked one substance, filling-in one questionnaire for that company covering the substance checked. In other companies, the inspector checked more than one substance, filling-in several questionnaires for the same company, one for each of the substances inspected. The questionnaire was also limited to a check of one specific use of the targeted substance. Accordingly, one inspection means one questionnaire completed for one substance inspected and for one specific use.

The decision in relation to which companies and Annex XIV substances to inspect was determined by the participating countries.

Inspectors decided to focus on the use of the identified Annex XIV substance with sunset dates that had passed by the project start date.

Substances with sunset dates after January 2021 were not checked by inspectors as part of the REF-9 project.

The operational phase of the project ran from January to December 2021. The participating countries were supported by the ECHA Forum Working Group 'Coordinated enforcement project REACH-EN-FORCE-9'.

**Table 2.** REACH provisions enforced under the REF-9 project

| Articles | Summary |
|---|---|
| 31 | The requirement for the supplier to include the substance identities and authorisation numbers in the SDS (authorisation requirements for SDSs according to Annex II of the REACH Regulation as amended by Regulation (EU) Nr 2015/830)[9]. |
| 37(5) | The requirement for a downstream user to identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified. |
| 56(1)(a),56(1)(b), 56(1)(e), 56(3), 56(4), 56(5), 56(6)[10] | The requirement not to place on the market for a use or use a substance covered within the scope of authorisation, after the sunset date unless the use is exempted or an authorisation for that use has been granted to his immediate downstream user. |
| 56(2) | The requirement for a downstream user to use a substance subject to authorisation in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use. |
| 60(9)(d), 60(9)(f) | The use is in accordance with the conditions or monitoring arrangements specified in the authorisation decision. |
| 61(1) | Review of authorisations. Submission of an update by the holder of an authorisation. |
| 65 | The requirement for a holder of an authorisation to include the authorisation number on the labels. |
| 66(1) | The requirement for downstream users using a substance in accordance with Article 56(2) to notify ECHA within three months of the first supply of the substance. |

[9] Annex II to the REACH Regulation as amended by Regulation (EU) Nr 2020/878 was not relevant in this project as it was mandatory only from 1 January 2023 onwards.

[10] Additional exemptions apply under Article 2(5) for uses in medicinal products and in food or feeding stuff and under Article 2(8) for intermediates, see Annex 1.

All inspections on substance suspected to be listed in Annex XIV reported with a filled in questionnaire from the participating European countries have been collected and considered in the compilation of this REF-9 project report. The inspection results of the participating countries cover both the placing on the market and the use of the inspected substances.

**Legal obligations covered in this project**

This REF-9 project on authorisation was limited to obligations stipulated by the REACH Regulation. Obligations imposed by the CLP Regulation were not included. Table 2 shows the REACH provisions related to REACH authorisation requirements enforced under the REF-9 project.

# III. Results of the project

## 3.1. Participating countries and number of inspections

**All inspections reported:**

28 European countries[11] participated in the project and submitted 690 questionnaires associated with the inspections. The number of questionnaires filled in equals the number of inspected substances suspected to be listed in Annex XIV with a sunset date that has passed by January 2021, not the number of inspected companies. Each participating country decided on the number of inspections to be conducted.

There were 188 inspections submitted where the inspection revealed that no substance from Annex XIV was actually placed on the market or used by the company at the time of the inspection, despite initial suspicions that a substance from Annex XIV may have been placed on the market or used. The results from those 188 inspections are not included in the detailed analysis in this report.

Those 188 inspections do not represent the situation in all participating countries, as some countries did not report back on inspections that turned out not to involve substances listed in Annex XIV. The countries that decided to report the 188 inspections provided the following reasons for conducting those inspections:

- The authorised substances were no longer used or placed on the market as they were phased out or replaced/substituted in the inspected company.
- The companies were more broadly selected by inspectors based on their company profile or activity: e.g. having submitted relevant REACH pre-registration data, suspected use and/or import of substance from Annex XIV on the basis of industrial site permits, considering the company activities and identification from customs data on consignments covered by relevant customs tariff numbers that could include the substance from Annex XIV under investigation. However, during the detailed investigation of the inspectors no substances from Annex XIV could eventually be found.
- The inspected company was an authorisation holder with a valid authorisation but has not yet started to use the authorised substance.

While the majority of the 188 cases are linked to reasons listed in the second indent, replacement and substitution of substances from Annex XIV has also been observed by inspectors for two different situations. In the first instance, inspectors were aware that the company had substituted the Annex XIV substance before commencing the REF-9 inspections and, in many instances, the company was not inspected as part of the REF-9 project. In the second situation, the substitution of the substance from Annex XIV only became apparent during the course of the REF-9 inspection. Whether the second situation was reported under REF-9 was dependent on the reporting country.

**Inspections included in detailed analysis**

The WG decided to focus the analysis and findings in the REF-9 project report on 502 out of the 690 inspections (73 % of all inspections submitted) where a relevant substance

[11] AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LI, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI and SK

from Annex XIV was placed on the market or used at the time when the inspection took place.

Therefore, all the results of the REF-9 project were calculated for the 502 inspections.

The number of reported inspections of substances per country together with the number of companies inspected in each country is presented in Table 3.

**Table 3.** Reported inspections per country included in detailed analysis[12]

| No | Country | Inspections included in detailed analysis | |
|---|---|---|---|
| | | Number of relevant substance inspections per country (where the substance was placed on the market or used) | Number of inspected companies per country (where the substance was placed on the market or used) |
| 1 | AT | 15 | 15 |
| 2 | BE | 22 | 15 |
| 3 | BG | 16 | 14 |
| 4 | CY | 1 | 1 |
| 5 | CZ | 8 | 8 |
| 6 | DE | 77 | 70 |
| 7 | DK | 11 | 11 |
| 8 | EE | 1 | 1 |
| 9 | EL | 9 | 8 |
| 10 | ES | 38 | 23 |
| 11 | FI | 14 | 14 |
| 12 | FR | 40 | 32 |
| 13 | HR | 10 | 8 |
| 14 | HU | 15 | 9 |
| 15 | IE | 18 | 13 |
| 16 | IT | 33 | 30 |
| 17 | LI | 9 | 2 |
| 18 | LT | 5 | 5 |
| 19 | LU | 9 | 6 |
| 20 | LV | 1 | 1 |
| 21 | NL | 28 | 20 |
| 22 | NO | 14 | 9 |

[12] See explanation in Section 3.1.

| | | | |
|---|---|---|---|
| 23 | PL | 55 | 46 |
| 24 | PT | 17 | 11 |
| 25 | RO | 8 | 6 |
| 26 | SE | 18 | 17 |
| 27 | SI | 3 | 3 |
| 28 | SK | 7 | 6 |
| | **SUM** | **502** | **404** |

## 3.2. Type of companies and substances inspected

404 companies inspected during the 502 substance inspections were selected for detailed analysis in the project report. The reported 502 inspections were related to 31 different substances from Annex XIV.

Inspections were executed both on-site (in 79 % of cases) and at desktops only (in 21 %).

While only 19 % of inspections focusing on the use of substances from Annex XIV have been desktop inspections, 38 % of inspections focusing on placing the Annex XIV substance on the market were desktop based. For example, two-thirds of the inspections on uses and three-quarters of inspections on placing on the market covered by exemptions from the authorisation requirements (see Section 3.3.2) have been conducted by desktop inspections. The inspections of exemptions do not need on-site visits as they can be primarily documentation-based investigations.

### 3.2.1. Type of companies inspected

Inspectors indicated in the questionnaires the main NACE[13]-codes of the 404 companies inspected. It resulted in the identification of 104 NACE economic sectors. For the sake of general insight, these values were grouped in sets of key economic sectors (see Table 4). As can be seen in the table a majority of the companies inspected indicated a 'manufacturing' activity (337) (see detailed division in Table 5), followed by the economic sector 'wholesalers and retail trade - repair of motor vehicles and motorcycles' and by the sector 'professional, scientific and technical activities'. Quite some companies also stated that their main activity was 'transportation and storage'. It is important to note that NACE 'manufacturing' does not mean manufacturer in the REACH context but all manufacturing activities: manufacturing of substances, formulation of mixtures and production of articles.

[13] NACE (Nomenclature des Activités Économiques dans la Communauté Européenne) is a European industry standard classification system.

**Table 4.** Economic sectors addressed during the REF-9 project

| | NACE code | Number of inspected companies |
|---|---|---|
| A - Agriculture, forestry and fishing | 01.11-3.22 | 3 |
| **C - Manufacturing** | 10.11-33.20 | **337** |
| D - Electricity, gas, steam and air conditioning supply | 35.11-35.30 | 5 |
| E - Water supply; sewage, waste management and remediation activities | 36.00-39.00 | 3 |
| F - Construction | 41.10-43.99 | 2 |
| **G - Wholesale and retail trade; repair of motor vehicles and motorcycles** | 45.11-47.99 | **21** |
| H - Transportation and storage | 49.10-53.20 | 9 |
| J - Information and communication | 58.00-63.99 | 2 |
| K - Financial and insurance activities | 64.11-66.30 | 2 |
| **M - Professional, scientific and technical activities** | 69.10-75.00 | 17 |
| O - Public administration and defence; compulsory social security | 84.00-84.30 | 1 |
| P - Education | 85.00-85.96 | 1 |
| R - Arts, entertainment and recreation | 90.00-93.29 | 1 |
| | **Grand Total** | **404** |

This distribution shows that most of the companies addressed have their main economic activities in the following sectors:

– C – Manufacturing (NACE codes 10.1-33.20) – 83 %. This sector can be detailed as shown in Table 5.
– G – Wholesale and retail trade; repair of motor vehicles and motorcycle (NACE codes 45.11-47.99) – 5 %,
– M – Professional scientific and technical activities (NACE codes 69.10-75.00) – 4 %.

**Table 5.** Detailed distribution of the economic sector 'C- Manufacturing' with a split up in NACE groups for the most numerous NACE divisions C20, C25 and C30

| NACE | Number of inspected companies |
|---|---|
| 10 Manufacture of food products | 1 |
| 13 Manufacture of textiles | 2 |
| 15 Manufacture of leather and related products | 1 |
| 16 Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting mat | 1 |
| 18 Printing and reproduction of recorded media | 9 |
| 19 Manufacture of coke and refined petroleum products | 3 |
| 20 Manufacture of chemicals and chemical products<br>• 20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms<br>• 20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics<br>• 20.4 Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations<br>• 20.5 Manufacture of other chemical products<br>• 20.6 Manufacture of man-made fibres | 46<br>• 19<br>• 12<br>• 1<br>• 13<br>• 1 |
| 21 Manufacture of basic pharmaceutical products and pharmaceutical preparations | 8 |
| 22 Manufacture of rubber and plastic products | 15 |
| 23 Manufacture of other non-metallic mineral products | 8 |
| 24 Manufacture of basic metals | 9 |
| 25 Manufacture of fabricated metal products, except machinery and equipment<br>• 25.1 Manufacture of structural metal products<br>• 25.2 Manufacture of tanks, reservoirs and containers of metal<br>• 25.4 Manufacture of weapons and ammunition<br>• 25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy<br>• 25.6 Treatment and coating of metals; machining<br>• 25.7 Manufacture of cutlery, tools and general hardware<br>• 25.9 Manufacture of other fabricated metal products | 143<br>• 4<br>• 1<br>• 3<br>• 1<br>• 122<br>• 6<br>• 6 |
| 26 Manufacture of computer, electronic and optical products | 3 |
| 27 Manufacture of electrical equipment | 3 |
| 28 Manufacture of machinery and equipment n.e.c | 21 |
| 29 Manufacture of motor vehicles, trailers and semi-trailers | 5 |

| | |
|---|---|
| 30 Manufacture of other transport equipment<br>• 30.3 Manufacture of air and spacecraft and related machinery<br>• 30.9 - Manufacture of transport equipment n.e.c. | 42<br>• 36<br>• 1 |
| 31 Manufacture of furniture | 6 |
| 32 Other manufacturing | 4 |
| 33 Repair and installation of machinery and equipment | 13 |
| **Sum** | **337** |

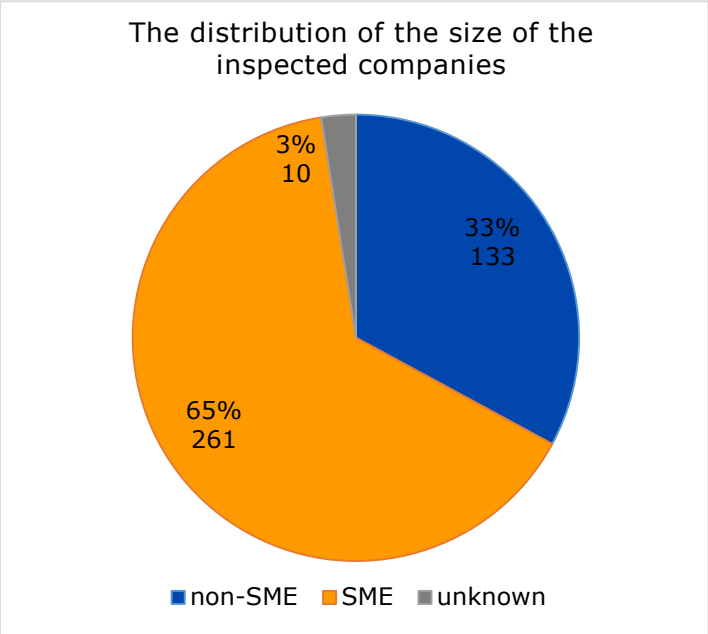
Table 5 shows that the inspections focused mainly on companies that are engaged in the NACE activity 'treatment and coating of metals; machining' or 'manufacture of other transport equipment'. This focus on companies is in line with the reported focus on the inspected substances from Annex XIV and the focus on the kind of uses (see Section 3.2.2): focus on the substances chromium trioxide and some chromates and the related use focus on 'functional chrome plating' and 'surface treatment' and a focus on the substance strontium chromate and the related use focus 'speciality coating'.

Company size

65 % of the companies inspected (261) were small and medium-sized enterprises (SMEs) according to the criteria of Commission Recommendation 2003/361/EC.

Chart 1 presents the overall distribution of the size of the inspected companies.

