Final Report on the first Forum pilot project on authorisation

Reporting period: March 2014 – December 2015
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Forum Final Report on the first Forum pilot project on authorisation

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Executive summary

The Forum for Exchange of Information on Enforcement (the Forum) conducted the first Forum pilot project on authorisation. Eighteen Member States (MSs)\(^1\) participated in the project, which was limited to the first two substances with the earliest sunset date in Annex XIV (21 August 2014) - Musk xylene and 4,4’-Diamoniodiphenylmethane (MDA).

This project aimed to check compliance with the REACH Regulation on the marketing and use of MDA and Musk xylene after their sunset date. There were no authorisations granted for these substances during the timeframe of the project. The focus of the project was to gather experience and build practice and processes for enforcing the authorisation-related obligations.

The project was set up in March 2014. National enforcement authorities (NEAs) from participating MSs conducted enforcement actions in the first half of 2015 using the manual and questionnaire prepared by the Working Group ‘First pilot project on authorisation’. The reporting phase took place in the second half of 2015.

The pilot project has been a successful first step towards the enforcement of authorisation under REACH. The detailed results of the project are based on 235 on-site inspections with completed questionnaires. A total of 421 inspections were completed as part of this project. These are made up of 235 on-site inspections and 186 desktop inspections or on-site inspections where a questionnaire was not filled out. Of these previously mentioned 186 inspections, there were no cases of non-compliance detected in relation to either of the substances being investigated.

In terms of the NACE system, about half of the enterprises (52 %) fall into the category “manufacturing of chemicals and chemical products” (NACE Code 20.00-29.99). Micro, small and medium-sized companies (SMEs) represented 71 % of the inspected companies. In terms of role within the supply chain, the vast majority of inspected enterprises (81 %) were downstream users.

The majority of companies inspected did not place on the market and/or use MDA. Six companies place this substance on the market for an exempted use and seven companies use this substance for an exempted use. Two companies place Musk xylene on the market and are in breach of Article 56 of REACH. Three companies place Musk xylene on the market for an exempted use. One company uses Musk xylene (also a breach of Article 56) and two companies use Musk xylene for an exempted use. All other inspected companies did not place Musk xylene on the market or use it (see table 1 below).

### Table 1: Result of the reported on-site inspections

<table>
<thead>
<tr>
<th></th>
<th>MDA</th>
<th>Musk Xylene</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placing on the market</td>
<td>0</td>
<td>2(^2)</td>
</tr>
<tr>
<td>Placing on the market for an exempted use</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Use</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Exempted use</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>13</td>
<td>8</td>
</tr>
</tbody>
</table>

\(^1\) AT, BE, BG, DK, EE, DE, EL, ES, FI, FR, HU, IE, IT, LI, NL, PL, SE and UK
\(^2\) Figures in bold indicate a breach of Article 56 of REACH
In total, three non-compliances in reference to Article 56 of REACH were found. Two written advices and two administrative orders were issued and, in two cases, a fine was given (multiple responses). Additionally, in one inspected company it was necessary to issue written advice in relation to the disposal of residual material containing MDA. For two cases, information was forwarded to another MS for further follow up.

Based on the findings of this project, the Working Group have outlined some recommendations for the Forum, Commission, ECHA, enforcement authorities, inspectors and for industry.
A. Introduction

At the Forum-17 plenary meeting, the Forum decided to engage in a pilot project on authorisation. Authorisation is a new legal obligation and national enforcement authorities (NEAs) need to gain experience in enforcing it. The Forum’s pilot project on authorisation aimed to check compliance with the REACH Regulation regarding the placing on the market and use of MDA\(^3\) and Musk xylene after their respective sunset dates (21 August 2014 – the earliest sunset date in Annex XIV).

There were no authorisations granted in relation to MDA and Musk xylene within the timeframe of this pilot project. The focus of the project was on gathering experience and building practice and processes for enforcing the authorisation-related obligations. The project was set up in 2014 with inspections taking place in the first half of 2015.

