ECHA
EUROPEAN CHEMICALS AGENCY
Forum For Exchange Of
Information On Enforcement

REPORT

Forum pilot project on CMRs and Skin Sensitisers

Presented on 14-06-2016
Forum-24

Table of contents

1. Executive summary

The Forum for Exchange of Information on Enforcement (the Forum) conducted the pilot project on CMRs and Skin Sensitizers. Five Member States (MSs)[1] participated in the project.

This project aimed to check compliance with the duty to provide in the registration dossier a harmonised classification and labelling for substances for which such harmonised classification is obligatory The project focused on checking a small number of specific high severity-low complexity cases of potential non-compliance which were identified by ECHA. Through automatic screening ECHA identified dossiers where substance composition would trigger harmonised classification for CMR and Skin Sensitisation properties, but where harmonised classification was not identified in the dossier.

Another purpose of the project was to test the cooperation between National enforcement authorities (NEAs) and ECHA where ECHA identifies cases of potential non-compliance and delivers them to NEAs for further investigation.

The project was set up in November 2014. NEAs from participating MSs conducted enforcement actions between June 2015 and January 2016 using the manual and questionnaire prepared by the Working Group 'Interlinks'. The reporting phase took place between October 2015 and January 2016.

The pilot project has successfully tested the cooperation between ECHA and NEAs and yielded useful experience in Member States about compliance with the duty to provide harmonised classification and enforcement approaches. The detailed results of the project are based on eight inspections with completed questionnaires. Inspectors identified four (50%) cases of non-compliance among the checked cases.

Broadly speaking, the most frequently encountered scenario (62% cases) was that inspectors found that the harmonised classification was indeed missing in the dossier submitted to ECHA, but the registrant explained that – for various reasons - the information sent to ECHA was in fact not correct. Most registrants indicated that in reality the substance does not contain the impurities/constituents in concentrations that trigger the harmonised classification and in one case the registrant indicates that they submitted incorrect classification but applied the correct classification in their SDS. These five cases, even though they bear some similarity were reported in a slightly different way by the participating countries, because different participants interpreted the questionnaire differently. Some recorded non-compliance only with Art. 4(3) of CLP (duty to apply harmonised classification and labelling), while others additionally reported non-compliance with related duties under Art. 10(a)(ii) or 10(a)(iv) of REACH (duty to include in substance identification and classification in the registration dossier). That warrants a discussion in the Forum to ensure that reporting of non compliance is treated in the same way in future Forum projects.

Based on the findings of this project, the Working Group has outlined some recommendations for the Forum, ECHA, enforcement authorities and for industry.

[1] FI, FR, IE, IT and NL

2. Introduction

At the Forum-18 plenary meeting, the Forum decided to launch a pilot project to gather experience about why registrants failed to comply with Harmonised Classification and Labelling (CLH). That subject was selected because ECHA found cases of potential non-compliance through automatic screening of registration dossiers.

The project was established to test and streamline cooperation between ECHA and NEAs where potential enforcement cases are identified by ECHA. The purpose of the project was to gather experience so that similar projects can be designed, carried out and assessed easily in the future allowing ECHA to routinely provide NEAs with relevant enforcement-related intelligence.

3. Scope, Objectives and participants of the project

The scope of this project was the investigation of eight specific cases where registrants failed to apply harmonised classification and labelling (Annex VI of the CLP Regulation) in their registration dossier.

The objectives of the project were to:

- Enforce harmonised classification in these cases and find out why it was not applied originally and consider to what extent it affected the protection of health and environment
- To assess whether neglecting harmonised classification is related to other breaches of EU legislation, such as restrictions in consumer uses or worker protection legislation
- To test run such cases to ensure that in the future the interlinks continue to work and similar cases can run easily
- To collect feedback from NEAs to allow ECHA to fine tune the methods used to select further cases
- To improve the case template to ensure that NEAs have all the information needed
- To identify and answer frequently asked questions
- To produce an entry into the Interlinks Guide based on the results of the pilot so that cooperation on such cases may be conducted routinely

Member States – IE, FI, NL, IT and FR participated in the project and controls were conducted from June 2015 until January 2016.