**Chart 1.** The distribution of the size of the inspected companies




Company role

The companies inspected could have one or more of six different roles:

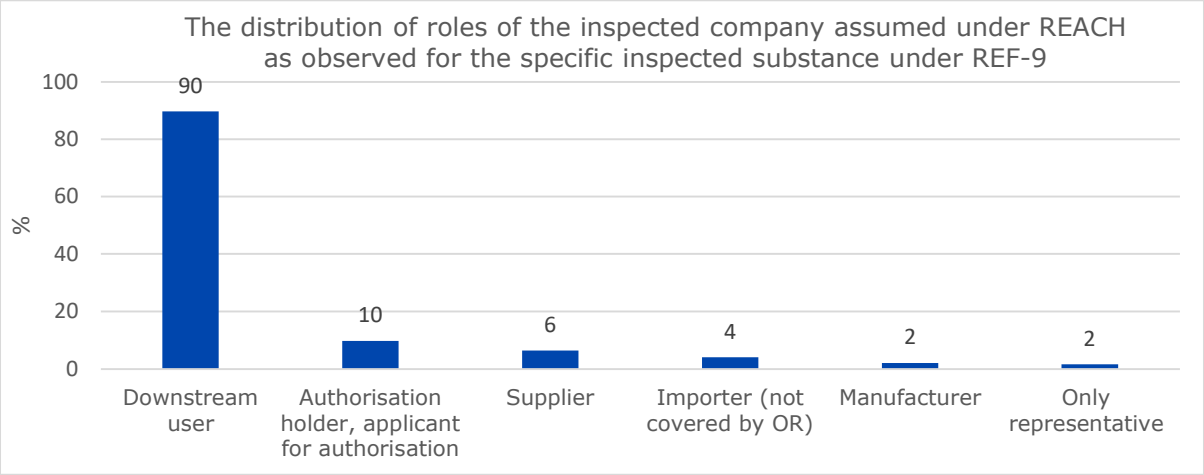
1. Manufacturer;
2. Importer (company not covered by an OR);
3. Only representative (OR) for the authorisation/for registration;

4. Downstream user (e.g. formulator, producer of an article, importer covered by an OR, end user);
5. Supplier; and
6. Authorisation holder, applicant for authorisation.

The company could assume all or part of these roles for a particular inspected substance (see Chart 2).

The received questionnaires showed that in 59 (12 %) of 502 inspections of the substances, the inspected companies played more than one role under REACH as observed for the specific inspected substance under REF-9.

**Chart 2.** The distribution of roles of the inspected company assumed under REACH as observed for the specific inspected substance under REF-9 (each company may assume more than one role)




In 443 of the 502 (88%) inspections, the companies inspected assumed only one role (81 % were only downstream users, 3 % only authorisation holders and 2 % only suppliers).

Accordingly, also in two-thirds of the 98 inspections focusing on substances from Annex XIV that were placed on the market, it could be established that the company inspected was a downstream user with respect to the inspected substance (e.g. the company was also formulating, mixing, bottling).

### 3.2.2. Substances inspected

During the 502 inspections, 31 different substances from Annex XIV were checked. In accordance with the scope of the REF-9 project, a total of 43 substance entries from Annex XIV (covering 75 substances of very high concern with a defined substance identity) have been included in the checklist (see Annex I 'The REF-9 questionnaire').

73 different identified uses of the substances from Annex XIV which have been defined either in the application for authorisation or in the authorisation decision were checked.

There were an additional 63 uses of the substances inspected and reported, however, those inspections revealed that the uses of those substances were mainly subject to exemptions: use as an intermediate or use in scientific research and development.

For one substance, several identified uses could be checked in the same company, but each identified use was reported as a separate inspection.

The most frequently checked substances were chromium trioxide (in 237 substance inspections), strontium chromate (61), trichloroethylene (30), sodium dichromate (26), potassium dichromate (24) and lead sulfochromate yellow (C.I. Pigment Yellow 34) (24).

The most frequently checked uses during the inspections were:

- 103 inspections in 18 countries of the use 'Functional chrome plating',
- 57 inspections in 14 countries of the use 'Application of paints, primers and specialty coatings containing strontium chromate in the construction of aerospace and aeronautical parts, including aeroplanes / helicopters, spacecraft, satellites, launchers, engines, and for the maintenance of such constructions',
- 38 inspections in 15 countries of the use 'Surface treatment for applications in the aeronautics and aerospace industries, unrelated to functional chrome plating or functional chrome plating with decorative character',
- 30 inspections in 16 countries of the use 'Surface treatment (except passivation of tin-plated steel (ETP)) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering (unrelated to functional chrome plating or functional chrome plating with decorative character)'.

98 (20 %) substance inspections were undertaken where inspectors checked more than one substance from Annex XIV in one company. Detailed country-specific information is shown in Table 3.

## 3.3. Compliance with authorisation duties

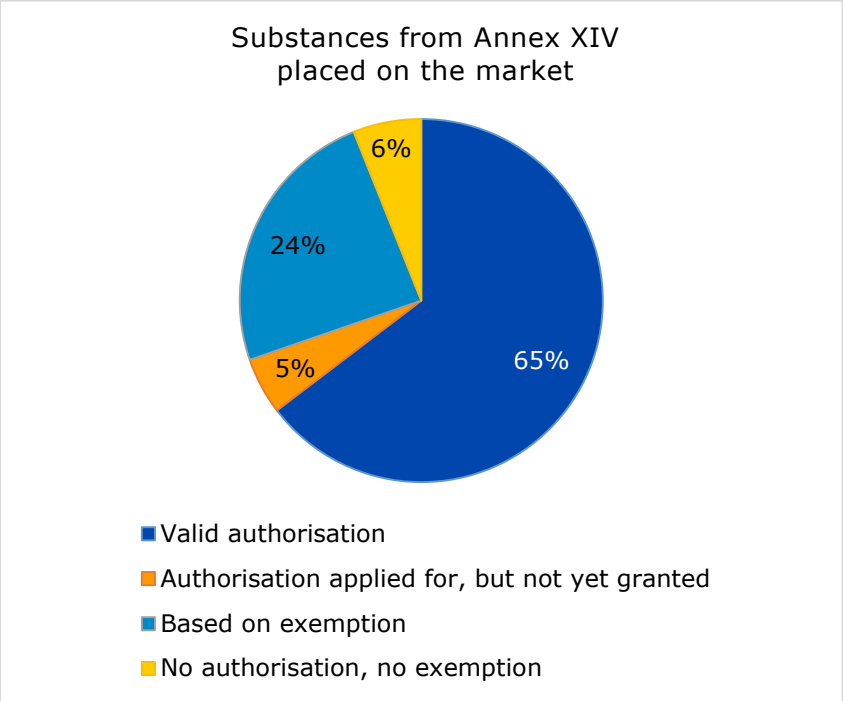
Inspectors checked if:

- the companies inspected (as a manufacturer, importer or downstream user, supplier) placed the substances subject to authorisation on the market for the specified uses after their sunset dates as set out in Annex XIV to REACH;
- the companies inspected used the substances subject to authorisation after their sunset date had passed, for the specified uses;
- the substance was used in accordance with the conditions set out in the authorisation decision; and
- exemptions from the authorisation requirement apply.

### 3.3.1. Placing of the substance on the market

A total of 502 inspections of substances from Annex XIV were reported as part of the REF-9 project. In 98 inspections, the substances from Annex XIV subject to inspection were placed on the market for a selected use (see Chart 3).

**Chart 3.** Substances from Annex XIV placed on the market




64 out of 98 (65 %) inspections found that the authorised substances were placed on the market based on an authorised use:

- 16 (25 %) inspections found that substances were placed on the market under the company's own authorisation. These companies were based in seven countries. The substances placed on the market under the companies' own authorisation were (in brackets the number of inspections):
    - 1,2 Dichloroethane (2)
    - Chromium trioxide (4)
    - Diarsenic trioxide (1)
    - Dichromium (tris) chromate (1)
    - Lead chromate molybdate sulphate Red (1)
    - Lead sulfochromate Yellow (1)
    - Sodium dichromate (2)
    - Strontium chromate (3)
    - Trichloroethylene (1)
- 48 (75 %) inspections found that substances were placed on the market under an upstream authorisation. The companies placing the substances on the market based on an upstream authorisation were based in 17 countries. The substances placed on the market under an upstream authorisation were (in brackets the number of inspections):
    - Chromium trioxide (25)
    - Lead sulfochromate Yellow (9)
    - Lead chromate molybdate sulphate Red (5)
    - Potassium hydroxyoctaoxodizincatedichromate (1)
    - Sodium dichromate (1)
    - Strontium chromate (5)
    - Trichloroethylene (2)

- The authorisation was valid for the relevant use with respect to the review provisions specified in the authorisation decision and Article 61 of REACH in 100 % of the inspections of authorised substances.

5 (5 %) inspections of authorised substances from Annex XIV found that they had been placed on the market based on a valid application for authorisation having been submitted but for which an authorisation decision had not been granted at the time of inspection:

- The specific use in 4 inspections of the substances from Annex XIV was covered in the application for authorisation submitted.
- The specific use of 1 of these substances inspected was not covered by the application for authorisation submitted[14].

**Table 6** details the number of inspected substances from Annex XIV which were placed on the market for a use covered by an exemption.

| Exemption | Frequency |
|---|---|
| On-site isolated intermediate/transported isolated intermediate | 4 |
| Use in medicinal products and/or the immediate packaging of medicinal products | 1 |
| Use in food or feeding stuffs | 0 |
| Use in scientific research and development | 17 |
| Use on plant protection products | 0 |
| Use in biocidal products | 0 |
| Use as motor fuel | 0 |
| Use as fuel in combustion plants of mineral oil products | 0 |
| Use in cosmetic products | 0 |
| Use in food contact materials | 0 |
| Use of substances referred in Article 57 d, e, and f when present in mixtures below a concentration limit of 0.1% w/w | 0 |
| Use of substances when present in mixtures below the lowest of the concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to Regulation (EC) No. 1272/2008 which results in classification of the mixture as dangerous | 0 |
| Others (e.g. use of/in an article) | 1 |
| **Total** | **23** |

A total 23 (24 %) inspections of substances from Annex XIV found that they were placed on the market for a use covered by a legitimate exemption (see Table 6).

[14] In case of an application for authorisation, "use" could only be interpreted in broad terms

A total of 6 (6 %) supply-related inspections found that the substances from Annex XIV have been placed on the market in breach of REACH authorisation obligations (Article 56(1) of REACH) – "free riders (supply only)":

- they did not have a valid authorisation;
- there was no ongoing/pending application for authorisation;
- there was no exemption from authorisation for their specific use[15].

In 62 inspections where substances from Annex XIV were placed on the market by the companies based on a granted authorisation, the results found that in:

- 45 (73 %) inspections the company provided the authorisation number on the label.
- 17 (27 %) inspections the company did not provide the authorisation number on the label.
- 45 (73 %) inspections the company provided a safety data sheet that contained the authorisation number(s) for the substances inspected.
- 17 (27 %) inspections the company did not provide a safety data sheet that contained the authorisation number(s) for the substances inspected.

In 19 % of cases with missing authorisation numbers on the label of an authorised substance a non-compliance of authorisation holders or downstream users (formulators) was identified by inspectors based on Article 65 of REACH which requires these two duty holders to ensure proper labelling. The remaining cases of missing authorisation numbers were related to other suppliers having no duties according to Article 65.

The figures show that there is no difference in the non-compliance rate for the obligation to include an authorisation number in the product label or in the safety data sheet (SDS). From the inspection data, it can be deduced that once a company is not providing the authorisation number on the label, it also does not provide the number in the SDS.

See Section 3.5.1 for more details on the inspector's checks of duties of the suppliers placing authorised substances on the market.

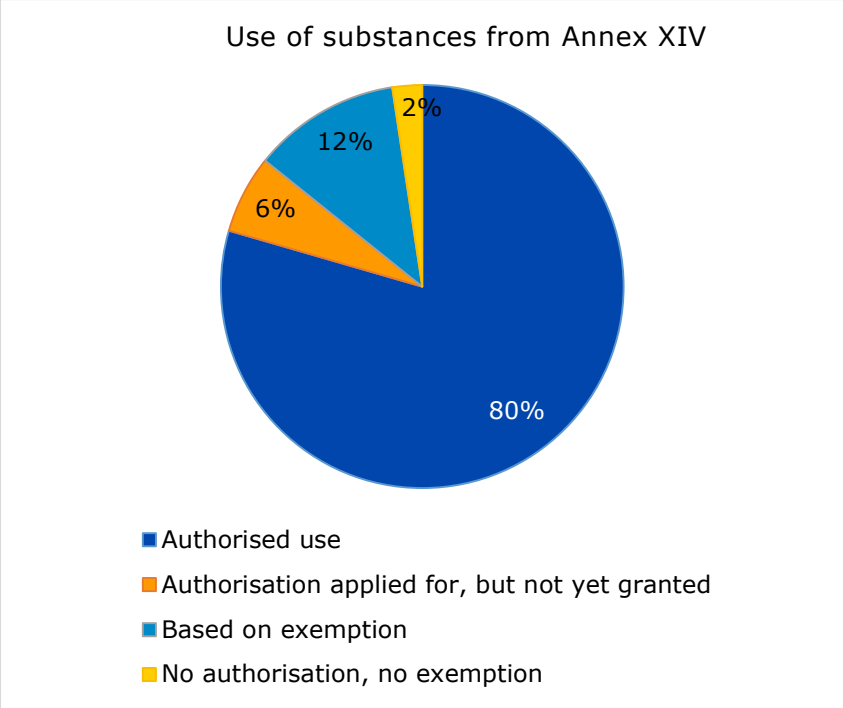
### 3.3.2. Use of the substance

A total of 502 inspections of substances from Annex XIV were reported as part of the REF-9 project. The results indicate that in 463 inspections, the substances from Annex XIV were used by companies for the selected use after the sunset date. In 39 inspections, the substances were not used but only placed on the market by the inspected company after the sunset date[16] (see Chart 4).

[15] See Section 3.6.1 for the overall non-compliance related to the placing on the market of substances from Annex XIV as indicated by the inspectors after their full assessment of the inspection case.