B. Objectives and participants of the project

The scope of the project was to clarify and establish a practical way of enforcing the authorisation obligations therefore building enforcement experiences and practices by checking compliance with REACH authorisation obligations and, where required, enforce compliance. The project was restricted to two substances – MDA and Musk xylene.

This pilot project focused on checking for the presence of substances on the market beyond their sunset dates and in particular on:

- targeting companies for compliance based on known submissions to ECHA (registrations, pre-registrations and classification and labelling (C&L) notifications, and any other information provided by interested parties during the SVHC identification and prioritisation steps e.g. responses to comments tables (RCOM) published on ECHA’s website) or other information available to NEAs\(^4\);
- checking in targeted companies that MDA and Musk xylene are not placed on the market for a use or used after 21 August 2014;
- checking whether uses are exempted if MDA and Musk xylene are found to be used.

Member States – AT, BE, BG, DK, EE, DE, EL, ES, FI, FR, HU, IE, IT, LI, NL, PL, SE and UK – participated in the project, which was conducted from March 2014 until December 2015.

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\(^3\) Besides MDA, Annex XIV also contains a different substance “technical MDA” (CAS 25214-70-4) for which the sunset date has not passed (see Regulation (EU) No 895/2014). Therefore, technical MDA is not yet subject to any limitation for placing on the market or for use according to Title VII of REACH. Inspectors will have to clearly distinguish these two substances listed in Annex XIV.

\(^4\) For example, information about substances through their substitution duties under workers protection legislation, or the data available to the inspectors in the framework of SEVESO (registry of hazardous substances) or IED (substances known to be released), environmental permits, product declarations, product registers, activity sectors of companies, import and export customs declarations.
C. Background information

1. Project history and background

This project is integrated in the implementation of several of Forum’s tasks as established by Article 77.4 of REACH, in particular:

- spreading good practice and highlighting issues at Community level;
- proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;
- identifying enforcement strategies, as well as best practice in enforcement;
- developing working methods and tools to be used by local inspectors.

Authorisation obligations fall under one of the strategic priorities of the Forum for 2014-2018 namely, the focus on enforcing obligations related to the safe use of substances.

The objectives of the project were to:

- establish a practical way of enforcing the authorisation obligations and build enforcement capacity;
- assess the target group’s compliance with REACH provisions on authorisation by using a uniform approach (target group = manufacturers, importers, downstream users);
- investigate the target group’s knowledge of REACH authorisation duties and advise about its authorisation obligations;
- where required, enforce non-compliances with regard to authorisation obligations;
- promote cooperation among enforcement authorities and contribute to harmonised enforcement in the EEA;
- foster information exchange between all enforcement actors at regional, national and international level;
- contribute to further improving the capabilities of enforcement authorities;
- raise awareness of REACH authorisation obligations.

2. Legislative background

This pilot project on authorisation is limited to the REACH Regulation. Obligations imposed by the CLP Regulation are not included.

The obligations to be checked and eventually enforced within the scope of this project are:

<table>
<thead>
<tr>
<th>Article</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>56(1)(a), 56(1)(b), 56(3), 56(4), 56(5), 56(6)</td>
<td>No placing on the market for a use or use after the sunset date unless it has been authorised and/or the use is exempted</td>
</tr>
</tbody>
</table>

---

5 Articles 64, 65 and 66 are also related to the authorisation process, but for the purposes of this pilot project in relation to MDA and Musk xylene, they are not required to be checked.

6 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.
D. Enforcement actions

1. Participating countries and number of inspections

Eighteen Member States\(^7\) (MSs) participated in the project, which was limited to the first two substances with an authorisation requirement - Musk xylene and MDA.

In total, there were 421 inspections conducted. For 235 on-site inspections, a questionnaire was filled in and only the results of these on-site inspections are taken into account in the results.

The remaining 186 inspections were desktop inspections (or on-site inspections without a questionnaire). For all of these 186 (desktop) inspections, no cases of non-compliance were detected. A reference to Musk Xylene and/or MSA was found in only two desktop inspections.

Further details on the results can be found in chapter E.

