Final report on the second Forum pilot project on authorisation

Reporting period: January 2016 – November 2016

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Forum Final Report on the second Forum pilot project on authorisation

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European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

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Executive summary

The Forum for Exchange of Information on Enforcement (The Forum) conducted the second Forum pilot project on authorisation. 17 countries[1] participated in the project, which was limited to checking for the placing on the market and/or use of substances subject to authorisation with sunset dates that were reached in 2015 and, where relevant, checking compliance with conditions in granted authorisations.

The project was set up in March 2015. National enforcement authorities (NEAs) from participating MSs conducted inspections in 2016 (January–October) using the manual and questionnaire prepared by the Working Group 'Second pilot project on authorisation'. The reporting phase took place from November 2016 to February 2017.

The pilot project has been successful. A total of 802 inspections were completed as part of this project. These are made up of onsite inspections and desktop inspections. A questionnaire was completed for each substance inspected.

A total of 367 (46 %) of the companies inspected fall into the NACE code category 'manufacturing of chemicals and chemical products' (NACE Code 20.00-28.89). Micro, small and medium-sized companies (SMEs) represented 78 % of the companies inspected. 20 % of the companies inspected have a downstream user role in the supply chain (the role of the company is only stated for 25 % of the substances inspected).

The majority of companies inspected did not place substances subject to authorisation with their sunset dates in 2015 on the market (735). 16 companies placed substances on the market based on an authorisation granted. 30 companies placed substances on the market for an exempted use. In addition, 16 companies placed these substances on the market based on a pending authorisation decision.

The majority of companies inspected did not use substances with their sunset date in 2015 (746). 28 companies used substances where an authorisation had been granted for their use(s). 13 companies used substances subject to authorisation for an exempted use. Furthermore, 10 companies used substances with an authorisation decision pending.

In total, 19 non-compliances in reference to Articles 56, 65 or 66 of REACH were found in 12 cases. Three verbal advices, five written advices and four administrative orders were issued. In two cases, a criminal complaint/handing over to the public prosecutor's office was undertaken. Follow up activities are still on-going for five cases (multiple responses). Information was forwarded to another MS in three cases for further follow up.

The Working Group have outlined some recommendations for the Forum, Commission, enforcement authorities, inspectors and for industry based on the findings of this project.

[1] AT, BE, CZ, DK, EE, DE, EL, ES, FI, FR, IE, IT, LI, LT, NL, SE and UK

A. Introduction

At the Forum 20 plenary meeting, the Forum decided to engage in a second pilot project on authorisation. Authorisation is a relatively 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 substances subject to authorisation with their sunset dates in 2015 (see Annex 2).

This pilot project is a follow-up project to the first pilot project on authorisation (related to placing on the market or using MDA and Musk xylene). The focus of the project was on gathering experience and building practice and processes for enforcing authorisation-related obligations. The project was set up in 2015 with inspections taking place in 2016.

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 thus building enforcement experiences and practices by checking compliance with REACH authorisation obligations and, where required, enforcing non-compliance. The project was restricted to substances subject to authorisation with their sunset dates in 2015.

This pilot project was targeted to manufacturers, importers and downstream users and focused on checking for the presence of substances on the market beyond their sunset dates and in particular on:

- Checking that substances with their sunset dates in 2015 (see Annex 2):
  - are placed on the market for a use and/or are used only in accordance with a granted authorisation; or
  - where an application has been submitted before the latest application date but not yet granted; or
  - where placing on the market or use is justified by an exemption from the authorisation requirement.
- Checking whether holders of authorisations and "Article 66 notifiers" for substances with their sunset dates in 2015 comply with authorisation decisions (see Table 1 and the list of authorisation decisions on the website: http://ec.europa.eu/growth/sectors/chemicals/reach/about/index_en.htm). This included checking if the use of a substance is exempted from the authorisation requirement or is an authorised use. Furthermore, it included checking whether any conditions and/or monitoring arrangements stipulated in the authorisation decisions are followed for each authorised use.

The following countries – AT, BE, CZ, DK, EE, DE, EL, ES, FI, FR, IE, IT, LI, LT, NL, SE and UK – participated in the project, which was conducted from March 2015 until November 2016.

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:

a) spreading good practice and highlighting problems at Community level;
b) proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;
c) identifying enforcement strategies, as well as best practice in enforcement;
d) 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 thus building enforcement capacity;
- assess the target group's compliance with REACH provisions on authorisation through 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 an information exchange between all enforcement actors at regional, national and international level;
- contribute to further improvement of 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 were:

Article	Description
56(1)(a)56(1)(b), 56(1)(e) 56(3), 56(4), 56(5), 56(6)[2]	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 an 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 the supply chain for that use
65	The requirement for a holder of an authorisation to include the

[2] 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.