4. Background information

4.1. Project history and background

The project originates from discussions held between Forum and the ECHA Secretariat about how ECHA could use their extensive database to practically support NEAs in their enforcement actions related to the quality of registration dossiers. This discussion, at Forum-16 and Forum-17, prompted ECHA to data mine for enforceable cases of potential non-compliance to provide to NEAs for further investigation. Initial screening for cases of potential non-compliance with Annex XVII (restriction) obligations revealed no cases of potential breaches of restriction that were suitably clear cut for direct enforcement. Initial screening related to harmonised classification and labelling seemed more likely to yield relevant cases, therefore, ECHA prepared a paper "Criteria for selection of enforceable cases from ECHA screening exercises" which was presented at Forum-18 outlining the criteria by which the cases for this project would be chosen. At that meeting the Forum and ECHA Secretariat agreed to prepare a small number of high severity-low complexity cases of potential non-compliance with harmonised classification and labelling (CLH) obligations as verified by ECHA's CLP experts.

The project was to collect experience about why registrants failed to apply CLH in their registration dossiers and also to streamline the cooperation between ECHA and NEAs so that similar projects can be designed, carried out and assessed more efficiently in the future.

4.2. Legislative background

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

Table 1: Legal scope of the project

Regulation	Article	Description
REACH	Article 10 (a) (iv) and Annex VI part 2.3.2, 2.3.3 and 4.1.	Obligation to include classification and labelling in the registration dossier, in line with Title 1 and 2 of the CLP Regulation, including information on impurities, additives or individual constituents.
CLP	Article 4 (3) and 11 (1)	Obligation to use harmonised classification and labelling where available. Substances contained within substances (e.g. as impurities, additive or individual constituent.) shall be taken into account for the purpose of classification.

5. Enforcement actions

5.1. Participating countries and number of inspections

Five Member States (MSs) participated in the project. In total, there were eight inspections conducted, one per case. Further details on the results can be found in chapter E.

5.2. Coordination of the project

The Forum WG "Interlinks", through the WG's coordinator of the pilot project and the Forum Secretariat, was responsible for project management. This included providing the manual and the project questionnaire, answering questions from the involved Forum members, collecting the results, evaluating them and reporting to the Forum.

The timelines of the project were:

Preparatory phase: 10 November 2014 – 31 May 2015
This phase consisted of preparing the cases and the manual for the project.

Operational phase: 1 June 2015 – 31 October 2015
This phase was when most of the inspections were done. Some inspections were done later with the results arriving in January 2016.

Reporting phase: 1 November – January 2016
During this phase the results were submitted, evaluated and the report prepared and adopted by the Forum.

5.3. Methods of enforcement

The project consisted of investigating specific cases of suspected non-compliance identified by ECHA. The inspection activity usually started with a desktop study, where the involved inspector consulted the RIPE database for further information on the company, information included in the registration dossier and the substance in question.

The desktop study may have been followed by an on-site visit at the registrants' premises or another form of contact with the registrant (letter/telephone/e-mail) to inform the involved company about the possible non-compliance. Communication with the registrant sought to enforce that, where necessary, the company updated the classification provided in the registration dossier. If necessary, enforcement action was taken.

The results of the investigations were recorded in the questionnaire for this pilot (see Annex 1) and were submitted to the Forum-S and to the WG coordinator for evaluation.

6. Results and conclusions

6.1. General overview

The table summarising the results of the project is included in Annex 3.

6.1.1. Overview of the number of inspections

Five Member States participated in the pilot project with a total of eight investigations[2] completed, one per case. Questionnaires were completed for all the inspections.

Table 2: Participating countries and reported inspections

	Country	Number of cases / inspections
1	Finland	2
2	France	1
3	Ireland	2
4	Italy	1
5	Netherlands	2
	Total	**8**

6.1.2. Number of cases where inspectors detected non-compliance with obligations related to Art 4(3) of CLP (obligation to use harmonised classification)?