2. Coordination of the project

A Forum Working Group “first Forum pilot project on authorisation” was responsible for project management. This included:

- providing the pilot project national coordinators (NCs) with all relevant project documents (e.g. manuals and questionnaires);
- conducting the webinar for NCs in November 2014;
- staying in close communication with them through the secure messaging system REACH Information Portal for Enforcement (RIPE) (all exchange of confidential information such as data and inspection reports was done through RIPE);
- collecting and compiling the inspection findings;
- project coordination at European level with the MSs participating in the project;
- evaluating the project’s findings; and
- reporting to the Forum.

The ECHA Secretariat supported the project management, prepared data and the pdf form for conducting the project and contributed to the preparation of the manual and the webinar for NCs. In addition, they provided all necessary logistic, administrative, financial and technical support as in the Forum’s previous enforcement projects.

\(^7\) AT, BE, BG, DK, EE, DE, EL, ES, FI, FR, HU, IE, IT, LI, NL, PL, SE and UK
3. Methods of enforcement

Based on data prepared by ECHA and submitted separately through RIPE to NCs (and on any other information provided by interested parties) and with the aid of the manual and questionnaire (translated in requested languages), a desk study was initially undertaken.

After this desk study, the inspectors sought evidence regarding placing on the market or using Musk xylene and/or MDA after the sunset date during on-site inspections at the registrants’ or notifiers’ premises.

In cases where the downstream user was in another MS, the NEA considered referring the matter/relevant information to the appropriate NEA for follow up. This was done using any suitable mode of bilateral information exchange through a secure exchange e.g. RIPE.
E. Results and conclusions

1. General overview

1.1 Overview of the number of inspections

Eighteen Member States participated in the pilot project with a total of 421 inspections completed. This consisted of 235 on-site inspections and 186 desktop inspections.8 Questionnaires were completed for 235 on-site company inspections.

As agreed by the Forum and as stated in the manual in this report, only the results of the on-site inspections with a completed, filled-in questionnaire are taken into account.

Table 2(a) details the number of on-site inspections completed by participating Member States.

Table 2(a): Participating countries and reported on-site inspections

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of submitted on-site inspection reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Austria</td>
<td>6</td>
</tr>
<tr>
<td>2 Belgium</td>
<td>38</td>
</tr>
<tr>
<td>3 Bulgaria</td>
<td>15</td>
</tr>
<tr>
<td>4 Denmark</td>
<td>0</td>
</tr>
<tr>
<td>5 Estonia</td>
<td>5</td>
</tr>
<tr>
<td>6 Finland</td>
<td>0</td>
</tr>
<tr>
<td>7 France</td>
<td>20</td>
</tr>
<tr>
<td>8 Germany</td>
<td>11</td>
</tr>
<tr>
<td>9 Greece</td>
<td>10</td>
</tr>
<tr>
<td>10 Hungary</td>
<td>22</td>
</tr>
<tr>
<td>11 Ireland</td>
<td>8</td>
</tr>
<tr>
<td>12 Italy</td>
<td>46</td>
</tr>
<tr>
<td>13 Liechtenstein</td>
<td>2</td>
</tr>
<tr>
<td>14 The Netherlands</td>
<td>27</td>
</tr>
<tr>
<td>15 Poland</td>
<td>0</td>
</tr>
<tr>
<td>16 Spain</td>
<td>25</td>
</tr>
<tr>
<td>17 Sweden</td>
<td>0</td>
</tr>
<tr>
<td>18 The United Kingdom</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>235</strong></td>
</tr>
</tbody>
</table>

Table 2(b) details the number of desktop inspections (or on-site inspections without a questionnaire) completed by participating Member States. For all of these 186 inspections, no cases of non-compliance were found relating to the use or placing on the market of Musk xylene and/or MDA.

A reference to Musk xylene and/or MDA was found in only two desktop inspections. One inspected company placed on the market and used Musk xylene and MDA for an exempted use (scientific research). A second company still held old stock of Musk xylene but there was no evidence of placing on the market.