[16] Calculations in the detailed analysis focus on those substance that were placed on the market or used. In 39 inspections the substances were only placed on the market but not used. These inspection findings are covered in Section 3.3.1

**Chart 4.** Use of the substances from Annex XIV




368 out of 463 (80 %) inspections found that the authorised substances were used based on an authorised use:

- 44 (12 %) inspections where substances were used based on the companies' own authorisation. The following substances were used by companies in 14 countries (in brackets the number of inspections):
  - Chromium Trioxide (22)
  - 1,2 Dichloroethane (7)
  - Lead sulfochromate Yellow (1)
  - Lead chromate molybdate sulphate Red (1)
  - Sodium dichromate (6)
  - Strontium chromate (1)
  - Arsenic acid (1)
  - Bis (2-ethpxymethyl)ether Diglyme (2)
  - Diarsenic trioxide (1)
  - Coal Tar Pitch, high temperature (2)
- 324 (88 %) inspections where substances were used based on an upstream authorisation. The substances were used by the companies in 25 countries (in brackets the number of inspections):
  - Chromium trioxide (178)
  - Diarsenic trioxide (1)
  - Dichromium tris (chromate) (12)
  - Lead chromate molybdate sulphate Red (9)
  - Lead sulfochromate molybdate sulphate Yellow (17)
  - Pentazinc chromate octahydroxide (4)
  - Potassium dichromate (6)
  - Potassium hydroxyoctaoxodizincatedichromate (12)
  - Sodium dichromate (11)
  - Strontium chromate (54)

- The authorisation was valid for the relevant use with respect to the review provisions specified in the authorisation decision and Article 61 of REACH for 356 (98 %) inspections of the authorised substances. It was not valid in 9 (2 %) inspections of substances.

A total of 29 (6 %) inspections found that the substances from Annex XIV have been used by companies based on a valid application for authorisation having been submitted but an authorisation decision had not been granted at the time of inspection:

- The specific use in 27 (93 %) inspections of the substances from Annex XIV was covered in the application for authorisation submitted.
- The specific use in 2 (7 %) inspections of the substances from Annex XIV was not covered by the application for the authorisation submitted[17].

A total 55 (12 %) inspections of substances from Annex XIV found that they were used for uses covered by a legitimate exemption (see Table 7).

**Table 7** details the number of inspected substances from Annex XIV which were used for uses covered by an exemption.

| Exemption | Frequency |
|---|---|
| On-site isolated intermediate/transported isolated intermediate | 7 |
| Use in medicinal products and/or the immediate packaging of medicinal products | 1 |
| Use in food or feeding stuffs | 0 |
| Use in Scientific Research and Development | 43 |
| Use on plant protection products | 0 |
| Use in biocidal products | 0 |
| Use as motor fuel | 0 |
| Use as fuel in combustion plants of mineral oil products | 0 |
| Use in cosmetic products | 1 |
| Use in food contact materials | |
| Use of substances referred in Article 57 d, e, and f when present in mixtures below a concentration limit of 0.1%w/w | 0 |
| Use of substances when present in mixtures below the lowest of the concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to Regulation (EC) No. 1272/2008 which results in classification of the mixture as dangerous | 0 |
| Others (e.g. use of/in an article) | 3 |

[17] In case of an application for authorisation, "use" could only be interpreted in broad terms

A total of 11 (2 %) use-related inspections of substances from Annex XIV found that the substances have been used in breach of REACH authorisation obligations (Article 56(1) or Article 56(2) of REACH)[18] – "free riders (use only)":

- they did not have a valid authorisation;
- there was no ongoing/pending application for authorisation;
- there was no exemption from authorisation for their specific use.

See Sections 3.5.2 and 3.5.3 for more details on the inspector's checks of duties of companies using an authorised substances on the market.

## 3.4. Enforceability of the authorisation conditions/chemical safety report/succinct summary

### Authorisation decision

In 399 out of the 502 inspections of substances from Annex XIV, the authorisation decisions were granted for the uses. In the remaining 103 inspections, the authorisation decisions were not granted for the substances checked due to reasons indicated in Sections 3.3.1 and 3.3.2 (pending applications for authorisation, uses exempted from authorisation)[19].

In the REF-9 project, inspectors also reported their experience in relation to the application of the authorisation decisions (with the chemical safety report (CSR)), the succinct summaries, the (extended) safety data sheet (SDS) and the enforceability of these formal documents during their inspections of authorisation conditions.

### Authorisation conditions

The authorisation conditions were clear enough to enable effective enforcement during 353 inspections of the authorised substances. They were less clear to enable effective enforcement during 43 inspections of the authorised substances. The inspectors indicated the following difficulties in relation to the enforceability of the conditions required in the authorisation decision:

- Extended safety data sheets were difficult to understand with respect to the information in the authorisation conditions. In addition, translation of the authorisation decisions into all EU official language versions would be helpful. In other inspections, the supplier did not provide a sufficient extended SDS, and relevant information is communicated through guidance documents, random monitoring was therefore based on these specifications.
- In various cases the authorisation decision was not sufficiently clear on the deadline applicable to obligations for downstream users and in another case it was not clear to which actor (authority) the downstream user should report their monitoring.
- It was also indicated that there was uncertainty as to which conditions in the decision apply to the workplace or the environment. There were difficulties to exactly match on-site use and use descriptions in the authorisation decision. It was also indicated that there were no exposure limits and best available technique associated emission

[18] See Section 3.6.1 for the overall non-compliance related to the use of substances from Annex XIV as indicated by the inspectors after their full assessment of the inspection case.

[19] In this section, results for substances for which the final decision on authorisation was pending are not provided.

levels (BAT AEL) provided for the downstream user who was in a Member State other than the authorisation holder, or the given workplace exposure limits were not in line with national rules, or the succinct summary allows the use of a wide spectrum of APF in relation to the durations of activity with an impact directly on the prevention and protection measures.

- In another case, an updated chemical safety report/succinct summary was not available on ECHA's website and neither were the updated exposure scenarios communicated in the supply chain through the extended safety data sheet. Another inspector mentioned that for enforceability, the consultation of ECHA's Committee for Risk Assessment (RAC) or the short summary of this is required. Also indicated as difficulties were the descriptions of the process categories in the extended safety data sheet, they were not described detailed enough compared to the descriptions consulted in RAC. In another case biomonitoring was not mentioned in the authorisation decision. The timing of environmental monitoring established under national procedure is different from that established under REACH authorisation decision.

**Succinct summary**

The succinct summary was used during 221 inspections of authorised substances. In 169 inspections, inspectors found that the information in the succinct summary was appropriate to easily enforce the authorisation decision. However, in 32 inspections of authorised substances, inspectors found that the information in the succinct summary was not appropriate to easily enforce as the following information was missing in the succinct summary:

- additional information on PPE (especially which assigned protection factors (APFs));
- completeness of steps in the CSR and availability of the succinct summary in the language of the country;
- an updated succinct summary was not always available on ECHA's website;
- the description of the RMMs was insufficient to provide efficient support for enforcement;
- downstream users having used the succinct summary for their own purpose find that the document is still too extensive;
- the succinct summaries were for some inspections a valuable complement to the authorisation decision and the exposure scenarios; in other cases, the texts were unclear or confusing and therefore difficult to inspect and additionally there were no clarifications on, e.g. which protective equipment/clothing is to be used in different operations or clarifications for ventilation requirements.

During 175 inspections of the authorised uses, the succinct summary was not used. It was not needed in 75 inspections, and unavailable for 64 inspections. In 36 inspections there were other reasons: e.g. the succinct summary was not checked or not supplied, summary table of ECHA was used, succinct summary was not in the correct language so the SDS was used, the extended SDS was used, guidance from the authorisation holder was more suitable.

**Check of OCs/RMMs in the SDS or in the CSR**

The information on OCs/RMMs provided in the safety data sheet (SDS) or chemical safety report (CSR) was found to be clear and specific enough for enforcement in relation to the specific use of the authorised substance in the company inspected in 307 inspections. It

was not clear and specific enough in 87 inspections for the following reasons: in general, REACH inspectors often do not have full knowledge to check environmental and workplace safety requirements; the exposure scenario was not in the official language of the Member State; in some cases, there was information missing, e.g. exposure limits, best available technique (BAT) values, assigned protection factors (APFs), or the information was not clear and specific enough; some parameters, like reduction rate and abatement efficiency were difficult to check.

The OCs/RMMs of the extended SDSs/CSRs were found to be in accordance with national law for environmental emissions or national workplace safety regulations in 301 inspections. It was not in compliance in 64 inspections. For those that were not in compliance, the following explanations were provided by the inspectors: REACH standards and workplace safety (EN 689) are not always complementary to each other, e.g. some scenarios do not prescribe PPE whereas in workplace safety PPE may be necessary; missing information in the SDS/CSR e.g. information on occupational exposure limits (OELs) or different OELs for Member States; biomonitoring/medical examination is not recognised as a legal requirement by some Member States; in general, REACH inspectors often do not have full knowledge to check environmental and workplace safety requirements.

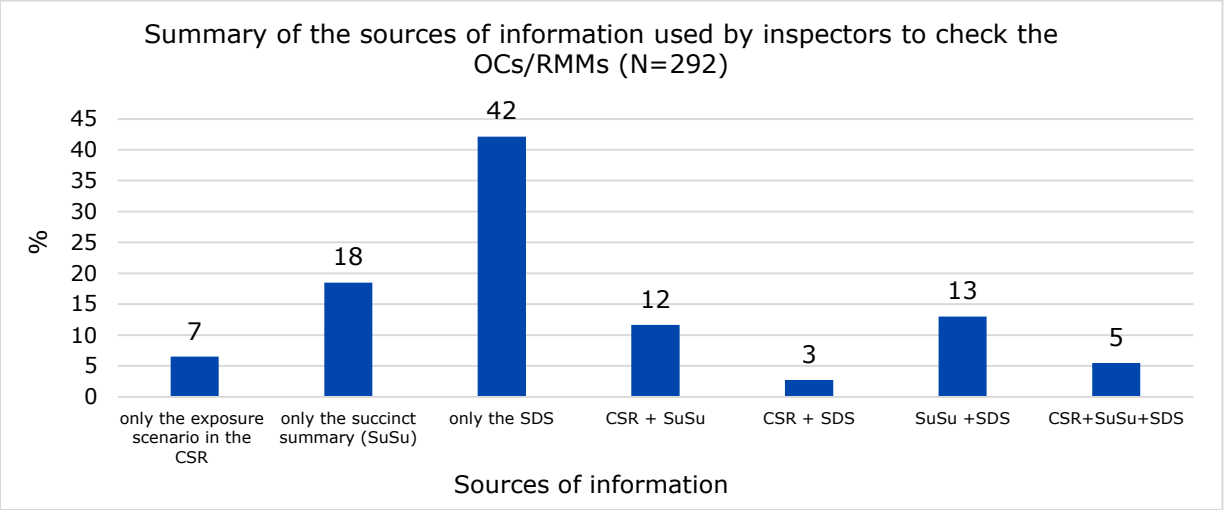
In 292 out of 399 inspections of authorised substances the inspectors checked the OCs/RMMs using information from a number of different sources that are presented in Chart 5. The inspectors could indicate which information source was easier for them to use for checking the OCs/RMMs required by the authorisation decision (multiple answers were possible).

In general, inspectors indicated for 185 substance inspections (63 %) that the safety data sheet (SDS) was the easiest source of information followed by the succinct summary (142 inspections, 49 %) and the chemical safety report (CSR) (77 inspections, 26 %). This feedback indicates, that inspectors are familiar with the information in the SDS and that the OCs/RMMs are covered in the SDS in a form that can be easily used for inspections in about two-thirds of cases. The succinct summary does not provide much added value in half of the cases. The low rate of use of the CSR shows that there is clearly a need to transfer the information in relation to the OCs and RMMs into a suitable format for use on inspections. Given that the succinct summary has been established to assist inspectors to inspect OCs/RMMs applied when using authorised substances, there is a need to improve this information instrument.

During 107 inspections of substances, the inspectors could not indicate which information source was easier to use (e.g. if only one information source was available).

This data in relation to sources for information used to check OCs/RMMs during inspections also shows to what extent multiple sources of information were used by inspectors to check OCs/RMMs when carrying out inspections (see Chart 5).

**Chart 5**. Summary of the sources of information used by inspectors to check OCs/RMMs




### 3.4.1. Situation for upstream authorisations

The suppliers (ultimately the authorisation holders) during 271 inspections provided exposure scenarios for the substances or other relevant information for safe use taken from the CSR or from the authorisation decision to the downstream users. This information was not provided for 54 inspections and for 63 inspections of substances, it was not applicable (no upstream applications).

175 inspections of the substances found that the downstream users provided relevant data (on exposure to workers or emissions to the environment to the authorisation holder or to ECHA according to monitoring arrangements in the granted authorisation or for the obligatory review report) whereas it was reported that the information was not provided for 116 inspections and not applicable for 95 inspections of substances (not upstream applications).

## 3.5. Practical check of the conditions of the CSR/authorisation decision/succinct summary

The practical check for compliance with the conditions of the CSR/authorisation decision/succinct summary was carried out during 369 inspections where the authorised substances were either placed on the market, or used by the authorisation holder itself or used by a downstream user in the supply chain of an authorisation holder.

In 19 (5 %) of the 369 inspections of authorised substances including the practical check of compliance with the conditions, the inspected companies were placing the substances on the market. In 38 (10 %) of the 369 inspections, the inspected companies were holders of an authorisation decision and were using the substances subject to inspections, whereas in 324 (88 %) of the 369 inspections, the inspected companies were downstream users of the substances subject to inspections and covered by an authorisation decision granted to an actor up in the supply chain.

The checks focused on the extent to which the following conditions of the authorisation decision have been observed:

- intended or actual use matching the prescribed authorised use;
- coverage of the OCs/RMMs;
- coverage of the required PPE;

- additional conditions according to the authorisation decision;
- monitoring arrangements.

### 3.5.1. Placing on the market

Out of the 19 inspections of authorised substances that were placed on the market by the inspected companies, that included checks of the conditions of the CSR/authorisation decision/succinct summary, it was noted that substances were placed on the market with details specifying the authorised uses included in the (extended) SDS for downstream users in 13 inspections, whereas in 6 inspections this was not the case.

In 10 (out of 19) inspections it was noticed that the inspected companies, which placed the authorised substances on the market, included the OCs/RMMs and the other obligatory requirements (such as additional conditions and monitoring arrangements) in the (extended) SDSs. In 8 inspections, the information was not included in the SDS and for 1 inspection this check was not relevant.