	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

D. Enforcement actions

1. Participating countries and number of inspections

17 Member States[3] participated in the project, which was limited to substances subject to authorisation requirements and with sunset dates in 2015.

A total of 802 substance inspections were completed. These consisted of both onsite and desktop inspections. A questionnaire was completed for each substance inspected. Further details on the results may be found in chapter E.

The inspected companies were selected for inspections of substances subject to authorisation requirements and with sunset dates in 2015 based on the data provided in their dossiers, e.g. pre-registrations, registrations, registrations of transported isolated intermediates, applications for authorisation, substance in articles, inquiries, and CLP notifications.

2. Coordination of the project

A Forum WG "Second Forum Pilot Project on Authorisation" was responsible for managing this pilot project.

This included:
- providing the pilot project national coordinators (NCs) with all relevant project documents (e.g. manual and questionnaire),
- conducting the webinar for NCs in November 2015,
- staying in close communication with them using a secure messaging system PD-NEA, (RIPE in the past). All exchange of confidential information such as data and inspection reports was done through PD-NEA,
- 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 also contributed to the preparation of the manual and the webinar for the NCs. In addition, they provided all necessary logistic, administrative, financial and technical support as in Forum's previous enforcement projects.

[3] AT, BE, CZ, DK, EE, DE, EL, ES, FI, FR, IE, IT, LI, LT, NL, SE and UK

3. Methods of enforcement

Inspections were carried out in accordance with the project manual guidance. The REACH inspector initially completed a desktop inspection based on data prepared by ECHA and submitted through PD-NEA to NCs as well as information available from other sources (e.g. environmental permits and Member State competent authority).

The desktop inspection was followed up by an on-site inspection at the manufacturer, importer or downstream user's premises if the inspectors deemed it appropriate to seek further evidence regarding the placing on the market or use of substances subject to authorisation with their sunset dates in 2015.

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 using a secure exchange e.g. PD-NEA. A questionnaire was completed for each substance subject to a desktop or onsite inspection.

E. Results and conclusions

1. General overview

1.1. Overview of the number of inspections

17 countries participated in the pilot project with a total of 802 inspections completed. This consisted of 359 onsite inspections and 443 desktop inspections. Questionnaires were completed for 802 inspections of substances. Table 1 details the number of inspections completed by participating Member States.

Table 1: Participating countries and reported inspections

	Country	Number of submitted inspection reports[4]
1	Austria	7
2	Belgium	37
3	Czech Republic	19
4	Denmark	120
5	Estonia	30
6	Finland	13
7	France	21
8	Germany	40
9	Greece	50
10	Ireland	26
11	Italy	162
12	Liechtenstein	6
13	Lithuania	25
14	Netherlands	48
15	Spain	76
16	Sweden	106
17	United Kingdom	16
	Σ	**802**

[4] Some countries indicated that they inspected more companies but based on the first results (no activities with the inspected substances) did not continue and did not fill in the questionnaire.

Section 1 of the questionnaire provided information in relation to the type of company inspected based on the NACE-Code (Statistical classification of economic activities), the size of the company, the role of the company and details of the substance subject to authorisation, which was the subject of the inspection. The results detailed below are based on the information provided by the participating Member States in the questionnaires associated with the 802 inspections of substances completed.

1.2. NACE codes of the inspected companies

Table 2 summarises the findings of question 1.4 of the questionnaire which sought to specify the type of business sector (based on the NACE-Code) of the companies inspected within the scope of the project.

In terms of the NACE-Code system, the majority of the companies belonged to two types of business sector: 367 companies (46 %) fall into the category 'manufacturing of chemicals and chemical products' (NACE Code 20.00-28.89). 41 % of companies inspected fall into the category 'Wholesale and retail' (NACE Code 45.00 – 47.99).

Table 2: Main business sectors of the companies inspected in the scope of the project.

NACE identifier	NACE category	Number of companies	Proportion of companies (N=802)
20.00-28.89	Manufacturing of chemicals and chemical products	367	46%
45.00-47.99	Wholesale and retail	332	41%

1.3. Size of the inspected companies

Companies of all size categories according to the EU[5] standard scale were included in the inspections. Table 3 summarises the findings of question 2 of the questionnaire which sought to determine the size of the companies inspected.

Micro, small and medium-sized companies (SMEs) represented 78 % of the companies inspected. The inspected companies were selected for inspection of substances based on the data provided in their dossiers, e.g. pre-registrations, registrations, registrations of transported isolated intermediates, applications for authorisations, substance in articles, inquiries, and CLP notifications.

Table 3: Company sizes determined according to Commission Recommendation 2003/361/EC.