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8 Or on-site inspections without a questionnaire
Table 2(b): Participating countries and reported desktop inspections

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of desk inspection (or on-site inspections without questionnaire)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Austria</td>
<td>11</td>
</tr>
<tr>
<td>2 Belgium</td>
<td>0</td>
</tr>
<tr>
<td>3 Bulgaria</td>
<td>0</td>
</tr>
<tr>
<td>4 Denmark</td>
<td>33</td>
</tr>
<tr>
<td>5 Estonia</td>
<td>0</td>
</tr>
<tr>
<td>6 Finland</td>
<td>8</td>
</tr>
<tr>
<td>7 France</td>
<td>0</td>
</tr>
<tr>
<td>8 Germany</td>
<td>0</td>
</tr>
<tr>
<td>9 Greece</td>
<td>16</td>
</tr>
<tr>
<td>10 Hungary</td>
<td>0</td>
</tr>
<tr>
<td>11 Ireland</td>
<td>4</td>
</tr>
<tr>
<td>12 Italy</td>
<td>0</td>
</tr>
<tr>
<td>13 Liechtenstein</td>
<td>5</td>
</tr>
<tr>
<td>14 The Netherlands</td>
<td>0</td>
</tr>
<tr>
<td>15 Poland</td>
<td>41</td>
</tr>
<tr>
<td>16 Spain</td>
<td>4</td>
</tr>
<tr>
<td>17 Sweden</td>
<td>46</td>
</tr>
<tr>
<td>18 The United Kingdom</td>
<td>18</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>186</strong></td>
</tr>
</tbody>
</table>

The results detailed below are based on the information provided by the participating Member States in the questionnaires associated with the 235 on-site inspections completed.

1.2 NACE codes of the inspected companies

The range of the main surveyed business sectors represented by the inspected (and reported) enterprises is specified by the NACE codes in Table 3. The table summarises the findings of the results related to question 1.4. (Company’s NACE-Code(s)) of the questionnaire.

In terms of the NACE-Code system, about half of the enterprises (52 %) fall into the category “manufacturing of chemicals and chemical products” (NACE Code 20.00-28.29).

Table 3: Main business sectors in the scope of the project

<table>
<thead>
<tr>
<th>NACE identifier</th>
<th>NACE category</th>
<th>Number of companies</th>
<th>Proportion of companies (N=185)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.11-18.12</td>
<td>Manufacturing of non-chemicals</td>
<td>48</td>
<td>26 %</td>
</tr>
<tr>
<td>20.00-28.29</td>
<td>Manufacturing of chemicals and chemical products</td>
<td>96</td>
<td>52 %</td>
</tr>
<tr>
<td>46.37-47.78</td>
<td>Wholesale and retail trade</td>
<td>33</td>
<td>18 %</td>
</tr>
</tbody>
</table>

1.3 Size of the inspected companies

Companies of all size categories according to the EU standard scale were included in the inspections (Table 4). The table below summarises the findings of the results related to question 2 (the size of company according to Commission Recommendation

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NACE, the Statistical Classification of Economic Activities in the European Community, is a European industry standard classification system for economic activities.

Commission Recommendation 2003/361/EC
2003/361/EC) of the questionnaire. Micro, small and medium-sized companies (SMEs) 
represented 71 % of the companies inspected.

**Table 4: Rates of company sizes determined according to Commission Recommendation 2003/361/EC.**

<table>
<thead>
<tr>
<th>Company size category</th>
<th>(N =235)</th>
<th>Number of companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micro</td>
<td>13 %</td>
<td>30</td>
</tr>
<tr>
<td>Small</td>
<td>20 %</td>
<td>47</td>
</tr>
<tr>
<td>Medium</td>
<td>38 %</td>
<td>90</td>
</tr>
<tr>
<td>sum SME</td>
<td>71 %</td>
<td>167</td>
</tr>
<tr>
<td>Non-SME</td>
<td>28 %</td>
<td>65</td>
</tr>
<tr>
<td>Not known</td>
<td>1 %</td>
<td>3</td>
</tr>
</tbody>
</table>

Enterprises may have one or more roles under REACH: manufacturer, importer, only 
representative or downstream user. The proportion of functions and their occurring 
combinations are listed in Table 5. The table summarises the findings of the results 
related to question 3 (Roles of the company under REACH in relation to Musk xylene and/or MDA) of the questionnaire. In terms of the role, the vast majority of enterprises (81 %) have a role as a downstream user. Multiple responses were possible and 10 companies reported having more than one role.