In total, 18 (out of 19) inspections noted that there were references in the authorisation decisions to the OCs/RMMs of the CSR of the inspected substances. In this context, the following findings could be identified:

In 10 (out of 18) inspections, the practical handling of authorised substances in the inspected companies were observed to be in compliance with the OCs/RMMs of the CSR (when placing on the market). That was not the case for 2 inspections, and for 7 inspections this check was not relevant.

In 16 (out of 19) inspections, the personal protective equipment (PPE) was prescribed in the authorisation decisions of the substances. In 13 of those inspections the companies provided (extended) SDSs for the substances with the prescribed use of PPE in compliance with the authorisation decision. This was not the case for 5 inspections.

In 12 (out of 19) inspections, there were additional conditions (related to the placing on the market) for the authorisation holders indicated in the authorisation decisions, of which the companies placed the substances on the market in compliance with the additional conditions in 8 inspections, whereas non-compliance was detected in 4 inspections, and for 7 inspections this check was not relevant.

In 15 (out of 19) inspections, there were monitoring arrangements indicated in the authorisation decisions for the authorisation holders, of which 8 inspections pointed out that the inspected companies performed the monitoring measures in compliance with the authorisation decision. Non-compliances were detected in 4 of the inspections and for 7 inspections this check was not relevant.

The statistical sample for the inspections of authorised substances placed on the market is rather small to be able to draw any detailed conclusions on the investigations targeting authorisation conditions. However, there seems to be a general trend that for obligations to observe and for obligations to communicate complex information on OCs/RMMs and on monitoring arrangements, the compliance rate by suppliers is low and can drop to a level of only 53 %.

This finding is a general indication that the supply chain and the quality of information flow on authorisation conditions along the supply chain is one of the major problems for the functioning of the authorisation instrument as a risk management pillar of the REACH Regulation.

See also Table 8A in Section 3.5.3 for a general comparison of the results of the inspector's checks of obligations of companies for communicating authorisation conditions in the supply chain of authorised substances.

### 3.5.2. Uses by holder of an authorisation decision

In all 38 inspections that included checks of the conditions of the CSR/authorisation decision/succinct summary, subjected to holders of an authorisation decision which were also using the authorised substances subject to inspections, the companies used the substances in line with authorised uses.

In all 38 inspections there were references in the authorisation decisions to the OCs/RMMs of the CSRs of the inspected substances, of which in 34 (89 %) inspections the practical uses of the authorised substances in the inspected companies were in compliance with the OCs/RMMs of the CSR, whereas this was not the case for 4 inspections.

In 24 (out of 38) inspections, there were additional conditions indicated in the authorisation decisions of which in 17 (71 %), the inspected company used the substance with these additional conditions in compliance with the authorisation decision. This was not the case for 6 inspections. For 12 inspections, this check was not relevant.

In 25 (out of 37) inspections, there was personal protective equipment (PPE) prescribed in the authorisation decision, of which in 21 (84 %) inspections, the inspected company used the PPE for the substance in compliance with the authorisation decision, whereas non-compliances were detected in 4 inspections. For 12 inspections, this check was not relevant.

In 34 (out of 38) inspections, the monitoring arrangements were required as part of the authorisation decision, of which in 28 (82 %) the inspected companies performed the monitoring arrangements in compliance with the authorisation decisions. Non-compliances were detected in 5 inspections, while for another 5 inspections the check was not relevant.

In general, it can be concluded that the compliance of authorisation holders with conditions in their own authorisation decisions when using the authorised substance is in the general range of 80-90% except for the additional conditions in the authorisation decisions for which the compliance drops to about 70 %. This level of compliance needs to be assessed against the fact that the authorisation holders know exactly the conditions of their authorisation decisions as they also have been involved in the detailed assessment of their application for authorisation which was conducted by ECHA before the authorisation was granted to them with a decision from the European Commission.

See also Table 8A in Section 3.5.3 for a general comparison of the results of the inspector's checks of obligations of companies using authorised substances in accordance with the authorisation conditions.

### 3.5.3. Use by downstream user

In 281 out of the 324 inspections targeting the use of authorised substances by downstream users, there were authorised uses prescribed in the received (extended) SDS and in 35 inspections of the substances (11 %) there were not. This check was not relevant for 8 inspections.

When comparing the actual use of the authorised substance with the information in the (extended) SDS and/or in the authorisation decision, 296 inspections found that the inspected companies used authorised substances in accordance with the authorised uses

set out in the (extended) SDS received or with the conditions in the authorisation decisions and that in 17 inspections (5 %) they did not use them in accordance. For 11 inspections, this check was not relevant.

In 261 inspections of authorised substances, the OCs/RMMs of the CSR referred to in the authorisation decisions were prescribed in the (extended) SDSs received and in 40 inspections (13 %) they were not. For 23 inspections, this check was not relevant.

In 245 inspections of authorised substances, the inspected companies used the authorised substance in accordance with the OCs/RMMs set out in the (extended) SDS received or with the conditions in the authorisation decision. In 63 inspections (20 %), they did not. For 14 inspections, this check was not relevant.

Where personal protective equipment (PPE) was required in the authorisation decisions, it was prescribed in the (extended) SDSs received for 252 inspections of authorised substances and for 33 inspections (12 %), it was not. This check was not relevant for 34 inspections.

For 242 inspections of authorised substances, the inspected companies used PPE in compliance with the (extended) SDS received or with the conditions in the authorisation decisions. In 49 inspections (17 %) they did not use PPE in accordance with the conditions specified in the authorisation decision or in the (extended) SDS. For 28 inspections, this check was not relevant.

164 inspections of authorised substances found that there were additional conditions of the authorisation decisions prescribed in the (extended) SDSs received. In 45 inspections (22 %), there were not. For 114 inspections, this check was not relevant.

In 157 inspections, the inspected companies used the authorised substance in compliance with the additional conditions specified in the (extended) SDSs or with the authorisation decision. In 31 inspections (17 %), they did not. For 135 inspections, this check was not relevant.

In 214 inspections of authorised substances, the monitoring arrangements of the authorisation decision were set out in the (extended) SDSs received and in 69 inspections (24 %) they were not. For 38 inspections, this check was not relevant.

191 inspections of authorised substances found that the inspected companies performed the monitoring in compliance with the (extended) SDSs or with the conditions in the authorisation decisions. In 84 inspections (30 %) they did not and for 47 inspections, this check was not relevant.

When summarising the findings in order to establish the overall non-compliance related to the Article 37(5) duties of REACH (duty to identify and apply risk reduction measures in relation to operational conditions, risk management measures, personal protective equipment, additional conditions and monitoring arrangements of the authorisation decision, see the previous eight paragraphs), inspectors identified a non-compliance rate of 26 % for the inspected authorised substances.

In 244 inspections, the companies inspected submitted Article 66 notifications for the authorised substance inspected within three months of the first supply of the substances. In 58 inspections (19 %), they did not submit. For 22 inspections, this check was not relevant. When investigating to what extent the notification for an inspected substance also included the monitoring data for the notified substance use as required by many

authorisation decisions, inspectors reported that for 116 out of 291 inspections (40 %), monitoring data had not yet been notified.

246 inspections found that the Article 66 notifications of the inspected authorised substance were in accordance with the uses of the authorised substances in the inspected companies and for 12 inspections (5 %) they were not. For 64 inspections, this check was not relevant.

When summarising the findings in order to establish the overall non-compliance related to the Article 66 duties of REACH, inspectors identified a non-compliance rate of 20 % for the inspected authorised substances.

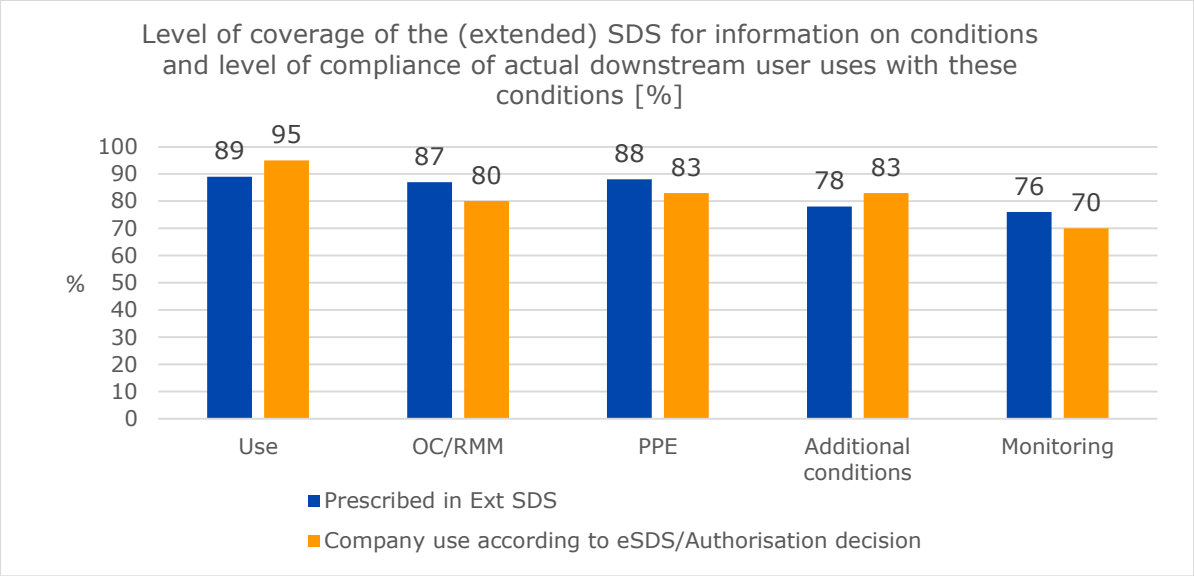
In 99 inspections of authorised substances (35 %), the information on authorised uses, OCs/RMMs of the CSR, PPE, additional conditions and monitoring arrangements became available to the inspected downstream users only after a first intervention by the inspector. This information was available before in 183 inspections. For 39 inspections, this check was not relevant.

The inspection results on the use of authorised substances by downstream users as described before can be summarised as follows and are also shown in Chart 6:

- 88 % of the total number of inspections of authorised substances related to downstream users.
- In 89 % of relevant cases, the authorised uses were prescribed in the eSDS received. The companies' uses were in accordance with the uses set out in the eSDS or in the authorisation decision in 95 % of relevant cases.
- In 87 % of relevant cases, the OCs/RMMs of the CSR were referred to in the eSDS. In 80 % of relevant cases, the company used the authorised substance in accordance with the OCs/RMMs set out in the eSDS or in the authorisation decision.
- In 88 % of relevant cases, the PPE required is prescribed in the eSDS. In 83 % of relevant cases, the company used the prescribed PPE in accordance with the eSDS or in the authorisation decision.
- In 78 % of relevant cases, the eSDS detailed additional conditions set out in the authorisation decision. In 83 % of cases, the company inspected used the substance subject to inspection in compliance with the additional conditions set out in the eSDS or in the authorisation decision.
- In 76 % of relevant cases, the monitoring arrangements of the authorisation decision were set out in the eSDS. In 70 % of the cases, the companies inspected perform monitoring in accordance with information in the eSDS or in the authorisation decision.
- In 81 % of substance inspections companies submitted a downstream user notification within 3 months of the first supply. 5 % of the notifications did not match properly with the use of the authorised substance by the downstream user. And 40 % of notifications did not include monitoring data for the actual use of the downstream user. The more broad absence of monitoring data in the notifications might be triggered by the related notification deadline defined in the most relevant authorisation decisions. This deadline was in December 2021 which was the last month of the one-year period of field inspections in this project and the majority of inspections have been finalised before. Some inspections reported that downstream users stopped using an authorised substance but did not notify ECHA about that and the notifications have not been cancelled.
- In 35 % of the inspections of authorised substances, information on uses, OCs, RMMs, PPE or monitoring arrangements only became available to the company after an initial

intervention from an inspector. This indicates that in about one-third of the supply chains, communication about authorisation requirements along these supply chains does not function at all.

**Chart 6**: Level of coverage of the (extended) SDS for **information on conditions** required by granted authorisations in the (extended) SDS for the authorised substance (as received by the downstream user) and level of compliance of actual downstream user uses with these conditions [%]




A conclusion to be drawn regarding the supply chain communication duties is that in about 10 % of the (extended) SDSs received, information from the authorisation decision is missing in relation to the OCs/RMMs as well as the PPE required. Even more (about 20 %) of (extended) SDSs received, do not contain information regarding additional conditions and monitoring requirements.

One reason for the latter information being missing in SDSs could be that new obligations for SDSs as defined in Annex II to REACH are only required from 2023 onwards. Only these new provisions explicitly require upstream suppliers to communicate information in relation to additional conditions and monitoring requirements in Section 15 of the SDS. As such, the inspection findings in relation to information missing in the SDS prove the importance of these new explicit requirements for SDSs.

However, in general it needs to be noted that the non-compliance rate of suppliers with SDS obligations as observed in the SDSs received by downstream users has to be seen in light of the obligation of Article 31(9) of REACH requiring all suppliers to update the SDS "without delay" and to provide it to all former recipients once an authorisation is granted. This important communication mechanism of REACH to ensure a functioning supply chain communication is obviously not functioning as intended.

As regards the obligation to implement risk reduction measures when using authorised substances, around 20 % of the downstream users inspected do not apply the OCs/RMMs, they do not use the required PPE and/or apply the additional conditions of the authorisation decision that are required in the (extended) SDS or in the conditions in the authorisation

decision. The obligatory monitoring arrangements are even more often not implemented (30 %).

This is in any case a breach of Article 37(5) of REACH requiring the implementation of risk reduction measures by the downstream users but – depending on the severity of the breach – it also can constitute an additional breach of Article 56(2) due to a disregard of the conditions of the authorisation decision.

A general comparison between duty holders (suppliers, authorisation holders, downstream users) and their duties to adhere to different elements of the authorisation conditions is provided in Table 8A and Table 8B. The tables summarise major findings of Sections 3.5.1 to 3.5.3.