In 50% of the cases the inspectors have confirmed non-compliance with obligation to apply harmonised classification. Reasons for that are explored in the next questions.

Table 3: Cases of non-compliance confirmed

Non-compliance determined?	Number of cases
Yes	4
No	4
Total	**8**

6.2. Responses to specific questions

1. If non-compliance with Art 4(3) was detected, what was it? (II.3)

In all cases where non-compliance was detected it was as described in the case information provided by ECHA. The non-compliance was lack of harmonised classification and labelling in the registration dossier (hazard categories: CMR[3] or Skin sensitisation) where the concentration of constituents or impurities in a substance specified in the registration dossier would trigger such classification.

[2] Investigations cover both desktop studies and on-site inspections
[3] Carcinogenic, Mutagenic, Toxic to Reproduction of category 1 (Carc. 1A or Carc. 1B, and/or Muta. 1A or Muta. 1B and/or Repr. 1A or Repr. 1B)

2. What was the reason for incorrect classification? (II.4)

Where inspectors judged the companies to be non-compliant

Each of the companies found to be non-compliant provided different explanations for the shortcoming. It was an accidental error, incorrect substance analysis or lack of clear information on the content of the impurity triggering the classification. In one case the company was in the process of changing its technological process to remove the impurity triggering classification and had prematurely updated its dossier with the expected classification of the substance after the improvement.

Where inspectors judged the companies to be compliant

In cases where the inspectors judged that companies were compliant, companies explained that the composition data submitted to ECHA was not accurate for various reasons. In two cases the impurities that would trigger the classification were in fact not present or in lower concentrations than specified in the registration dossier (below 0.1%). Companies provided inspectors with analytical results. In one case the registrant submitted outdated information in the registration dossier but used correct harmonised classification in the SDS used internally. In one case the registrant conducted a test for the specific endpoint (skin sensitisation) which indicated that the classification is not necessary.

3. Did the wrong classification impact health and safety of workers? (II.5)

No. In all cases where the inspectors found the classification was wrong they judged that despite this the risks were controlled adequately.

One of the reasons for this assessment is that while the data in the dossier did point towards harmonised classifications the investigations revealed that, the substances in five cases (62%) did not – in reality – contain the constituents/impurities in concentrations that trigger classification.

Other case-specific explanations available in the data are: in one case the company has actually produced a SDS that included the carcinogenic classification of the impurity of the substance and that SDS was delivered to the substance's two recipients. In another case the substance was distributed in controlled conditions (pipeline), in yet another it was registered by an OR and was not even imported and distributed in the EU, thus entailing no impact on health and safety of workers in the EU. In one case, additional tests revealed that the concentration of the impurity that would trigger carcinogenic classification was lower than 0.1%.

4. Did the wrong classification impact the environment? (II.6)

No. In all cases where the inspectors found the classification was wrong they judged that despite this the risks for the environment were controlled adequately. The reason are likely similar as those outlined in responses to question 5.

5. Did you detect any other non-compliance caused by or related to non-compliance with Art 4(3) of CLP? (II.7)

In one case the inspector found a related non-compliance. Deficiencies in the classification of the substance were also evident in the SDS that the company prepared

for the substance. Wrong classification of the substance was also specified in the PPORD notification of the same substance from this company.

In this case it did not have any impact on the health and safety of workers and the environment because the information on the risks of the substance had been communicated via the SDS, which included the carcinogenic classification of the impurity of the substance. The SDS had been delivered to two workplaces for experimental use only.

6. Was legal action initiated against the offender? (III.8)

Inspectors determined non-compliance with Art 4(3) in four cases (50%). They initiated legal action in three cases (75% of cases found to be non-compliant). In two cases it was a written advice to the registrant. In one case the inspectors applied administrative penalties.

7. Are you aware that the registrant has updated the dossier with harmonised C&L[4] as a result of enforcement actions? (III.9)

Inspectors indicate that in seven out of eight cases the registrant has sent an update or were excepting an update at some point. Inspectors did not expect an update in one case where the registrant provided analytical data to justify that harmonised classification is not necessary.