Company size category	% (N =802)	Number of companies
Micro	22	180
Small	33	261
Medium	23	184
Σ SME	**78**	**625**
Non-SME	18	148
Not known	4	29

[5] Commission Recommendation 2003/361/EC

1.4. Roles of the inspected companies under REACH

Enterprises may have one or more roles in relation to authorisation provisions under REACH: manufacturer, importer, only representative or downstream user.

Table 4 summarises the findings of the results related to question 3.3 of the questionnaire which sought to specify the roles of the companies inspected under REACH in relation to the authorised substance subject to inspection. The role of the company (at least one) was stated for only 25 % of the substances inspected (for 207 substances inspections). Eight companies reported having more than one role (it is possible for a company to have multiple roles). 20 % of the companies inspected have a downstream user role in the supply chain (157 out of 802). 603 of the companies inspected had no present role.

Table 4: Company roles under REACH (present role).

Company roles under REACH	Number of companies (N = 207)
Manufacturer (M)	4
Importer (I)	37
Only representative (OR)	9
Downstream user (DU)	157

2. Number of companies inspected, per substance subject to inspection.

Table 5 summarises the findings of the results related to question 3.1 of the questionnaire. Question 3.1 asked the inspector to specify which substance was the subject of inspection.

Table 5: Number of inspections related to inspected substance.

No	Substance subject of inspection	EC number	Number of inspections related to substance
1	Diisobutyl phthalate (DIBP)	201-553-2	80
2	Dibutyl phthalate (DBP)	201-557-4	119
3	Benzyl butyl phthalate (BBP)	201-622-7	83
4	Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	119
5	Diarsenic pentaoxide	215-116-9	7
6	Diarsenic trioxide	215-481-4	33
7	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	121
8	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	87
9	Lead chromate	231-846-0	36
10	Tris(2-chloroethyl)phosphate (TCEP)	204-118-5	31
11	2,4 Dinitrotoluene (2,4-DNT)	204-450-0	13
12	Hexabromocyclododecane (HBCDD), alpha-exabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane	221-695-9, 247-148-4	62
13	DBP + DEHP	201-557-4 + 204-211-0	11
	Σ		**802**

The table in Annex 1 summarises the findings of the results related to question 3.2 of the questionnaire (the specific use of the substance).

3. Number of inspected companies placing a substance subject to inspection on the market after its sunset date.

Table 6 summarises the findings of the results in relation to question 4 of the questionnaire (Has the company as a manufacturer, importer or downstream user placed the substance subject to inspection on the market for use after its sunset date defined in Annex XIV?).

A total of 802 substance inspections were completed. In 735 cases (92 %), the substances inspected were not placed on the market for use after their sunset date. The substances subject to authorisation in those cases were not present in the companies (even if companies pre-registered the substance) or the companies were not placing substances on the market after the sunset date.

In 67 cases, it was found that the substances subject to inspection were placed on the market by the companies after the sunset date. Six companies were identified as being in breach of the REACH Regulation. In one case, there was a non-compliance with the authorisation granted. This represents a non-compliance rate of 8.9 % of cases where the substance was placed on the market.

The non-compliance for all inspected substances was low – approximately 0.7 %. In 16 cases, companies placed substances on the market based on the authorisation granted. In an additional 16 cases, the companies placed the substances inspected on the market based on a pending authorisation decision at the time of inspection. The decisions on these substances are still pending and the companies are therefore deemed to be in compliance on this issue.

There were 30 cases where companies placed substances on the market for an exempted use. The exempted uses are broken down as follows, four exempted cases based on use as an intermediate, one case for use in medicinal products, 17 cases for scientific research, one case for use below a concentration limit of 0.1% weight by weight and seven cases for other reasons (multiple responses were possible).

Table 6: Number of inspected companies placing a substance on the market and applied exemption.

No	Substance subject of inspection	Number of inspections where substances were **placed** on the market	Number of inspections where substances **were not placed** on the market	Number of inspections where substances **were placed** on the market based on an **authorisation granted**	Number of inspections where inspected substances were **placed** on the market for the **exempted uses**	Number of inspections where substances **were placed** on the market based on an **pending authorisation**	Number of the inspections where inspected substances were **in breach**
1	Diisobutyl phthalate (DIBP)	3	77	0	3	0	0
2	Dibutyl phthalate (DBP)	10	109	3	4	0	3
3	Benzyl butyl phthalate (BBP)	2	81	0	2	0	0
4	Bis(2-ethylhexyl) phthalate (DEHP)	10	109	0	7	3	0
5	Diarsenic pentaoxide	1	6	0	1	0	0
6	Diarsenic trioxide	5	28	1	4	0	0
7	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	14	107	5	2	7	1[6]
8	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	13	74	5	2	6	0
9	Lead chromate	1	35	0	1	0	0
10	Tris(2-chloroethyl)phosphate (TCEP)	1	30	0	1	0	0
11	2,4 Dinitrotoluene (2,4-DNT)	1	12	0	1	0	0
12	Hexabromocyclododecane (HBCDD), alpha-exabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane	5	57	2	1	0	2
13	DBP + DEHP	1	10	0	1	0	0
	Σ	**67**	**735**	**16**	**30**	**16**	**6**