**Table 5: Company roles under REACH.**

<table>
<thead>
<tr>
<th>Company roles under REACH</th>
<th>(N = 114)</th>
<th>Number of companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (M)</td>
<td>5 %</td>
<td>6</td>
</tr>
<tr>
<td>Importer (I)</td>
<td>21 %</td>
<td>24</td>
</tr>
<tr>
<td>Only representative (OR)</td>
<td>3 %</td>
<td>4</td>
</tr>
<tr>
<td>Downstream user (DU)</td>
<td>81 %</td>
<td>93</td>
</tr>
</tbody>
</table>

2. **Number of inspected companies placing MDA on the market and applied exemption**

For question 4 (Placing on the market of MDA) of the questionnaire, the majority (229) of the 235 companies inspected did not place MDA on the market. Six companies placed MDA on the market for an exempted use. Three companies had an exemption based on use as intermediate; four were for scientific research. One company placed MDA on the market for use in mixtures below the lowest concentration limit set by Directive 1999/45/EC or the CLP Regulation ((EC) No. 1272/2008) (multiple responses were possible).
3. Number of inspected companies using MDA on the market and applied exemption

For question 5 (Use of MDA) of the questionnaire, the majority (228) of the 235 companies inspected did not use MDA. Seven companies used MDA for an exempted use. Six companies had an exemption based on use as an intermediate; three were for scientific research. One company used MDA in mixtures below the lowest concentration limit set by Directive 1999/45/EC or the CLP Regulation ((EC) No. 1272/2008) and one use was in another country (multiple responses were possible).

4. Number of inspected companies placing Musk xylene on the market and applied exemption

For question 6 (Placing on the market of Musk xylene) of the questionnaire, the majority (230) of the 235 companies inspected did not place Musk xylene on the market. Two companies were found to have placed Musk xylene on the market and are in breach of Article 56 of REACH. Three companies placed Musk xylene on the market for an exempted use. Two companies had an exemption based on use in biocidal products and two for use in mixtures below the lowest concentration limit set by Directive 1999/45/EC or the CLP Regulation ((EC) No. 1272/2008) (multiple responses were possible).

5. Number of inspected companies using Musk xylene on the market and applied exemption

For question 7 (Use of Musk xylene) of the questionnaire, the majority (232) of the 235 companies inspected did not use Musk xylene. One company used Musk xylene and is also in breach of REACH. Two companies used Musk xylene for an exempted use. Two companies had an exemption based on use for biocidal products and one for use in mixtures below the lowest concentration limit set by Directive 1999/45/EC or the CLP Regulation ((EC) No. 1272/2008) (multiple responses were possible).

6. Number of non-compliances

There were three non-compliances with REACH noted as part of the 235 company inspections completed in this pilot project.

7. Number and kind of legal action initiated against the offender

There were three non-compliances in reference to Article 56 found. Two written advices and two administrative orders were issued and in two cases a fine was given (multiple responses). In addition, for one other case written advice was issued in relation to the disposal of residual material containing MDA although no non-compliance with REACH was noted in the inspected company.

8. Number of cases forwarded to other Member States

For two cases, the information was forwarded to another MS.
9. Any additional information

A number of countries submitted information about bulk CLP notifications related to Musk xylene. The inspectors reported that the inspected companies were not aware that they were included in the notification group and did not use or place Musk xylene on the market.

It would appear that the bulk notifications covered multi-national companies with companies in many Member States and the notifications did not reflect the actual situation in each of those MSs. It was also found that bulk notifications cannot be changed if they do not reflect the present situation.

For the three inspections where non-compliances were found, the reasons for the breaches with Article 56 were:

- Self import of a small quantity of third country products by an etno shop\(^\text{11}\).
- Raw material mix containing Musk xylene in stock at a formulators premises, which was not used and finally was disposed of.
- Sell off after the deadline of business stock by a formulator.