**Table 8A.** Number of inspections on the SDS of authorised substances that contain complete information (shown for different authorisation conditions)

| Authorisation condition | Supplier's SDS when placing on the market [%] | SDS received by downstream user [%] |
|---|---|---|
| authorised use | 68 % | 89 % |
| OC/RMM | 56 % | 87 % |
| PPE | 72 % | 88 % |
| additional conditions | - | 78 % |
| monitoring arrangements | - | 76 % |
| *Total number of relevant substance inspections* | *19 cases* | *324 cases* |

**Table 8B.** Number of inspections on the use of authorised substances at different duty holders and compliance of the use with different authorisation conditions

| Authorisation condition | Supplier's own use [%] | Authorisation holder's own use [%] | Downstream user's use [%] |
|---|---|---|---|
| authorised use | - | 100 % | 95 % |
| OC/RMM | 55 % | 89 % | 80 % |
| PPE | - | 84 % | 83 % |
| additional conditions | 67 % | 74 % | 84 % |
| monitoring arrangements | 53 % | 85 % | 69 % |
| *Total number of relevant substance inspections* | *19 cases* | *38 cases* | *324 cases* |

The comparison in Table 8A shows that the completeness of information on authorisation conditions in the SDS is, in general, lower when checked with the supplier compared to

the check of the SDS received by the downstream user (however, the statistical sample of inspections at suppliers in general is low). In addition, completeness of information on additional conditions and on monitoring arrangements of the authorisation decision shows the lowest rate and can be missing in a quarter of the SDSs of authorised substances.

The comparison in Table 8B shows that authorisation holders themselves when using the authorised substance are somewhat more compliant in adhering to the authorisation conditions than downstream users (this is not the case for compliance with "additional conditions").

Inspections of suppliers of authorised substances in general (authorisation holders and other suppliers) reveal that the suppliers' own uses seem to be particularly often non-compliant with the authorisation conditions (however, the statistical sample of inspections at different kind of suppliers is low).

When using authorised substances, compliance with the required monitoring arrangements is particularly low and can be absent in one-third of inspected substance uses. Only authorisation holders themselves seem to have less problems implementing the correct monitoring arrangements which are well known to them from the application phase when they have been involved in the corresponding assessment work of ECHA.

## 3.6. Infringements and enforcement measures

### 3.6.1. Infringements

At least one non-compliance with the REACH obligations checked in the scope of the REF-9 project was found in 203 of 502 reported inspections on substances from Annex XIV, resulting in a 40 % non-compliance rate for inspected substances.

All non-compliances and their relation to different provisions of the REACH Regulation in the scope of REF-9 are presented in Table 9 and in Chart 7 (multiple violations could be detected for one inspected substance).

**Chart 7.** Non-compliances with authorisation obligations of REACH [%]

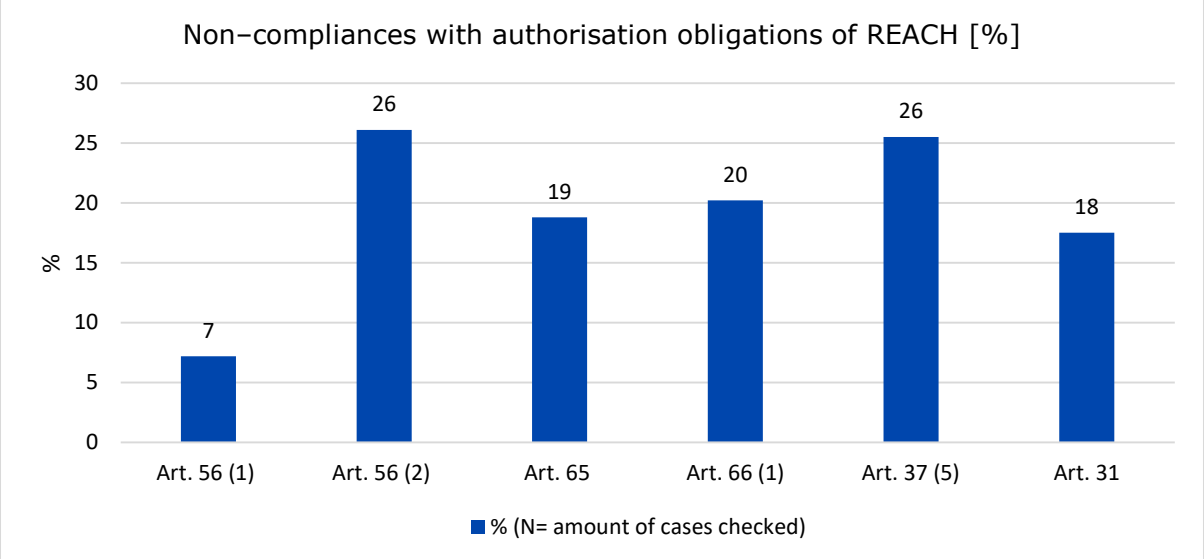


**Table 9**. Non–compliance with REACH obligations (multiple violations for the same inspected substance are possible) for all inspections in which the Annex XIV substance was used or placed on the market

| REACH obligation (Article of REACH Regulation) | Number of substance inspections focusing on the REACH obligation | Number of violations reported for substance inspections | Non-compliance rate for substances inspected [%] [N=no of cases checked] | Number of violations for substances placed on the market (in total 36 out of 98) | Number of violations for substances used (in total 187 out of 463) |
|---|---|---|---|---|---|
| Art. 56 (1) of REACH (placing the substance subject to inspection on the market or use without authorisation) | 319 | 23 | 7 | 8 | 16 |
| Art. 56 (2) of REACH (using the substance subject to inspection in accordance with the conditions of a granted authorisation to an actor up his supply chain for that use) | 371 | 97 | 26 | | 97 |
| Art. 65 of REACH (including the authorisation number on the label) | 165 | 31 | 19 | 12 | |
| Art. 66 (1) of REACH (notification of DUs using the substance in accordance with Article 56 (2)) | 361 | 73 | 20 | | 73 |
| Art. 37 (5) of REACH (DU identifies, applies and where suitable, recommends, appropriate measures to adequately control risks identified) | 388 | 99 | 26 | | 99 |
| Art. 31 of REACH (including the substance identities and authorisation numbers in the SDS) | 234 | 41 | 18 | 23 | 29 |

In general, the highest infringement rates can be seen for downstream user related duties (Article 37(5), Article 56(2), Article 66).

The most common non-compliances with REACH reported were for the following substances from Annex XIV (in brackets the number of non-compliant inspections and the rate of non-compliance for each substance): chromium trioxide (84, 35 %), strontium chromate (31, 51 %), lead sulfochromate yellow (C.I. Pigment Yellow 34) (15, 63 %), sodium dichromate (13, 50 %), and trichloroethylene (11, 37 %). It can be seen that there can be significant differences in the rate of non-compliance for an individual substance selected by the inspectors for the inspections.

Regarding placing the inspected substance on the market in at least 25 out of 36 substance inspections (69 %), non-compliances were observed in SMEs and in at least 9 substance inspections (25 %) in non-SME companies (for two inspections the size of the companies was not provided).

Regarding the use of the inspected substance in 135 out of 187 substance inspections (72 %) non-compliances were observed in SMEs and in 52 substance inspections (28 %) in non-SME companies.

Overall, 162 out of 404 companies checked during the 502 inspections of substances (40 %) were non-compliant with REACH obligations checked in this project.

As indicated in Section 3.3.1, for companies placing the Annex XIV substance on the market and in Section 3.3.2, for companies using the Annex XIV substance, some inspection cases of non-compliance could be identified in which the substance is neither authorised for the specific use, nor had an application for authorisation been submitted, or was still ongoing, nor the specific use is exempted from authorisation requirements.

Referring to this, a total of 6 supply-related inspections found that the substances from Annex XIV have been placed on the market in breach of REACH authorisation obligations. In addtion, a total of 11 use-related inspections of substances from Annex XIV found that the substances have been used in breach of REACH authorisation obligations.[20]

In these cases, the inspected companies obviously completely failed to observe authorisation duties for Article 56(1) and Article 56(2) of REACH. In this way, the inspections have identified 17 out of all 502 (3 %) substance inspections in which the duty holders (i.e. either users or duty holders placing on the market) can be regarded as free riders – "free riders (supply and use)".

In addition, Section 3.3.1 summarises further non-compliances for companies placing the Annex XIV substance on the market:

- The company did not provide the authorisation number on the label in 17 inspections of substances from Annex XIV.
- The company did not provide a safety data sheet that contained the authorisation number(s) in 17 inspections of substances from Annex XIV.

Any differences between the summarised information on non-compliances in Sections 3.3.1 and 3.3.2 (and any other section) compared to the information provided in Table 9 ('Non–compliance with REACH obligations (multiple violations for the same inspected substance are possible) for all inspections in which the Annex XIV substance was used or placed on the market') can be explained by the fact that some inspections reported in Sections 3.3.1 and 3.3.2 were still ongoing at the time of reporting. In addition, in this Section 3.6.1, the overall non-compliance related to the use of substances from Annex XIV as indicated by the inspectors after their full assessment of the inspection case is described.

### 3.6.2. Enforcement actions

Enforcement measures

For 198 out of 203 inspections of substances from Annex XIV, where a non-compliance with the obligations checked in the REF-9 project was detected, the following enforcement measures were imposed by the enforcement authorities (multiple actions could be taken). For 5 out of 203 inspections of the substance specific enforcement measures were not

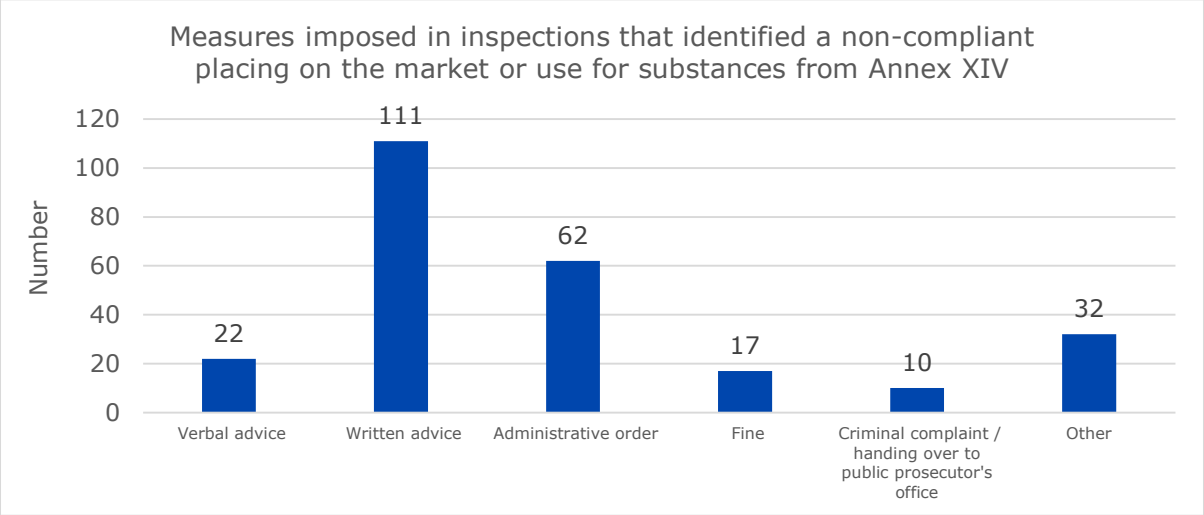
[20] In the project report, these identified cases are referred to as „free riders (supply only)" for the 6 supply-related inspection cases and „free riders (use only)" for the 11 use-related inspection cases.

reported due to follow-up activities still ongoing or due to non-compliances fixed immediately after the inspection.

Altogether, 254 enforcement actions were initiated to bring companies into compliance. These measures were (see Chart 8):

- 22 verbal advices;
- 111 written advices;
- 62 administrative orders;
- 17 fines;
- 10 criminal complaints/handing over to public prosecutor's office;
- 32 other measures (e.g. initiation of disciplinary proceedings, daily penalty payment, written request for correction and presentation of documentation, shutdown (under the workplace safety legislation), warnings, one-months' time for complying, request to notify NEAs or supplier's local authority).

**Chart 8.** Measures imposed in inspections that identified a non-compliant placing on the market or use for substances from Annex XIV




Follow-up actions

For those 203 inspections where non-compliant substances were reported, 147 (72 %) follow-up activities (e.g. further investigations) were still ongoing and 56 were completed (when the inspection report was finished).

Regarding all 502 inspections carried out, the inspections were reported as complete for 302 inspections while follow-up activities were still ongoing for 200 inspections at the time of reporting.

The high numbers of inspections in which not all follow-up activities were concluded by the time the project questionnaire for the inspection was submitted (up to 72 % of cases, 147 out of 203 cases) indicates the high complexity of at least some of the details of the relevant investigations. When inspecting REACH authorisation requirements, the time consuming investigations are mainly related to the difficulties with having good and complete supply chain communication, which can involve several actors and to the assessment of the conditions for the substance uses at the borderline of REACH authorisation requirements and general national workplace safety and environmental legislation.

### 3.6.3. Cooperation

Information on 15 inspections was shared with other participating countries through REF-9 national coordinators (7 cases), national enforcement/competent authority (6 inspections) or dedicated focal points (2 inspections).

# IV. Conclusions and recommendations

Based on the data received from the inspections and the analyses that could be conducted on the data in Section III, the following conclusions and recommendations can be drawn from the project.

## 4.1. Conclusions

The majority of inspections reported during the REF-9 project intentionally related to duty holders (90 %) in a downstream user role with respect to the Annex XIV substances inspected. Even more significant is that 81 % of the substance inspections related to duty holders assuming only one role as a downstream user. The substance most frequently inspected was chromium trioxide (47 % of inspections). With this in mind, the most relevant conclusions of this project can be drawn concerning the use of the authorised substances by downstream users.

In general, the project shows an overall non-compliance rate of 40 %, both in terms of substance inspections and of companies. This is higher than the usual average level of non-compliance found by inspectors in relation to provisions of EU chemicals legislation. This can be, in part, related to the situation that both placing authorised substances on the market and using authorised substances in accordance with the conditions of the authorisation decision are new and complex duties for affected duty holders. The REF-9 inspections took place in 2021. This was only a few months after several upstream authorisation decisions for chromium trioxide came into force in December 2020.

Currently, there is no comprehensive ECHA guidance document available for suppliers and users of authorised substances which clearly sets out the details of the duties and requirements in terms of placing on the market and using authorised substances. Duty holders have just started to find answers and solutions for new requirements in relation to their obligations under Title VII of the REACH Regulation.