Ultimately ECHA received dossier updates from registrants in seven out of eight cases. The one case where the registrant did not send an update was where the registrant ceased manufacture rendering the registration inactive.

Impact on the project on the inspected dossiers
As a result of the project, registrants updated or changed the status of their registrations so that in six out of eight cases (75%) the reason for suspecting non-compliance was removed and in one case (12.5%) the dossier was made inactive.

Seven out of eight (88%) dossiers were brought into compliance, and therefore, will not be identified as potentially non-compliant by ECHAs automatic algorithms which screens dossiers for issues with harmonised classification and labelling.

1) In three cases (37.5%) registrants updated their registration with the expected harmonised classification and labelling
2) In three cases (37.5%) registrants updated their registration by changing the composition of the substance so that the harmonised classification and labelling is no longer obligatory
3) In one (12.5%) case there was no update, but the registrant notified cease of manufacture
4) In one (12.5%) case, there was an update, but the registrant did not submit to ECHA information that would remove ECHA's concern about non compliance. In this case the registrant upheld the information submitted to ECHA but delivered a read-across study indicating that the harmonised classification and labelling is not needed. The involved NEA and ECHA agreed to undertake further follow up action

[4] "Harmonised C&L" here means harmonised classification and labelling (CLH)

8. Was the information from ECHA sufficient to conduct the investigation and conclude the case? (IV.10)

In six out of eight cases the information provided by ECHA was deemed sufficient for investigation and conclusion of the case.

9. If not, what information was missing from the case documentation? (IV.11)

In the two cases where information was not deemed sufficient, inspectors indicate that information in the excel files sent by ECHA to NEAs did not clearly describe where in the registration/IUCLID dossier the information came from. Having information in three separate excel sheets in the file sent to NEAs made the handling of the information confusing. Ultimately, despite having the information in the excel files, inspectors needed to get the IUCLID dossier of the substance to have a clear understanding of the data given by the company in their registration.

10. Was direct support from ECHA sought? If yes, was the required information available from ECHA? (VI.12)

Direct support and further information from ECHA was sought in one case. Inspectors needed information on composition of the substance in other dossiers from the same company. ECHA had the information and provided it.

11. Which information given by ECHA in the case was not useful, if any? (IV.13)

In two cases inspectors suggested that information for a specific file (registration) should not be provided in several excel sheets as it is not practical for inspections.

7. General observations

Feedback on cases

Based on the information provided in at least five cases (62%) the results of the investigations appear to be very similar.

In four cases the harmonised classification and labelling is missing in the registration dossier submitted to ECHA, however, the registrant indicates that – for various reasons - the composition information sent to ECHA is in fact not correct and in reality the substance does not (or will not) contain the impurities/constituents in concentrations that trigger the harmonised classification. In one case the registrant claimed that the substance will not contain the impurities triggering classification soon after updating the technological process, and prior to registration the substance containing impurities that trigger classification, was no longer placed on the market.

Three observations can be made with relation to this finding:

1. It appears that in the specific cases covered in this project the information on substance composition submitted to ECHA in registrations was not accurate. Registrants provided different explanations for this and were treated differently by NEAs, but the general trend seems to be that the data in registration dossiers is not sufficiently reliable.

   This conclusion can be strengthened by the fact that in two further cases, even though they do not fit the pattern described above, the inspectors indicate that information on composition was unclear or that the error in the dossier was “accidental”.

   However this does not seem to be a widespread issue in all dossiers. The cases for this project were selected using many criteria to identify dossiers where the potential of non-compliance was high. As ECHA identified only a small number of such dossiers, it suggests that in general the information on substance composition in registrations seems to be accurate.