[6] In one case, there was a non-compliance with the authorisation granted

4. Number of inspected companies using a substance subject to inspection and applied exemption

Table 7 summarises the findings of the results in relation to question 5 of the questionnaire (Does the company use the substance subject to inspection for which its sunset date has passed in 2015?).

746 of the 802 substances inspected were not used after their sunset date. Inspections have shown that, in most of those cases, the substances were e.g. not used for many years or after the sunset date; eliminated from the production cycle; used in the past for scientific research; only pre-registered as a precautionary measure; notified (through bulk notification) by parent companies centrally although the substance in question was never intended to be used in the MS.

56 companies used substances with a sunset date that had passed in 2015. Six of these companies were found to be in breach of Article 56 of REACH. In one case, there was a non-compliance with the authorisation granted. This represents a non-compliance rate of 10.7 % of cases where the substance was used after the sunset date.

The non-compliance for all inspected substances was low - approximately 0.7 %. 12 companies used the substance based on an authorisation granted to the company inspected. 16 companies used the substance based on an authorisation granted to an actor up the supply chain for that use. 10 of the companies inspected were using the substances subject to authorisation based on a pending decision in relation to an application for authorisation at the time of inspection. The decisions on these substances are still pending and the companies are, therefore, deemed to be in compliance on this issue.

There were 13 cases identified where companies used a substance subject to authorisation after its sunset date for an exempted use. The exempted uses are broken down as follows: one case based on use as an intermediate, one case for use in medicinal products, four cases for scientific research, two cases for use in food contact materials, and five cases for other reasons (multiple responses were possible).

Table 7: Number of inspected companies using a substance and applied exemption.

No	Substance subject of inspection	Number of inspection where companies **used** inspected substance	Number of inspections where companies **did not use** inspected substance	Number of inspections where companies **used** inspected substance based on **an authorisation granted to the company inspected**	Number of inspections where companies **used** substance based on **an authorisation granted to an actor up the supply chain for that use**	Number of inspections where companies **used** inspected substance for the **exempted uses**	Number of inspections where companies used substance based on **an pending authorisation**	Number of the inspections were inspected substances were **in breach**
1	Diisobutyl phthalate (DIBP)	0	80	0	0	0	0	0
2	Dibutyl phthalate (DBP)	9	110	1	4	2	0	2[7]
3	Benzyl butyl phthalate (BBP)	0	83	0	0	0	0	0
4	Bis(2-ethylhexyl) phthalate (DEHP)	10	109	0	0	7	3	0
5	Diarsenic pentaoxide	0	7	0	0	0	0	0
6	Diarsenic trioxide	4	29	1	0	1	0	2
7	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	16	105	4	6	1	5	1[8]
8	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	11	76	4	4	1	2	0
9	Lead chromate	0	36	0	0	0	0	0
10	Tris(2-chloroethyl)phosphate (TCEP)	0	31	0	0	0	0	0
11	2,4 Dinitrotoluene (2,4-DNT)	0	13	0	0	0	0	0
12	Hexabromocyclododecane (HBCDD), alpha-exabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane	5	57	2	2	0	0	1
13	DBP + DEHP	1	10	0	0	1	0	0
	Σ	**56**	**746**	**12**	**16**	**13**	**10**	**6**

[7] In one case, there was a breach of Article 56(2) of REACH since the company did not follow the risk management measures given in the chemical safety report and in the authorisation decision.

[8] In one case, there was a non-compliance with the authorisation granted

5. Number of non-compliances

This paragraph summarises the findings of questions 6-9 of the questionnaire. These questions related to non-compliances in the companies inspected in relation to the following Articles of REACH:

- Article 56(1) - placing the substance subject to inspection on the market or use without authorisation
- Article 56(2) - using the substance subject to inspection in accordance with the conditions of a granted authorisation to an actor up to the supply chain for that use
- Article 65 - including the authorisation number on the label
- Article 66(1) - notification of downstream users using the substance in accordance with Article 56(2)

There were 12 non-compliances with REACH cases (most of the non-compliant substances were in breach of two or more REACH articles) noted as part of the 802 substance inspections completed in this pilot project: six in relation to Article 56(1), seven in relation to Art 56(2)[9], four in relation to Article 65 and two in relation to Article 66(1) (multiple responses).