Non-compliance can also be related to very complex supply chains that present serious challenges in relation to the communication of information in a clear and concise form to the downstream users using the authorised substance.

In general, the highest non-compliance rates observed in this project were for duties related to downstream users (e.g. Article 56(2) or Article 37(5) of REACH).

**Inspection results related to the supply chain**

For downstream users, the very low level of communication of information by their supply chain continues to be a serious impediment:

- In 35 % of inspections at downstream users, inspectors found that relevant information in relation to uses/OC/RMM/PPE or monitoring arrangements from the authorisation decision has not been communicated down the supply chain to the downstream users in the extended SDS. Since Article 31(9) of REACH requires suppliers to update an SDS “without delay” once an authorisation is granted, this finding is alarming. This non-functioning of obligatory supply chain communication puts the risk management instrument covering downstream users by upstream authorisations (Article 56(2) of REACH) in question.

- It is also noteworthy that there were still a number of downstream users who had not received an extended SDS at the time of inspection (e.g. the information in the annexes of an extended SDS was not yet provided by the suppliers).
- A number of inspections identified, that the information provided in the SDS can be complex and difficult to understand for the downstream users resulting in a poor understanding of safety measures required by the downstream users. The challenge is similar to the one already reported in the 2018 REF-5 project[21].
- The extended SDS shows significant quality deficits and poor-quality information (even information gaps) as identified in the inspections (see the analysis in Section 3.5). Downstream users often lack the experience and expertise to understand that they need to ask their suppliers for better quality information.

These findings represent a significant challenge of the REACH authorisation instrument as the extended SDS is the primary source of information for the downstream users using authorised substances, which are the largest user group of authorised substances in the internal market. One improvement to this could come into play with the new general obligations for SDSs to contain details of authorisation conditions as stipulated in Regulation (EU) No 2020/878 and being obligatory for all SDSs from January 2023 onwards.

**Inspection results related to the use of authorised substances**

The inspections revealed that the majority of downstream users observe the basic authorisation requirements in relation to the use of an Annex XIV substances (e.g. the substance is authorised for the use or at least an application for this authorisation is submitted, or the use is exempted from authorisation requirements). There are only 2 % of use-related substance inspections that could establish that authorisation requirements have been ignored, that is, the Annex XIV substance was in a use requiring an authorisation – "free riders (use only)".

Downstream users are less compliant with the implementation of more complex authorisation requirements such as monitoring arrangements, notification of monitoring data to ECHA or implementation of risk reduction measures (Article 37(5) of REACH). This finding seems to be in line with the results of the assessment of the supply chain duties which have shown that the specific information in relation to the authorisation requirements is, in many instances, not communicated, not completely communicated or communicated with poor quality to downstream users.

**Inspections focusing on authorised substances**

For national enforcement authorities, the most important sources of information for enforcing the operational conditions and risk management measures at downstream user level are:

- The extended safety data sheet provided by the supplier (which is supposed to also cover all the additional conditions relevant for downstream users in the authorisation decision).
- The succinct summary prepared by the authorisation holder based on the information provided in the chemical safety report. This is particularly useful in cases where the

[21] REF-5 project on the extended safety data sheets, exposure scenarios, risk management measures and operational conditions, see the report on ECHA's website.

downstream user had not yet received the extended safety data sheet from the supplier or the SDSs did not have the exposure scenarios attached.
- National enforcement authorities are entitled to receive a succinct summary from the authorisation holder upon request as stipulated in most of the upstream authorisations.
- However, requesting a succinct summary from the authorisation holders may not be practical as part of routine enforcement, which may involve a number of chemicals delivered in different supply chains.

Therefore, it would be useful if an up-to-date succinct summary would be available to NEAs on a dedicated European Commission or ECHA web page. ECHA currently publishes the succinct summaries on their internet pages when an authorisation is granted. However, the succinct summary may be updated by the authorisation holder, for example, as a result of obligations specified in the authorisation decision or as part of a review report submitted to ECHA. It would be very useful if a system could be put in place to ensure that ECHA would receive the succinct summary from the authorisation holder whenever it is updated and ECHA would publish the updated succinct summaries.

Authorisation conditions include measures which are also addressed by national workplace safety legislation or by national environmental legislation and the resulting overlapping obligations of the duty holders are not clearly clarified in the authorisation decisions or in related guidance. In general, REACH inspectors in many cases do not have the full knowledge to check environmental and workplace safety requirements. It, therefore, remains difficult to conduct inspections for these overlapping obligations.

## 4.2. Recommendations

### 4.2.1. To industry

1. **Suppliers** to improve the quality and completeness of the extended safety data sheets in relation to the conditions of use of the authorised substances to ensure compliance as an actor in the supply chain and to ensure that all relevant information is communicated down the supply chain in clear and concise language which can be easily understood by the downstream users. In particular, the prompt update of safety data sheets according to Article 31(9) and according to the deadlines specified in the authorisation decisions is critical. It is important that the safety data sheets are in the languages of the Member States an.
2. **Suppliers** to actively communicate by all possible means to downstream users in relation to their obligations when using the authorised substance. This shall also include procedures to follow in relation to requests for further clarification of information in relation to authorisation conditions and particularly to the operating conditions/risk management measures required in relation to the specific uses of the downstream user.
3. **Downstream users** to ensure that if they use a substance subject to authorisation that they use it in accordance with the conditions of use and particularly in accordance with the operational conditions and risk management measures set out in the authorisation decision for their specific use. If it is unclear from the extended safety data sheet what operational conditions and risk management measures are required for their specific use, then they should seek clarification from their supplier of the substance. In addition, downstream users also have to ensure that the Article 66 notification is kept up-to-date including an update if they cease to use the authorised substance.

### 4.2.2. To the ECHA Forum

1. In the upcoming revision of REACH considerable changes in the authorisation instrument of REACH are foreseen. Forum to assess new and changed elements of this new REACH authorisation in light of the findings, conclusions and recommendations of the REF-9 project to guide inspectors based on established experience once the new authorisation under REACH comes into force.

### 4.2.3. To the inspectors

1. Inspectors having gained experience from inspections carried out as part of the REF-9 project are encouraged to continue the inspections on authorisation duties with a focus on suppliers and downstream users as part of their routine inspection programme.
2. The general awareness of suppliers and actors in the supply chain including downstream users in relation to authorisation duties needs to be improved. Inspectors are encouraged to assist in raising awareness with the various duty holders in respect to their specific obligations in relation to authorised substances under REACH as part of their regular contact with these duty holders.

### 4.2.4. To ECHA Secretariat

1. The ECHA Secretariat to develop a comprehensive and consistent guidance to suppliers and users of authorised substances. Also the two previous Forum pilot projects on authorisation identified the need for a comprehensive ECHA guidance document which provides clarification and guidance to suppliers and users of authorised substances in relation to their duties and provides answers and solutions for them to enhance compliance. Results of the REF-9 project clearly confirm the lack of such comprehensive and consistent guidance.
2. Inspections by NEAs of the duty of downstream users to submit and update Article 66 notifications to ECHA shall be supported to a better extent by providing more details of the information available on Article 66 notifications in REACH-IT to inspectors. Access to more detailed information should become a new feature in the Interact Portal NEA. In the interim, this information shall be provided in the format of a regularly updated table extracted from the REACH-IT data which is made available to inspectors.

### 4.2.5. To the European Commission

1. The European Commission to ensure that the most up-to-date succinct summaries/chemical safety reports/authorisation decisions are available on one dedicated website as these are the primary/authoritative sources of information used by enforcing inspectors in the various Member States when enforcing authorisation duties. Communication of information in the supply chain can be poor at the best of times particularly to downstream users in a long supply chain. It would be very difficult and time consuming for inspectors in many instances to check with the authorisation holder who may be located in another Member State.
2. Authorisation decisions should be clear enough to be implemented by duty holders and to enable effective enforcement:
    - The authorisation decision should always clearly identify who is the responsible actor when it comes to the authorisation conditions. This allows the relevant actor in the enforcement to be addressed.
    - Duties for providing information in the supply chain between the authorisation holder and downstream users using authorised substances

should explicitly and in detail be regulated in the authorisation decision for all suppliers. This will improve communication in the supply chain.

- Authorisation decisions should be published in the language of all relevant Member States (i.e. for upstream authorisations also in the languages of the Member States in which downstream users are using the authorised substances).
- Relevant threshold values should be regulated in the authorisation decision (e.g. concentration at the workplace, emission into the environment) and clear instructions to users of authorised substances on alignment of authorisation conditions with the relevant overlapping existing legislation (workplace safety, environment) should be provided.
- In general, overlap with other existing relevant legislation should be considered and clarified in the conditions of the authorisation decision (e.g. monitoring requirements in workplace safety or in environmental legislation or hierarchy of control of occupational safety and health (OSH)). When it is not clarified in advance, this is inefficient for implementing and enforcing the authorisation conditions.
- For monitoring requirements, details on the measuring method (sampling and laboratory analysis) need to be regulated in the authorisation decision to ensure a harmonised approach for this authorisation condition.
- Authorisation decisions should follow the general principles of implementability and enforceability, i.e. technical requirements are clarified in the decision with the required details or with a reference to an approved standard setting out the details of the technical requirement included in the decision.
- A clarification needs to be provided on what is regarded as a minor change in a use condition and can still be regarded as covered by the conditions set out in the authorisation decision, and what is regarded as a relevant change in a use condition and not covered by an existing authorisation condition and, thus, requiring the need for a new authorisation covering this new use with the relevant change in the use condition.

3. The European Commission to improve the information flow and the control in the supply chain of an authorised substance: it should be implemented that downstream users in an authorisation holder's supply chain may only receive / can only purchase the authorised substance once the downstream user, if Article 66 requires the notification, can demonstrate the completed Article 66 notification to its supplier

## Annexes:

Annex I: Questionnaire

Annex II: Inspectors additional comments on enforceability of the authorisation conditions /CSR/succinct summary

## Annex I: Questionnaire

| QUESTIONNAIRE<br>(One (1) questionnaire per substance per inspected company) | |
|---|---|
| **0. Section – General information about the inspection (questions 0.2 to 0.5 will not be recorded)** | |
| 0.1. Participating country: | |
| 0.2. Authority:<br>0.3. **Person in Charge:**<br>Telephone:<br>Fax:<br>Email:<br>0.4. **Date of inspection:**<br>0.5. **File reference:** | This data is only for internal use |
| 0.6. **Type of inspection**<br>◯ Only desk top check<br>◯ On-site check | |

| **I. Section – General information about the inspected company** (questions 1.1. to 1.3. will not be recorded) | |
|---|---|
| 1.1. Name of company: | This data is only for internal use. |
| 1.2. Name and telephone of the contact person:<br>1.3. Contact person's qualification: | This data is only for internal use. |
| 1.4. Company ID code | Unique code assigned by the inspector to the company (e.g. 'AT001' (for Austria) etc.).<br>Use this code to fill in additional questionnaires for additional substances checked in the same company. |
| 1.5. Company's NACE Code(s): | Source for NACE Code see Annex 4, please provide 4-digit NACE class, e.g. "01.11" |
| 2. According to Commission Recommendation 2003/361/EC, the company qualifies as:<br>◯ Micro ◯ Small ◯ Medium ◯ not SME ◯ unknown<br>Micro: <10 employees and ≤2 million euro annual turnover<br>Small: <50 employees and ≤10 million euro annual turnover<br>Medium: <250 employees and ≤50 million euro annual turnover<br>Not SME: >250 employees and > 50 million euro annual turnover | |

3.1. Specify which substance is subject to inspection according to EC number:

*In the iPDF questionnaire, substances are in numerical order in the dropdown menu.*

| | EC No. | Substance name | Sunset Date |
|---|---|---|---|
| O | 202-974-4 | 4,4'- Diaminodiphenylmethane (MDA) | 21/08/2014 |
| O | 201-329-4 | 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) | 21/08/2014 |
| O | 201-622-7 | Benzyl butyl phthalate (BBP) | 21/02/2015 |
| O | 204-211-0 | Bis(2-ethylhexyl) phthalate (DEHP) | 21/02/2015 |
| O | 201-557-4 | Dibutyl phthalate (DBP) | 21/02/2015 |
| O | 201-553-2 | Diisobutyl phthalate (DIBP) | 21/02/2015 |
| O | 215-116-9 | Diarsenic pentaoxide | 21/05/2015 |
| O | 215-481-4 | Diarsenic trioxide | 21/05/2015 |
| O | 231-846-0 | Lead chromate | 21/05/2015 |
| O | 235-759-9 | Lead chromate molybdate sulfate red (C.I. Pigment Red 104) | 21/05/2015 |
| O | 215-693-7 | Lead sulfochromate yellow (C.I. Pigment Yellow 34) | 21/05/2015 |
| O | 204-450-0 | 2,4-dinitrotoluene (2,4-DNT) | 21/08/2015 |
| O<br>O<br>O<br>O<br>O | <br>221-695-9<br>247-148-4<br>-<br>-<br>- | **Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified**<br>1,2,5,6,9,10-hexabromocyclododecane CAS No. 3194-55-6<br>Hexabromocyclododecane (HBCDD)<br>alpha-hexabromocyclododecane CAS No.: 134237-50-6<br>gamma-hexabromocyclododecane CAS No. 134237-52-8<br>beta-hexabromocyclododecane CAS No. 134237-51-7 | 21/08/2015 |
| O | 204-118-5 | Tris(2-chloroethyl) phosphate (TCEP) | 21/08/2015 |
| O | 201-167-4 | Trichloroethylene | 21/04/2016 |
| O | 231-901-9 | Arsenic acid | 22/08/2017 |
| O | 203-924-4 | Bis(2-methoxyethyl) ether (Diglyme) | 22/08/2017 |
| O | 500-036-1 | Formaldehyde, oligomeric reaction products with aniline | 22/08/2017 |
| O<br>O<br>O<br>O | -<br>231-801-5<br>-<br>236-881-5 | **Acids generated from chromium trioxide and their oligomers**<br>Chromic acid<br>Oligomers of chromic acid and dichromic acid<br>Dichromic acid | 21/09/2017 |
| O | 232-143-1 | Ammonium dichromate | 21/09/2017 |
| O | 215-607-8 | Chromium trioxide | 21/09/2017 |
| O | 232-140-5 | Potassium chromate | 21/09/2017 |
| O | 231-906-6 | Potassium dichromate | 21/09/2017 |
| O | 231-889-5 | Sodium chromate | 21/09/2017 |
| O | 234-190-3 | Sodium dichromate | 21/09/2017 |
| O | 203-458-1 | 1,2-dichloroethane (EDC) | 22/11/2017 |
| O | 202-918-9 | 2,2'-dichloro-4,4'-methylenedianiline (MOCA) | 22/11/2017 |
| O | 246-356-2 | Dichromium tris(chromate) | 22/01/2019 |
| O | 256-418-0 | Pentazinc chromate octahydroxide | 22/01/2019 |
| O | 234-329-8 | Potassium hydroxyoctaoxodizincatedichromate | 22/01/2019 |
| O | 232-142-6 | Strontium chromate | 22/01/2019 |
| O | 276-158-1 | 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich | 04/07/2020 |
| O | 271-084-6 | 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters | 04/07/2020 |
| O | 284-032-2 | 1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear | 04/07/2020 |
| O | 203-445-0 | 1-bromopropane (n-propyl bromide) | 04/07/2020 |
| O | 204-212-6 | Bis(2-methoxyethyl) phthalate | 04/07/2020 |
| O | 210-088-4 | Diisopentyl phthalate | 04/07/2020 |
| O | 205-017-9 | Dipentyl phthalate | 04/07/2020 |
| O | 933-378-9 | n-pentyl-isopentylphthalate | 04/07/2020 |
| O | 292-602-7 | Anthracene oil | 04/10/2020 |
| O | 266-028-2 | Pitch, coal tar, high-temp. | 04/10/2020 |

Only one substance per company per questionnaire.