2. It appears that inspectors in different countries reported on similar cases of lack of Harmonised Classification & Labelling rather differently. The inspectors have assessed these cases rather differently, even though in effect they appear rather similar. In three such cases the NEAs judged that the registrant was compliant with Art 4(3) of CLP and in two cases the registrant was judged as non-compliant. Feedback from inspectors indicates that the difference stems from how broadly the inspectors interpreted the question on non compliance. Some reported only non compliance with Art 4(3) of CLP. Others also included in their answer their assessment of compliance with related obligations (e.g. under Art 10(a)(ii) and (iv) of REACH). In the cases where the substance composition information in the dossier was not correct and the actual composition of the substance would not trigger harmonised classification and labelling, companies were not in breach of Art 4(3) of CLP, but they were in breach of Art 10(a)(ii) and/or Art 10(a)(iv) of REACH for submitting incorrect information to ECHA. In the questionnaire of the pilot project question 7 (detection of other non-compliance) should have been answered. In addition there may be a different approaches amongst the MSs as to

when they assess non-compliance reported in the project – at the time of investigation (what the NEA originally finds) or after the company undertakes corrective action (what the NEA action results in). This would merit discussion for further (pilot) projects at the Forum level to find a common approach among NEAs in order to ensure consistent and reliable reporting for future projects.

3. The information collected in the project does not specify whether in cases where registrants indicate that they submitted incorrect information to ECHA (e.g. on substance composition such as indicating an impurity where there is none) or incorrect classification, inspectors are willing to enforce under Art. 10, e.g. Art. 10 (a)(ii) requiring registrants to provide correct information on substance identity in the registration dossier or Art. 10(a)(iv) requiring registrants to submit classification and labelling information. It appears to be the current practice, but since the data from the project are not explicit on this aspect, it would be useful to discuss and verify this with the Forum.

In one case the registrant did not contest the data that was submitted to ECHA, which did trigger harmonised classification, but produced a read-across study record to justify that the application of harmonised classification is not appropriate in this case. The inspector assessed the registrant to be compliant because the study results would indicate that the substance was not hazardous for that endpoint. The data submitted by the registrant as a result of the inspection was not sufficient to remove ECHA's concern about non compliance. The NEA and ECHA agreed to undertake further follow up action.

Cases from ECHA, operation of the interlinks

Results indicated that in all cases the issue was as described in the case information provided by ECHA, i.e. the concentration of constituents or impurities in a substance specified in the registration dossier would trigger a harmonised classification.

In the majority of cases (75%) the information provided in the case description was sufficient for NEA to conduct the investigation. In two cases the NEA found the information to be delivered in a format that was not clear enough and they needed to delve directly into the IUCLID dossier. In the future, ECHA should therefore consider simplifying the way that information is provided. This may result in the need for the NEAs to directly access the dossier. The specific needs of the NEA would be discussed in advance of the next exercise. Direct interaction from ECHA was sought only in one case and the information was provided.

8. 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 Forum from MSs participating in the project.

8.1. Recommendations to the Forum

1) The attention of the Forum is asked for the treatment of cases where registrants provide incorrect information in the registration dossier which has implications for C&L. The project experience indicates that enforcement of Art. 4(3) of CLP needs to go hand in hand with the enforcement of Art. 10 of REACH.

   In many cases covered by the project information in the dossier showed substance composition that triggers harmonised classification (CLH) but the company claimed that the information is incorrect/outdated and that the substance's different composition does not, in fact, trigger CLH.
   i) In such cases the company may be considered as compliant with Art. 4(3) of CLP
   ii) The submission of incorrect information to ECHA should be enforced as non-compliance with Art. 10(a)(ii) or Art. 10(a)(iv) of REACH

2) Discuss and clarify for future projects more general questions on reporting non compliance in Forum projects in order to ensure consistent results. Forum will be requested for written feedback:
   a) Should compliance be only assessed with respect to the very specific legal provision addressed in the question on compliance reporting in the questionnaire or should it cover also related provisions? This will affect how the questionnaires are prepared[5]. Should more guidance on this matter be offered in the manual and/or the questionnaire?
   b) What is the reference time for assessing non-compliance to be reported in the project?
      i) at the time of investigation (reflecting what the NEA originally finds) or
      ii) after the company undertakes corrective action (what the NEA action results in)