During one inspection, it was found that the inspected company ceased use of MDA on 15 August 2014 just before the sunset date and ceased supply to its customers just before the sunset date. The remaining MDA raw material had been sent for approved disposal; however, two tins of products containing MDA were found on the production floor shelves. Written advice was issued in relation to the appropriate disposal of this material.

Note: this case indicates that manufacturers/importers/formulators can place substances on the market up to the sunset date as per this case, but there is no period of grace after the sunset date for the use of mixtures containing authorised substances by the downstream users.

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\(^{11}\) Shop with folk culture articles
F. Recommendations

Recommendations are based on the experience of the members of the Working Group as well as on the results of the project and the feedback in the questionnaire from the national coordinators.

1. Recommendations to the Forum
   • Continuation of the (pilot) enforcement of authorisation (pilot 2).

2. Recommendations to ECHA
   • If possible, check the correctness of bulk C&L notifications.
   • Introduce the possibility to change (bulk) C&L notifications within the REACH-IT notification system.

3. Recommendations to enforcement authorities and inspectors
   • National coordinators (NCs) must check the completeness of the submitted questionnaires.
   • For electronic questionnaires, NCs must only accept questionnaires in xml format. Therefore, only complete questionnaires could be sent in.

4. Recommendations to industry
   • Communicate with receivers of the goods about (bulk) C&L notifications.

5. Recommendation to the Commission
   • Provide the missing clarifications for exemptions from authorisation applicable to the supply chain of uses that are exempt from the authorisation requirements. Provide clarifications for the exemptions on intermediates (Article 2(8)(b) of REACH), on scientific research (Article 56(3) of REACH) and on SVHCs in low concentrations in mixtures (Articles 56(6)(a) and 56(6)(b) of REACH).
# Annex 1: Questionnaire on the Forum pilot project on authorisation

**QUESTIONNAIRE**
*(One (1) questionnaire 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:
- **0.3.** **Person in charge:**
  - Telephone:
  - Fax:
  - E-mail:
- **0.4.** **Date of inspection:**
- **0.5.** **File reference:**

*Only for internal use – do not submit data*

## I. Section – General information about the inspected company
*(questions 1.1. to 1.3. will not be recorded)*

- **1.1.** Name of company:
- **1.2.** Name and telephone of the contact person:
- **1.3.** Contact person’s qualification:
- **1.4.** Company’s NACE-Code(s):

*Source for NACE Code see Annex 7, please provide 4-digit NACE class, e.g. "01.11"*

## 2. According to Commission Recommendation 2003/361/EC, the company qualifies as:

- Micro
- Small
- Medium
- not SME
- unknown

- Micro: <10 employees and ≤2 million euro annual turnover
- Small: <50 employees and ≤10 million euro annual turnover
- Medium: <250 employees and ≤50 million euro annual turnover
- Not SME: >250 employees and > 50 million euro annual turnover

## 3. Roles of the company under REACH in relation to Musk xylene and/or MDA:

- [ ] Manufacturer
- [ ] Importer (company not covered by an OR)
- [ ] Only representative (OR)
- [ ] Downstream user (e.g.: formulator, producer of an article, importer covered by an OR, end-user)

*Note:*
- Article 3.9 of REACH
- Article 3.11 of REACH
- Article 8.1 of REACH
- Article 3.13 of REACH
### II. Section - Compliance with authorisation duties by the company

<table>
<thead>
<tr>
<th>4. Has the company as M, I or DU placed MDA on the market for use after the sunset date defined in Annex XIV (21/08/2014)?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes, as substance as such, in mixtures or to be included in articles</strong></td>
</tr>
<tr>
<td><strong>Yes, as substance as such, in mixtures or to be included in articles based on the exemptions</strong></td>
</tr>
<tr>
<td>If the use of the substance is exempted, specify the reason</td>
</tr>
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<td>☐ On-site isolated intermediate / transported isolated intermediate</td>
</tr>
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<tr>
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<td>☐ Use on plant protection products</td>
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<tr>
<td>☐ Use in biocidal products</td>
</tr>
<tr>
<td>☐ Use as motor fuel</td>
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<tr>
<td>☐ Use as fuel in combustion plants of mineral oil products</td>
</tr>
<tr>
<td>☐ Use in cosmetic products</td>
</tr>
<tr>
<td>☐ Use in food contact materials</td>
</tr>
<tr>
<td>☐ Use of substances referred in Article 57 d, e, and f when present in mixtures below a concentration limit of 0.1%w/w</td>
</tr>
<tr>
<td>☐ 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</td>
</tr>
<tr>
<td>☐ Others (e.g. substance in articles): Please specify.</td>
</tr>
<tr>
<td><strong>No</strong></td>
</tr>
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**Note:** Article 56 of REACH