If more substances are checked per company, then additional questionnaires should be filled in.

See List of substances included in Annex XIV to REACH ("Authorisation List").

| | | | |
|---|---|---|---|
| | 618-541-1 | **4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated** | 04/01/2021 |
| O | 618-344-0 | 2-[[]4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethanol | |
| O | 219-682-8 | 20-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-3,6,9,12,15,18-hexaoxaicosan-1-ol | |
| O | 621-345-9 | 2-[[]4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethan-1-ol | |
| O | 621-341-7 | 2-{2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethoxy}ethanol | |
| | - | **4-Nonylphenol, branched and linear, ethoxylated** | 04/01/2021 |
| O | 248-743-1 | 20-(4-nonylphenoxy)-3,6,9,12,15,18-hexaoxaicosan-1-ol | |
| O | 500-045-0 | 4-Nonylphenol, ethoxylated | |
| O | 932-688-1 | Nonylphenol, branched, ethoxylated (CAS# 68412-54-4) | |
| O | 931-756-8 | Nonylphenol, ethoxylated (15-EO) (9016-45-9) | |
| O | 931-755-2 | Nonylphenol, ethoxylated (10-EO) (9016-45-9) | |
| O | 604-395-6 | 26-(4-nonylphenoxy)-3,6,9,12,15,18,21,24-Octaoxahexacosan-1-ol | |
| O | 931-753-1 | Nonylphenol, ethoxylated (6,5-EO) (9016-45-9) | |
| O | 500-024-6 | Nonylphenol, ethoxylated | |
| O | 243-816-4 | 2-[2-(4-nonylphenoxy)ethoxy]ethanol | |
| O | 500-209-1 | Nonylphenol, branched, ethoxylated | |
| O | 230-770-5 | 2-[2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]ethoxy]ethanol | |
| O | 931-754-7 | Nonylphenol, ethoxylated (8-EO) (9016-45-9) | |
| O | 247-816-5 | 26-(nonylphenoxy)-3,6,9,12,15,18,21,24-octaoxahexacosan-1-ol | |
| O | 931-562-3 | Poly(oxy-1,2-ethanediyl), a-(nonylphenyl)-w-hydroxy- (CAS 9016-45-9) | |
| O | 609-346-2 | Isononylphenol, ethoxylated | |
| O | 500-315-8 | 4-Nonylphenol, branched, ethoxylated | |
| O | 939-993-9 | Nonylphenol, ethoxylated (EO = 10) | |
| O | 939-975-0 | Nonylphenol, ethoxylated (EO = 4) | |
| O | 938-618-6 | Nonylphenol, ethoxylated (polymer) | |
| O | 687-833-9 | 2-{2-[4-(3,6-dimethylheptan-3-yl)phenoxy]ethoxy}ethanol | |
| O | 687-832-3 | 2-[4-(3,6-dimethylheptan-3-yl)phenoxy]ethanol | |
| O | 932-998-7 | Nonylphenolpolyglycolether | |

3.2. Specify the use(s) of the substance that became relevant during the inspection

**Please select the use by inserting the correct ID number as it is listed on ECHA's website** https://echa.europa.eu/applications-for-authorisation-previous-consultations

3.3. Roles of the company under REACH in relation to the Annex XIV substance subject to inspection:

| | |
|---|---|
| ☐ Manufacturer | Art. 3.9 of REACH |
| ☐ Importer (company not covered by an OR) | Art. 3.11 of REACH |
| ☐ Only representative (OR) for the authorisation/for registration | Art. 8.1 of REACH |
| ☐ Downstream user (e g: formulator, producer of an article, importer covered by an OR, end-user) | Art. 3.13 of REACH |
| ☐ Supplier | Suppliers which are distributors are typically not relevant in this project |
| ☐ Authorisation holder, applicant for authorisation | |
| ☐ No present role for the inspected substance (further details are reported in section VI) | |

## II. Section - Compliance with authorisation duties by the company

| | |
|---|---|
| 4.1 Has the company as a manufacturer, importer or downstream user **placed** the substance subject to inspection (mentioned in question 3.1) **on the market** for (a) specified use(s) after its sunset date defined in Annex XIV?<br>○ **No**<br>○ **Yes,**<br>O as a substance as such, in mixtures or to be included in articles based on (an) authorised use(s) (valid and applicable authorisation)<br>○ company's own authorisation<br>Authorisation number(s):<br>○ under an upstream authorisation<br>Authorisation number(s):<br>Notification number(s):<br>Is the authorisation valid for the relevant use(s) with respect to the (use specific) review provisions specified in the authorisation decision and in Article 61 of REACH?<br>O Yes<br>O No<br>O as a substance as such, in mixtures or to be included in articles and a valid application for authorisation has been submitted and an authorisation is not granted, so far<br>O uses exist, which are covered by the application:<br>application number(s) of the uses:<br>O uses exist, which are not covered by the application<br>O as a substance as such, in mixtures or to be included in articles based on the use exemptions<br>If the use of the substance is exempted, specify the reason<br>Exempted uses:<br>☐ On-site isolated intermediate/transported isolated intermediate<br>☐ Use in medicinal products and/or the immediate packaging of medicinal products<br>☐ Use in food or feeding stuffs<br>☐ Use in Scientific Research and Development<br>☐ Use on plant protection products<br>☐ Use in biocidal products<br>☐ Use as motor fuel<br>☐ Use as fuel in combustion plants of mineral oil products<br>☐ Use in cosmetic products<br>☐ Use in food contact materials<br>☐ Use of substances referred in Article 57 d, e, and f when present in mixtures below a concentration limit of 0.1% w/w<br>☐ Use of substances when present in mixtures below the lowest of the concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to Regulation (EC) No. 1272/2008 which results in classification of the mixture as dangerous<br>☐ Others (e.g. use of/in an article):<br>Please specify<br>O as a substance as such, in mixtures or to be included in articles based neither on a valid authorisation granted, nor on an ongoing/pending application for authorisation, nor on any applicable exemption | Art. 56 of REACH<br><br>Please give here the exemptions that are the most relevant in the situation of the company. For exemptions, see Annex 8.<br><br>Please note that manufacturers, importers or downstream users may place a substance on the market for a use, for which they do not have an authorisation itself. In such a case, the authorisation had to be granted for that use to its immediate downstream user in the supply chain.<br><br>For example: In a case where a formulator has an authorisation for formulating a substance, the manufacturer may place the substance on the market for the formulation by the formulator despite the manufacturer not having an authorisation itself.<br><br>Exemptions for use in cosmetic products (Art. 56(5)(a) REACH) – this is only viable if the substances meet the criteria in Article 57(a), (b) or (c) or are identified in accordance with Article 57(f) only because of hazards to human health.<br><br>If this answer is selected, the company is not compliant.<br>That confirms also that the company is not in a valid supply chain of an authorisation granted or |

| | |
|---|---|
| | an ongoing/pending application for authorisation. |
| 4.2 Has an authorisation been granted for the use(s)?<br>O No<br>O Not relevant<br>O Yes<br><br>If Yes,<br>4.2.1 Did the inspected company provide the authorisation number(s) on the label when placing the substance on the market?<br>O Yes<br>O No | |
| 4.2.2 Did the inspected company provide a safety data sheet that contains the authorisation number(s) when placing the substance on the market and supplying the substance?<br>O Yes<br>O No | In the safety data sheet (SDS), the authorisation number should be indicated in Section 2.<br>For details of the legal requirements and related guidance see entry 7 in Annex 5 of this manual. |

| | |
|---|---|
| 5.1_Does the company **use** the substance subject to inspection (mentioned in question 3.1) for which its sunset date has passed, for the specified use(s)?<br>◯ **No**<br>◯ **Yes** | Art. 56 of REACH |
| O as a substance as such, in mixtures or to be included in articles based on (an) authorised use(s) (valid and applicable authorisation)<br>O company's own authorisation<br>Authorisation number(s)<br>O under an upstream authorisation<br>Authorisation number(s):<br>Notification number(s):<br>Is the authorisation valid for the relevant use(s) with respect to the (use specific) review provisions specified in the authorisation decision and in Article 61 of REACH?<br>O Yes<br>O No | |
| O as a substance as such, in mixtures or to be included in articles and a valid application for authorisation has been submitted and an authorisation is not granted so far<br>O uses exist, which are covered by the application:<br>application number(s) of the uses:<br>O uses exist, which are not covered by the application | Give the application numbers as provided on ECHA's website, once not available in the safety data sheet (SDS). |
| O as a substance as such, in mixtures or to be included in articles based on the use exemptions<br>If the use of the substance is exempted, specify the reason:<br>☐ On-site isolated intermediate/transported isolated intermediate<br>☐ Use in medicinal products and/or the immediate packaging of medicinal products<br>☐ Use in food or feeding stuffs<br>☐ Use in Scientific Research and Development<br>☐ Use on plant protection products<br>☐ Use in biocidal products<br>☐ Use as motor fuel<br>☐ Use as fuel in combustion plants of mineral oil products<br>☐ Use in cosmetic products<br>☐ Use in food contact materials<br>☐ Use of substance referred in Article 57 d, e, and f when present in mixtures below a concentration limit of 0.1%w/w<br>☐ Use of substance when present in mixtures below the lowest of the concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to Regulation (EC) No. 1272/2008 which results in classification of the mixture as dangerous<br>☐ Others (e.g. use of/in an article):<br>Please specify: | Please give here the exemptions that are the most relevant in the situation of the company. For exemptions, see Annex 8.<br><br>Exemptions for use in cosmetic products (Art. 56(5)(a) REACH) – this is only viable if the substances meet the criteria in Article 57(a), (b) or (c) or are identified in accordance with Article 57(f) only because of hazards to human health. |
| O as a substance as such, in mixtures or to be included in articles based neither on a valid authorisation granted, nor on an ongoing/pending application for authorisation, nor on any applicable exemptions | That confirms that the company is not in a valid supply chain.<br>The company is not compliant. |

| **III. Section – Enforceability of the authorisation conditions/CSR/succinct summary**<br>**When a final decision of authorisation is pending, Q 7-13 in this Section should not be answered.** | |
|---|---|
| 6. Has an authorisation decision been granted?<br>◯ Yes<br>◯ No<br><br>7. Are the authorisation conditions clear enough to enable enforcement?<br>◯ Yes<br>◯ No<br>If no, please specify difficulties in enforceability of the conditions required in the authorisation decision: | The intention of Section III is to answer questions only if an authorisation is already granted.<br><br>For inspection of users that are also the authorisation holders, the authorisation decision is the directly relevant reference document.<br><br>For inspection of downstream users supplied with the authorised substance, the authorisation conditions of the authorisation decision communicated down the supply chain in the (extended) safety data sheet are the directly relevant reference. In such cases it is important that the inspector also checks that the relevant content of the (extended) safety data sheet is in line with the conditions of the authorisation decision (e.g. whether the content of the relevant exposure scenarios/safe use information in the (extended) safety data sheet and in the authorisation decision match in terms of content and whether specific authorisation conditions are mentioned in Section 15 of the SDS, see entry 7 of Annex 5 of this manual). |

| | |
|---|---|
| 8. Was the succinct summary used during the inspection of the authorised use(s)?<br>◯ Yes<br>O information was appropriate to easily enforce the authorisation decision[22]<br>O information was not appropriate to easily enforce the authorisation decision[20]<br>Please specify what kind of information was missing in the succinct summary in order to easily enforce the authorisation decision:<br>O other:<br>◯ No<br>O succinct summary was not available<br>O succinct summary was not needed<br>O other: | According to the requirements of authorisation decisions the NEAs can ask to have the succinct summary available in their official language(s) from the authorisation holder [23]<br><br>"Easy to enforce" shall be in place if the safe use information detailed in the succinct summary has clearly supported the NEAs in their inspection work<br><br>Specify also "No" if the NEAs decided to conduct the inspection without making use of the succinct summary (only using the ES/CSR or the safe use information in the (extended) SDS. |
| 9. Usefulness of the succinct summary.<br>Is it easier for the NEA to check the OCs/RMMs based on the information provided in?:<br>☐ the exposure scenario in the CSR<br>☐ the succinct summary<br>☐ safe use information in the safety data sheet (SDS) (e.g. ES attached to an extended SDS of a substance)<br>☐ not applicable | In general, authorisation decisions refer to the OCs/RMMs provided in the CSR of the applicant submitted during the application for authorisation. For communication in the supply chain, this information has to be provided as part of the safe use information in the (extended) SDS. |
| 10. Are the OCs/RMMs of the SDS/CSR enforceable, e.g. is the information realistic, clear and specific enough, and applicable to the situation of the inspected company?<br>O Yes<br>O No<br>Why not? | See comment provided for Question 8. |
| 11. Are the OCs/RMMs of the SDS/CSR in accordance with national law related to environmental emissions or national OSH regulation?<br>O Yes<br>O No<br>Why not? | Please indicate here findings that relate (non-harmonised) to national legislation on environmental emissions or on OSH to the authorisation conditions (OCs/RMMs). |
| **For upstream applications** | |
| 12. Did the supplier (ultimately the authorisation holder) provide the exposure scenarios or other relevant safe use information, such as out of the CSR or authorisation decision to the downstream user?<br>O Yes<br>O No<br>O Not applicable (not an upstream application) | |

[22] Note: for users that are also the authorisation holders, the authorisation decision is the directly relevant reference document. For downstream users supplied with the authorised substance, the authorisation conditions of the authorisation decision communicated down the supply chain in the (extended) safety data sheet are the directly relevant reference.