3) Forum to consider whether NEAs accept test results that show that classification for a multi constituent substance is not needed as a justification from a registrant for not applying CLH as prescribed by provisions of Art. 4(3) of CLP. The Forum will be asked for written feedback on:
   a) Do NEAs accept test results that show that harmonised classification for a multi constituent substance is not needed as justification for non-compliance with provisions of Art. 4(3) of CLP[6].
   b) If the NEAs do this, would there be a solution for ECHA to keep track of such cases? For example by ensuring that the registrants update the dossier with the results of the study that was used to override the CLH? This would allow excluding such registrations from future screening rounds related to harmonised classification and labelling

[5] In the questionnaire of this pilot project there was a question about any other non-compliance but this question was often not answered

[6] In Article 6.1 of CLP and the relevant guidance it is not quite clear whether the possibility to use test results to classify mixtures should apply also to multi-constituent substances. In one case in this project registrant brought forward a study report to justify that harmonised classification and labelling defined in Annex VI of CLP of would not be appropriate for one of the endpoints of the multi-constituent substance.

Based on this feedback the matter can be brought further to HelpNet or as a practical issue.

8.2. Recommendations to ECHA

1) Simplify the case forms – in particular so that for one dossier the information is available in one excel sheet
2) Clarify where – exactly - the information in the case sheets is originating from (e.g. which parts of the IUCLID dossier)
3) Provide a direct route of communication with ECHA (e.g. phone conference) to discuss or explain the reasoning behind the selection of the particular case

8.3. Recommendations to industry

1) Provide reliable information about the composition of registered substances. The project reveals that companies often submit inaccurate information in the dossiers

Annex 1: Questionnaire used in the pilot project on CMRs and Skin Sensitisers

QUESTIONNAIRE (One (1) questionnaire per registration)	
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 company and case (questions 1.1. to 1.3. will not be recorded)	
1.1. Name of company: 1.2 Registration number:	
1.3. Name and telephone of the contact person: 1.4. Contact person's qualification:	

II. Section – Feedback on the case	
2. Has non-compliance with obligations of the inspected company related to Art 4(3) of CLP (obligation to use harmonised classification) been detected? ◯ Yes ◯ No 3. What exactly was the non-compliance related to Art 4(3) of CLP (obligation to use harmonised classification)? ☐ As indicated in ECHA intelligence ☐ Other (e.g. for other endpoints, if checked). Please specify: 4. What was the reason for incorrect classification? ◯ Accidental error	

◯ Potentially intentional

◯ Other. Please specify:

Remarks:

5. Did the wrong classification impact health and safety of workers?

◯ Yes, wrong risk management measures were prescribed

◯ No, risks were controlled

Remarks:

6. Did the wrong classification impact the environment?

◯ Yes, wrong risk management measures were prescribed

◯ No, risks were controlled

Remarks:

7. Did you detect any other non-compliance caused by or related to non-compliance with Art 4(3) of CLP?

◯ Yes.

If yes, what was it:

◯ No.

III. Section – Summary / action (company related)

8. Was legal action initiated against the offender?

◯ Yes

If yes, under what Regulations and Articles was the enforcement action taken?

If yes, what action was taken

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

◯ No

9. Are you aware that the registrant has updated the dossier with harmonised C&L as a result of enforcement actions?

◯ Unknown

◯ Registrant has sent an update

When was it sent?

◯ Registrant will send an update

When do you expect it will be sent?

IV. Section – Feedback on operation of the interlink

10. Was the information from ECHA sufficient to conduct the investigation and conclude the case?

- ◯ Yes
- ◯ No

11. If not, what information was missing from the case documentation?

Remarks:

12. Was direct support from ECHA sought?

- ◯ Yes
- ◯ No

If yes, was the required information available from ECHA?

- ◯ Yes
- ◯ No
- ◯ Other. Please specify:

13. Which information given by ECHA in the case was not useful, if any?

Remarks:

V. Section – Informal comments[7]

14.

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