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

This paragraph summarises answers to question number 10 of the questionnaire.
There were 13 legal actions initiated: three verbal advices[10], five written advices and four administrative orders issued. In two cases, a criminal complaint/handing over to the public prosecutor was undertaken and in five cases follow up activities are still on-going (multiple responses).

7. Number of cases forwarded to other Member States and the identity of the receiver of the information

This paragraph summarises answers to question number 11 of the questionnaire.
Information was forwarded to another MS in three cases for follow up.

8. Enforceability of the authorisation decision/succinct summary

This paragraph summarises answers to question number 12 of the questionnaire related to enforceability of the conditions referenced or provided in the authorisation decision with the potential use of the succinct summary once the authorisation was granted.

Question 12 was only answered for 18 inspections.
In nine cases, it was found that the information about the conditions in the actual authorisation decision enabled good enforceability of the authorised uses. In those nine cases, the succinct summary was: not available in three cases, not needed in five cases and not checked by inspector in one case.
For the remaining nine cases the information in the authorisation decision did not provide any additional assistance in relation to enforcement.

[9] One company did not follow the risk management measures given in the chemical safety report and in the authorisation decision.
[10] In one case, the substance is not used from 2010 but the company had it in stock. Following a verbal advice, the stocked substance was correctly disposed.

The succinct summary was used during the inspection of the authorised use in only two cases. The following difficulties were identified in relation to the enforcement of the operational conditions and risk management measures required in the authorisation decision (using information in the authorisation decision and/or succinct summary):

- Authorisation was pending;
- Substance supplied from a non-EU source. This made it difficult to monitor the downstream users who are primarily based in the construction industry. The safety data sheet was not updated since authorisation;
- In the authorisation decision, there is a reference to circumstances of use, risk management measures and monitoring presented in the authorisation application and chemical safety assessment. This reference is not always workable in practice. The succinct summary of circumstances of use and risk management measures would make enforcement easier.

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 on the feedback from the questionnaires completed by the national coordinators.

1. Recommendations to the Forum

- Further pilot or REF project on authorisation for substances whose sunset dates have passed. During this project, the succinct summaries were inspected only on very few occasions. It would be beneficial to gain more experience with enforcing authorisation decisions and the underlying conditions.

2. Recommendations to enforcement authorities and inspectors

- National coordinators to report the results back to the Working Group within the timeframe set out in the manual to ensure overall project deadlines are achieved in line with the activity plan. Follow up in Member States with national projects on authorisation for substances whose sunset dates have passed.

3. Recommendations to industry

- Implement appropriate operational controls and risk management measures as set out in the authorisation decision for any authorised substance in use past its sunset date.

4. Recommendation to the Commission

- Provide clarification in relation to only representative status with regard to authorisation decisions of the Commission.

List of annexes:

Annex 1: Responses to question 3.2 of the questionnaire
Annex 2: Table 1: List of substances included in Annex XIV to REACH ("Authorisation List") with their sunset dates in 2015
Annex 3: Questionnaire

Annex 1: Responses to question 3.2 of the questionnaire

The Annex 1 summarises the findings of the results related to question 3.2 of the questionnaire (the specific use of the substance)

No	EC number	Types of use
1	201-553-2	- Activator - Additive - Formulation - Formulation in compounds as denaturant - Formulation of granules of plastic material containing DIBP to produce plastic articles - Formulation of granules of PVC containing DIBP to produce PVC articles - Formulation of plastic material containing DIBP to produce articles - Hardener - Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles - plasticizer - plasticizer for paints and varnishes - Protective coating - Scientific research - Solvent (polyester catalyst) - substance on its own and in a mixture - to denature/to adulterate the mixtures - to produce pigmented paste for wood industry paints - Transported isolated intermediate used in a catalyst. - Used as a plasticizer in coatings for metals
2	201-557-4	- Additive - Additive Plasticizer and softening agent for the leather sector - Adhesive plasticizer for glue - Ceramic products. Decoration for tiles and bonding for decoration - Chemical injection mass - component for paraffin wax remover - component of a thermoplastic resin - Fishing bait - Formulation - Formulation of a glue used in the Aerospace Industry - Formulation of decoration products for glass - Formulation of granules of plastic material containing DBP to produce plastic articles - Industrial use of DBP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements - Inspection following CLP-notification - plastic - Plasticiser in paint manufacturing - plasticizer - Plasticizer additive for polymers