Please give here the Exemption(s) that is (are) the most relevant in the situation of the company. For exemptions, see in Annex 1.

This substance is on Annex XIV because of its CMR properties (human health). So exemption for use of MDA in mixtures according to Article 56.6 (a) does not apply.
5. Does the company use\textsuperscript{12} MDA?

- Yes, as substance as such, in mixtures or to be included in articles
- Yes, as substance as such, in mixtures or to be included in articles based on the exemptions
  - If the use of the substance is exempted, specify the reason
    - On-site isolated intermediate / transported isolated intermediate
    - Use in medicinal products
    - Use in food or feeding stuffs
    - Use in scientific research
    - Use on plant protection products
    - Use in biocidal products
    - Use as motor fuel
    - Use as fuel in combustion plants of mineral oil products
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    - Others (e.g. substance in articles):
      - Please specify.
- No

\textsuperscript{12} Inspector must be aware that for this substance (MDA), consumer uses are not allowed because of Annex XVII restrictions.

Note: Article 56 of REACH

Please give here the Exemption(s) that is (are) the most relevant in the situation of the company. For exemptions, see in Annex 1.

This substance is on Annex XIV because of its CMR properties (human health). So exemption for use in mixtures of MDA according to Article 56.6 (a) does not apply.
6. Has the company as M, I or DU placed Musk xylene on the market for use after the sunset date defined in Annex XIV (21/08/2014)?

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<tr>
<th>Option</th>
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</tbody>
</table>

Note: Article 56 of REACH

Please give here the Exemption(s) that is (are) the most relevant in the situation of the company. For exemptions, see in Annex 1.

This substance is on Annex XIV because of its vPvB properties (environment). So exemptions for use in cosmetic products and in food contact materials according to Articles 56.5 and 56.6(b) do not apply.
7. Does the company use Musk xylene?

| Yes, as substance as such, in mixtures or to be included in articles |
| Yes, as substance as such, in mixtures or to be included in articles based on the exemptions |

If the use of the substance is exempted, specify the reason:

- [ ] On-site isolated intermediate / transported isolated intermediate
- [ ] Use in medicinal products
- [ ] Use in food or feeding stuffs
- [ ] Use in scientific research
- [ ] Use on plant protection products
- [ ] Use in biocidal products
- [ ] Use as motor fuel
- [ ] Use as fuel in combustion plants of mineral oil products
- [ ] Use in cosmetic products
- [ ] 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

- [ ] 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

- [ ] Others (e.g. substance in articles): Please specify.

| No |

Note: Article 56 of REACH

Please give here the Exemption(s) that is (are) the most relevant in the situation of the company. For exemptions, see in Annex 1.

This substance is on Annex XIV because of its vPvB properties (environment). So exemptions for use in cosmetic products and in food contact materials according to Articles 56.5 and 56.6(b) do not apply.
### III. Section – Summary/action (company related)

8. Has non-compliance with REACH obligations of the inspected company related to Article 56 of REACH (Authorisation) been detected?

- Yes
- No

9. Was legal action initiated against the offender?

- Yes

  - If yes,
    - Verbal advice
    - Written advice
    - Administrative order
    - Fine
    - Criminal complaint / handing over to public prosecutor's office
    - Other:
      - Follow up activities still on-going

- No

10. Have any cases been forwarded to other Member States?

- Yes

  - If yes,
    - National enforcement authority
    - National competent authority
    - Forum member
    - National pilot project coordinator
    - NEA contact point/focal point in RIPE
    - Feedback from the other Member State approached is already available

- No

### IV. Section – Informal comments

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

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