[23] http://echa.europa.eu/documents/10162/13552/afa_inst_format_succint_summary_rmm_oc_en.pdf

| | |
|---|---|
| 13. Did the downstream user provide relevant data on exposure to workers or emissions to the environment to the authorisation holder or to ECHA according to monitoring arrangements in the granted authorisation or for the obligatory review report?<br>O Yes<br>O No<br>O Not applicable (not an upstream application) | |

## IV. Section – Practical check of the conditions of the CSR/authorisation decision/succinct summary

| | |
|---|---|
| 14. Were the conditions of the CSR/authorisation decision/succinct summary checked?<br>◯ Yes<br>◯ No<br><br>☐ IF the inspected company is or is not a holder of an authorisation decision and is placing the substance subject to inspection on the market, fill in **questions 15-22**<br><br>☐ IF the inspected company is a holder of an authorisation decision and is using the substance subject to inspection, fill in **questions 23-31**<br><br>☐ IF the inspected company is a downstream user of the substance subject to inspection in relation to an authorisation decision, fill in **questions 32-41** | |
| • **Placing on the market**<br><br>15. Does the inspected company place the substance subject to inspection on the market with details specifying the authorised uses included in the (extended) SDS for downstream users?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>16. Has the company inspected, which places the authorised substance on the market for the specific uses, included relevant information in relation to the OCs/RMMs and the other obligatory requirements (such as additional conditions and monitoring arrangements) in the (extended) SDS for downstream users?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>17. Is there a reference in the authorisation decision to the OCs/RMMs of the CSR of the substance subject to the inspection?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>18. When placing on the market, is the practical handling of an authorised substance in the company inspected in compliance with the OCs/RMMs of the CSR?<br>◯ Yes | See Annex 5 entry 7 for details.<br><br>Article 31(2) and (7) of REACH.<br>For details of the legal requirements and related guidance see entry 7 in Annex 5 of this manual.<br><br>The main issues of the CSR must be in the succinct summary that can be requested. |

| | |
|---|---|
| ◯ No<br>◯ Not relevant<br><br>18a. Is personal protective equipment (PPE) prescribed in the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>18b. Does the inspected company provide an (extended) SDS for the substance subject to inspection, with the prescribed use of PPE in compliance with the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>19. Are there additional conditions related to the placing on the market in the authorisation decision for the authorisation holder?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>20. Does the inspected company place the substance subject to inspection on the market in compliance with the additional conditions identified in question 19?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>21. Are there monitoring arrangements in the authorisation decision for the authorisation holder?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>22. Does the inspected company perform the monitoring measures in compliance with the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant | |
| • **Uses by holder of an authorisation decision or holder of a valid application for authorisation**<br><br>23. Does the inspected company use the substance subject to inspection in line with an authorised use included in the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>24. Is there a reference in the authorisation decision to the OCs/RMMs of the CSR of the substance to the inspection?<br>◯ Yes<br>◯ No<br>◯ Not relevant | The main issues of the CSR must be in the succinct summary that can be requested. |

| | |
|---|---|
| 25. Is the practical use of the authorised substance in the company inspected in compliance with the OCs/RMMs of the CSR?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>26. Are there additional conditions in the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>27. Does the inspected company use the substance subject to inspection with these additional conditions in place in compliance with the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>28. Is personal protective equipment (PPE) prescribed in the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>29. Does the inspected company use the PPE for the substance subject to inspection in compliance with the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>30. Are monitoring arrangements required as part of the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>31. Does the inspected company perform the monitoring arrangements in compliance with the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant | There can be two types of monitoring arrangements:<br>- for the use according to the authorisation decision.<br>- for the review report. |
| • **Use by downstream user**<br><br>32. Are authorised uses prescribed in the received (extended) SDS?<br>◯ Yes<br>◯ No<br>◯ Not relevant<br><br>32a. Does the inspected company use the authorised substance in accordance with the authorised uses set out in the (extended) SDS received or with the conditions in the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant | See Annex 5 entry 7 for details.<br>Art. 56(2) of REACH. |

| | |
|---|---|
| 33. Are OCs/RMMs of the CSR referred to in the authorisation decision prescribed in the received (extended) SDS?<br>◯ Yes<br>◯ No<br>◯ Not relevant | |
| 33a. Does the inspected company use the authorised substance in accordance with the OCs/RMMs set out in the (extended) SDS received or with the conditions in the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant | Art. 56(2) of REACH |
| 34. Is personal protective equipment (PPE) required in the authorisation decision prescribed in the received (extended) SDS?<br>◯ Yes<br>◯ No<br>◯ Not relevant | |
| 35. Does the inspected company use PPE for the substance subject to inspection in compliance with the received (extended) SDS or with the conditions in the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant | Possible non-compliance with Article 37(5) of REACH.<br>Art. 56(2) of REACH |
| 36a. Are the additional conditions of the authorisation decision prescribed in the received (extended) SDS?<br>◯ Yes<br>◯ No<br>◯ Not relevant | |
| 36b. Does the inspected company use the substance subject to inspection with these additional conditions in place in compliance with the (extended) SDS or with authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant | Possible non-compliance with Article 37(5) of REACH. |
| 37. Are the monitoring arrangements of the authorisation decision set out in the (extended) SDS received?<br>◯ Yes<br>◯ No<br>◯ Not relevant | |
| 38. Does the inspected company perform the monitoring in compliance with the (extended) SDS or with the conditions in the authorisation decision?<br>◯ Yes<br>◯ No<br>◯ Not relevant | Possible non-compliance with Article 37(5) of REACH.<br>Art. 56(2) of REACH |
| 39. Has the inspected company submitted an Article 66 notification within three months of the first supply of the substance?<br>◯ Yes<br>◯ No<br>◯ Not relevant | Article 66(1) of REACH. |

| | |
|---|---|
| 40. Is the Article 66 notification in accordance with the use of the authorised substance in the inspected company?<br>◯ Yes<br>◯ No<br>◯ Not relevant | Article 66(1) of REACH. |
| 41. Did any of the information addressed in questions 32, 33, 34, 36a or 37 only become available to the inspected downstream user after a first intervention by the inspector has occurred?<br>◯ Yes<br>◯ No<br>◯ Not relevant | In question 41, inspectors can indicate that in the situation reported the information from the authorisation decision initially missing in the (e)SDS was made available to the DU following an action of the inspector. |

## V. Section – Summary / action (company related)

42. Has non-compliance with REACH obligations of the inspected company been detected?

Art. 56 (1) of REACH (placing the substance subject to inspection on the market or use without authorisation)
O Yes
O No
O No duties

Art. 56 (2) of REACH (using the substance subject to inspection in accordance with the conditions of a granted authorisation to an actor up to his supply chain for that use)
O Yes
O No
O No duties

Art. 65 of REACH (including the authorisation number on the label)
O Yes
O No
O No duties

Art. 66 (1) of REACH (notification of DUs using the substance in accordance with Article 56 (2))
O Yes
O No
O No duties

Art. 37 (5) of REACH (DU identifies, applies and where suitable, recommends, appropriate measures to adequately control risks identified)
O Yes
O No
O No duties

Art. 31 of REACH (including the substance identities and authorisation numbers in the SDS)
O Yes
O No
O No duties

43. Was an enforcement action initiated against the offender?

◯ Yes
- ☐ Verbal advice
- ☐ Written advice
- ☐ Administrative order
- ☐ Fine
- ☐ Criminal complaint / handing over to public prosecutor's office
- ☐ Other:

◯ No

44. Are the follow-up activities?
- ◯ completed
- ◯ on-going

45. Has information related to the inspected substance been forwarded to another Member States?

◯ Yes

- ☐ National enforcement authority
- ☐ National competent authority
- ☐ Forum member
- ☐ National project coordinator
- ☐ NEA contact point / focal point in Interact Portal
- ☐ Feedback from the other Member State approached is already available

◯ No

## VI. Section – Informal comments[24]

47.……
……

[24] Please fill this section if you would like to inform on obstacles overcome, lessons learned, need for clarification/harmonisation.

## Annex II: Inspectors additional comments on enforceability of the authorisation conditions/CSR/succinct summary

1. Difficulties in enforceability of the conditions required in the **authorisation decision**

   Overall finding: there is vagueness in the authorisation decision e.g. it was not always precise if certain sub-articles are intended for an authorisation holder which is not a product user. Or conditions sometimes address more obligations for the authorisation holder established in another Member State. The conditions of the authorisation are also general prescriptions and not specific or accurate enough.

   Some RMMs are not precise enough e.g.:
   - Not clear which conditions apply to the work environment and outer environment. Suggestion: dividing the conditions under different sections and headings;
   - In some cases, it is not clear to which actor/authority, downstream users should report their monitoring;
   - No conditions for specific use defined in the authorisation decision;
   - Exposure limits and best available technique (BAT) values are not given for the Member State where the substance is used.

   Some RMMs in the safety data sheet (SDS) represent an unrealistic duration of the activity or are vaguely formulated e.g. 'emissions should be insignificant'.

   SDSs (as an authorisation decision) are systematically written in English, often very long documents and contain many very technical and specific words. Therefore, inspectors with a mother tongue that is not English might have difficulties with understanding their content.

   The overall finding in enforceability of the conditions required in the authorisation decision is that the prescriptions according to risk management measures/operating conditions (RMMs/OCs), occupational exposure limits (OELs) and best available technique (BAT) values etc. in the authorisation decision are not specific enough and no distinction is made between the standards of different Member States. Thereby, the authorisation decision can generally only be accessed in English and is difficult to interpret because of the length of the document and the content with very technical and specific words.

2. Information **missing in the succinct summary** and, therefore, the succinct summary was not appropriate to easily enforce inspected substances.

   Overall finding: inspectors find that the succinct summary was not appropriate to easily enforce because they find out that the worker contributing scenario (WCS) does not distinguish between the different assigned protection factors (APFs) between different countries and sometimes the identification of personal protective equipment (PPE) is missing. Inspectors find it difficult that the succinct summary (SS) is not in their official language.

   Sometimes information is missing in the extended safety data sheets (eSDS) of the succinct summary, e.g. risk management measures (RMMs) are not clearly described,

the annual monitoring programme is not mentioned although it is mentioned in the authorisation decision, specific exposure scenarios are missing and inspectors find it difficult to verify full compliance.

The most actual information e.g. chemical safety report (CSR)/succinct summary is not always present on ECHA's website. And the succinct summary contains too extensive information for a downstream user.

3. Additional comments on the **used succinct summaries during inspections**

Overall finding: inspectors find the succinct summary to be a good complement to the permission and exposure scenarios. They find the information in the succinct summaries appropriate, but in many cases they still had to check the chemical safety report (CSR) to get a better understanding of the conditions or guidelines. Inspectors were positive about the succinct summary in English, and sometimes another language was provided and used. The usefulness of the succinct summary was not always clear, there were difficulties in understanding the clarifications e.g. which protective equipment/clothing had to be used in different operations and which ventilation rate was required.

4. **Other reasons** why the **succinct summary was not used** during inspections

Overall finding: the succinct summary was not used in cases where the substance wasn't used anymore, the company was a distributor, the company did not use the substance under a valid authorisation or there was no inspection on-site. Sometimes, the inspectors used only the extended SDS or used a summary table of ECHA. Also an obligatory guidance from the authorisation holder was more suitable or in the authorisation decision, they found more specific information.

5. **Additional reasons** why the information on OCs/RMMs provided in the SDS/CSR was found to be not clear and specific enough for enforcement in relation to the specific use of the authorised substance in the company inspected

Overall findings:

- In some cases, the REACH inspectors did not have the competency for environmental and OSH checks.
- The extended SDSs were not in the official language of the Member State.
- There was an incompleteness of information e.g. exposure limits and best available technique (BAT) values were not given for the Member State where the substance was used, relevant monitoring information, ventilation and control requirements were missing.
- Sometimes, the information was not clear enough and difficult to assess and in some cases the exposure scenario was missing.
- Inspectors find differences in standards according to the required assigned protection factors (APF) in the succinct summary and the CSR and a lack of clarity relating to requirements between different countries.
- There were difficulties in controlling the efficiency of the treatment of air emissions, working hours, duration of activities and required distance from the source.

- Regarding the "environmental" scenarios, there was a difference in the risk management measures of the CSR, the succinct summary and the technical data sheets.
- Sometimes the SDSs had inconsistencies concerning some process categories (PROCs) e.g. in a PROC, the installation of an extraction unit was provided as a risk management measure while the conditions of use only mention general ventilation.
- It is impossible to check if the 99 % efficiency is met.
- The information was not specific enough regarding the design and dimensioning as well as the maintenance and control of process ventilation.
- Other reasons why the information was not clear are that the CSR was not updated on ECHA's website and updated information on OCs/RMMs was not supplied to downstream users in an updated SDS. Or the SDS had to be downloaded from the supplier's website, or was a lengthy, complex document. Also the mixture SDS provides very general information.

6. **Explanations** provided by the inspectors for **non-compliant cases** where OCs/RMMs of the SDS/CSR were found to be not in accordance with national law with respect to environmental emissions or national OSH regulations

   Overall finding: the EN-NEN 689 (Strategy to perform representative measurements of exposure) and REACH requirements are difficult to apply together. There are differences between countries e.g. in how many times monitoring is required and there are differences in exposure limits between Member States. For personal protective equipment (PPE), some scenarios do not provide for PPE, whereas in terms of OHS it may be necessary.

**EUROPEAN CHEMICALS AGENCY**
**TELAKKAKATU 6, P.O. BOX 400,**
**FI-00121 HELSINKI, FINLAND**
**ECHA.EUROPA.EU**