		- Plasticizer paint used in coatings for metals - priming plasticiser for construction - Production / distribution of solvent mixtures - production of mixtures used in tanning - Propellant powder - resale - Research and Development - resins and paints plasticiser - scientific research - solution for the manufacturing of maleic anhydride. - substance in mixture - the substance is Used in two-component mixtures with functions of "hardening" - to produce paints for the wood industry - Transported isolated intermediate - Transported isolated intermediate used in a catalyst. - Use in propellant powders - Use in reaction bath - Use of DBP-containing propellant grains in manufacture of ammunition. - Used as a plasticizer in coatings for metals - Used as raw material in the production of articles like hoses and cables in cars - wintering machine propulsion
3	201-622-7	- Activator - Additive - chemical mixture (inkt) - component of sealant - Fishing bait - Formulation - Formulation of granules of plastic material containing BBP to produce plastic articles - plasticizer for paints and varnishes - Plasticizer. Raw material in mixture used for the inner lining of tanks - scientific research - to produce paints for the wood industry
4	204-211-0	- Additive - articles - chemical mixture - Cleaning. - Component of a film for decorating injected plastic parts - DEHP formulation in mixtures, dry mixtures and Plastisol formulations. - Epoxy filler component bi-component for boating - Fishing bait - Formulation of decoration products for glass - Formulation of DEHP in compounds for ceramic sheets and printing pastes for production of ceramic elements and tiles for build constructions - Formulation of DEHP in compounds, dry-blends and Plastisol formulations

		- Formulation of granules of plastic material containing DBP to produce plastic articles - Industrial use for PVC articles precursors - industrial use in chemical product - Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, small household items (<10cm) that can be swallowed by children, clothing intended to be worn against the bare skin; also toys, cosmetics and food contact material (restricted under other EU regulation)] - Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, small household items (<10cm) that can be swallowed by children, clothing intended to be worn against the bare skin; also toys, cosmetics and food contact material (restricted under other EU regulation)] - Industrial use of plastic material containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce plastic articles - Ingredient; precatalyst in polymerization; intermediate - Intermediate - marginal use in paints and coatings - Medical Device - Medical Device - mixture (food packaging) - Plasticizer - Plasticizer additive for elastomers and technical plastics - plasticizers for the formulation of colored masterbatch - presumed use as plasticizer - production of mixtures used in tanning - Scientific research - substance on its own and in a mixture - The substance was only pre-registered as a precautionary measure. - to denature/to adulterate the mixtures - to produce pigmented paste for wood industry paints - Transported isolated intermediate used in a catalyst. - unclear; inspection after CLP notification - Used as plasticizer in medical devices - Used in articles like hoses and cables in cars - Was used as a plasticizer; use stopped in 2012
5	215-116-9	- Adjusting acidity in ore concentrating - Scientific research
6	215-481-4	- For formulators of paint - Formulation of diarsenic trioxide into a mixture - Formulation of diarsenic trioxide into a mixture. Reagents for laboratory - Scientific research - semiconductors production - substance on its own and in a mixture - They sell it to the pharmaceutical industry that use it as a reference standard in their analysis - Use of diarsenic trioxide in the purification of metal impurities from the leaching solution in the zinc electrowinning process.
7	215-693-7	- colouring of glassware under 1935/2004 (food contact material) - Component for the manufacturing of plastic sheets.

		- Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use - "Use 1" - Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non consumer use - "Use 4" - dye in the paint - Dye plastics - formulation into paints for road marking - Formulation of granules of plastic material containing Pigment Yellow 34 to produce plastic articles - Formulation of mixtures - formulator of paints for road marking - Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)- "Use 2" - industrial use for the mixture preparation - Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use) - "Use 5" - mixing pigment powder in an industrial environment into solvent based paints for non consumer use. - Paint and coating - paint pigment - Pigment - pigment for paint - pigment for paints for the wood industry - Pigment used in paint formulation. - pigments in the manufacture of colored masterbatch - production of mixtures used in tanning - Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking) - "Use 3" - road marking - Scientific research - the company does not use the substance - The substance was only pre-registered as a precautionary measure. - use as pigment in article; use stopped before sunset date - use as pigment in mixture; stopped before sunset date - Use in formulation of mixtures for coloring plastics for industrial use - waste potentially containing the substance transformed in end-of-waste produce
8	235-759-9	- Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use - "Use 1" - Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)- "Use 2" - colouring of glassware under 1935/2004(food contact material) - Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non consumer use - "Use 4" - dye in the paint - Formulation of granules of plastic material containing Pigment Red 104 to produce plastic articles - industrial use for the mixture preparation - Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use) - "Use 5"

		- mixing pigment powder in an industrial environment into solvent based paints for non consumer use. - Paint and coating - Pigment - pigment for paint - pigment for paints for the wood industry - Pigment used in paint formulation. - pigments in the manufacture of colored masterbatch - Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking) - "Use 3" - Sale of pigment. - Scientific research - The substance was only pre-registered as a precautionary measure. - use as pigment in article; stopped before sunset date - use as pigment in mixture; stopped before sunset date - Use in formulation of mixtures for coloring plastics for industrial use
9	231-846-0	- detonators production - Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use - "Use 1" - Formulation for decoration products for production of ceramic elements and tiles for build constructions - Formulation of granules of plastic material containing Pigment Red 104 to produce plastic articles - formulation to colour plastic - Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)- "Use 2" - Pigment - pigment for paints for the wood industry - Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking) - "Use 3" - Scientific research
10	204-118-5	- Additive (plasticiser / flame retarding s.) - flame retardant - industrial use in chemical product - Scientific research - The substance was only pre-registered as a precautionary measure. - Was used as a flame retardant; use stopped in 2010
11	204-450-0	- Additive - Moderator for powders - Propellant powder - Scientific research - use for explosives and ammunition
12	221-695-9, 247-148-4	- Additive to fire retardant - EPS - flame retardant - Flame retardant in EPS - Flame retardant in thermal insulation boards. - Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using hexabromocyclododecane as the

		flame retardant additive (for onward use in building applications) - formulation of flame retarded of masterbatche electric cables - inspection following suspicion of HBCDD use to form articles - Insulation Products - light concrete with recycling EPS - Manufacture of flame retarded expanded polystyrene (EPS) articles for use in building applications." - Molding of self-extinguishing parts - production of flame retarded EPS (pellets and articles) - Scientific research
13	201-557-4 + 204-211-0	- additive - plasticiser - Scientific research and development

Annex 2: List of substances included in Annex XIV to REACH ("Authorisation List") with their sunset dates in 2015[11].

Name	EC Number	CAS Number	Sunset date	Latest application date	Number of AfAs[12] received	Opinions delivered (per Use)	Decision taken (per AfA)	Date of submission of opinions to COM (AfA)	Timeline of decisions (AfA)[13]
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	21 February 2015	21 August 2013	0	0	0	N/A	N/A
Dibutyl phthalate (DBP)	201-557-4	84-74-2	21 February 2015	21 August 2013	2	4	2	Apr 2014 (1) Dec 2014 (1)	Dec 2014 (1) April 2016 (1)
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	21 February 2015	21 August 2013	0	0	0	N/A	N/A
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	21 February 2015	21 August 2013	5	14	2	Jan 2014 (1) Oct 2014 (3) Feb 2015 (1)	Aug 2014 (1) June 2016 (1)
[DBP + DEHP]	201-557-4 204-211-0	84-74-2 117-81-7	21 February 2015	21 August 2013	1	3	1	June 2014 (1)	March 2015 (1)
Diarsenic pentaoxide	215-116-9	1303-28-2	21 May 2015	21 November 2013	0	0	0	N/A	N/A
Diarsenic trioxide	215-481-4	1327-53-3	21 May 2015	21 November 2013	4	5	4	Oct 2014 (3) Jan 2015 (1)	Sept 2015 (3) May 2015 (1)
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	21 May 2015	21 November 2013	1 (covering both pigments)	12	1	Jan 2015 (1)	Sept 2016 (1)
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	21 May 2015	21 November 2013					
Lead chromate	231-846-0	7758-97-6	21 May 2015	21 November 2013	1	1	0	Sept 2015 (1)	
Tris(2-chloroethyl)phosphate (TCEP)	204-118-5	115-96-8	21 August 2015	21 February 2014	0	0	0	N/A	N/A
2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	121-14-2	21 August 2015	21 February 2014	0	0	0	N/A	N/A
Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane	221-695-9 247-148-4	134237-50-6 134237-51-7 134237-52-8 25637-99-4 3194-55-6	21 August 2015	21 February 2014	1	2	1	Jan 2015 (1)	Jan 2016 (1)

[11] http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

[12] Application for Authorisation

[13] This information is regularly updated and available on ECHA website at: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/received-applications and on COM website http://ec.europa.eu/growth/sectors/chemicals/reach/about/index_en.htm

Annex 3: Questionnaire on the Forum second pilot project on authorisation

QUESTIONNAIRE

(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: 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

0.6. Type of inspection

○ Only desk top check

○ 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: 1.2. Name and telephone of the contact person: 1.3. Contact person's qualification:	Only for internal use – do not submit data
1.4. Company's NACE-Code(s):	Source for NACE Code see Annex 5, 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

3.1. Specify which substance is subject to inspection according to EC number: ○ 201-553-2 Diisobutyl phthalate (DIBP) ○201-557-4 Dibutyl phthalate (DBP) ○201-622-7 Benzyl butyl phthalate (BBP) ○204-211-0 Bis(2-ethylhexyl) phthalate (DEHP) ○215-116-9 Diarsenic pentaoxide ○215-481-4 Diarsenic trioxide ○215-693-7 Lead sulfochromate yellow (C.I. Pigment Yellow 34) ○235-759-9 Lead chromate molybdate sulphate red (C.I. Pigment Red 104) ○231-846-0 Lead chromate ○204-118-5 Tris(2-chloroethyl)phosphate (TCEP) ○204-450-0 2,4 Dinitrotoluene (2,4-DNT) ○221-695-9, 247-148-4 Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane ○201-557-4 + 204-211-0 (DBP + DEHP)	3.1. Note Only one substance per company per questionnaire. If more substances are checked per company then additional questionnaires should be filled in.
3.2. Specify the use(s) of the substance	3.2. Note Please check the Annex 6 column H
3.3. Roles of the company under REACH in relation to the substance subject to inspection with its sunset date in 2015: ☐ 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) ☐ No present role for the inspected substance (further details are reported in section V)	3.3 Note: Art 3.9 of REACH Art 3.11 of REACH Art 8.1 of REACH Art 3.13 of REACH

II. Section - Compliance with authorisation duties by the company	
4. Has the company as M, I or DU placed the substance subject to inspection (mentioned in Q3) on the market for use after its sunset date defined in Annex XIV? ○ Yes, ☐ as substance as such, in mixtures or to be included in articles based on an authorisation granted ☐ as substance as such, in mixtures or to be included in articles ☐ 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 Exempted uses ☐ On-site isolated intermediate / transported isolated intermediate ☐ Use in medicinal products and/or the immediate packaging of 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: Art 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. Please note that a manufacturer, importer or a downstream user may place a substance on the market for a use, for which he does 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. 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.
5. Does the company use the substance subject to inspection (mentioned in Q3) for which its sunset date has passed in 2015? ○ Yes, ☐ as substance as such, in mixtures or to be included in articles based on an authorisation granted to the company inspected ☐ as substance as such, in mixtures or to be included in articles based on an authorisation granted to an actor up the supply chain for that use	Note: Art 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.

☐ as substance as such, in mixtures or to be included in articles ☐ 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 and/or the immediate packaging of 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 substance referred in Article 57 d, e, and f when present in mixtures below a concentration limit of 0.1%w/w ☐ 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 ☐ Others (e.g. substance in articles): Please specify. ○ No	

III. Section – Summary / action (company related)

6. Has non-compliance with REACH obligations of the inspected company related to Art 56 (1) of REACH (placing the substance subject to inspection on the market or use without authorisation) been detected?

○ Yes
○ No

7. Has non-compliance with REACH obligations of the inspected company related to 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) been detected?

○ Yes
○ No

8. Has non-compliance with REACH obligations of the inspected company related to Art 65 of REACH (including the authorisation number on the label) been detected?

○ Yes
○ No

9. Has non-compliance with REACH obligations of the inspected company related to Art 66 (1) of REACH (notification of DUs using the substance in accordance with Article 56 (2)) been detected?

○ Yes
○ No

10. 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

11. Has information related to the inspected substance been forwarded to another 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 – Enforceability of the authorisation decision/succinct summary

12.1 Once an authorisation has been granted: have the actual authorisation conditions referenced or provided in the authorisation decision (Note 1.) enabled good enforceability of the authorised uses(s) (including general conditions, monitoring arrangements, the required risk management measures and operational conditions of the exposure scenarios)?

◯ Yes
◯ No

If no, please specify difficulties in enforceability of the conditions required in the authorisation decision: …

◯ Not relevant

12.2. Once an authorisation has been granted: was the succinct summary (Note 2.) used during the inspection of the authorised use(s)?

◯ Yes

If yes,
- ☐ information was appropriate to easily enforce the authorisation decision
- ☐ information was not appropriate to easily enforce the authorisation decision
- ☐ other: …

Please specify what kind of information was missing in the succinct summary in order to easily enforce the authorisation decision: …

◯ No

If no,
- ☐ succinct summary was not available
- ☐ succinct summary was no needed
- ☐ other:….

Note:
The intention of this question is to answer only if the authorisation is granted.

1. For downstream users supplied with the authorised substance, the authorisation conditions of the authorisation decision are communicated in the extended safety data sheet. In such cases it is important that the inspector 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 in the extended safety data sheet and in the authorisation decision do match in terms of content)
2. According to the requirements of authorisation decisions the Member States can ask to have the succinct summary available in their official language(s) [14]

V. Section – Informal comments[15]

13.……
……
……

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

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