Reports from Member State investigations concerning the obligation to submit testing proposals for vertebrate animal tests under REACH

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Version	Changes	

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Table of contents

1. Background

It is a task of the Agency "*to decide on the programmes of testing proposed by manufacturers and importers"* (Recital 63 of the REACH Regulation).

ECHA has previously reported statistical information[1] on new 'higher-tier'[2] studies on vertebrate animals submitted in registration dossiers, without first submitting a testing proposal (TP) and awaiting a prior regulatory decision from ECHA (or the European Commission) to conduct the testing.

The findings reported did not necessarily mean that registrants had not fulfilled their obligations to submit a testing proposal and await ECHA's decision before commencing testing. There could be other reasons why such studies are available. For example, if new tests are available (e.g. not conducted for REACH purposes) and fall within the information requirements, registrants are, according to REACH, obliged to include them in their registrations.

ECHA conducted a further analysis and survey of registrants aimed at identifying the possible reasons why registrants had submitted the studies. ECHA published its findings[3]. It concluded that "[The] *MSCAs and NEAs[4] have the most effective means to clarify whether in the cases described that the registrants are complying with their obligations and whether these cases may warrant investigation by MSCAs/NEAs. ECHA has invited the MSCAs/NEAs to provide feedback on the outcomes of any investigations in such cases."*

ECHA consistently informs the Member State authorities if a registrant has performed a higher-tier vertebrate test, without having sought a prior decision from ECHA approving their testing strategy. This gives the Member State authorities the opportunity to consider the need for any necessary investigations and enforcement actions.

ECHA provided the details of its survey results to the concerned Member State authorities, so they, in cooperation with the national enforcement authorities (NEAs), have the opportunity to consider the need for any necessary investigations and enforcement actions.

This report summarises the feedback ECHA received from the NEAs on their investigations.

2. Scope of the analysis

In its appendix to the aforementioned report[3], ECHA listed the substances for which registrants submitted at least one higher-tier vertebrate animal study without submitting a testing proposal (TP) together with categories of reasons the registrants provided for having performed the test or where reasons were not provided.

Dataset – 295 studies

There were 70 studies for environmental endpoints and 225 for human health endpoints. These studies were submitted by companies located in 18 EU (+1 EEA[5]) Member States (MSs).

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[1] Report on Alternatives to Animal Testing (2014).
[2] By 'higher-tier' test, we refer to the tests listed in Annexes IX and X to the REACH Regulation and required for substances manufactured or imported at tonnages higher than 100 tonnes per year.
[3] Survey results - analysis of higher tier studies submitted without testing proposals (2015).
[4] National enforcements authorities.
[5] European Economic Area

"Potential interest" to NEAs: 121 in 15 EU countries

ECHA grouped the categories of reasons as being of "potential interest to NEAs" (121 studies) or of "low priority" (174 studies) (see table below).

ECHA analysis of reasons of "potential interest to NEAs" versus "low priority"	
Potential interest to NEAs (PI)	**Low priority (L)**
36 (No explanation)	82 (Other regulatory purposes)
50 (Complex explanations)	14 (Terminated TPE)
4 (Responsible care)	6 (Not a new test)
31 (Different legal entity with REACH obligations)	15 (Misunderstanding of REACH requirements)
	57 (Different legal entity without REACH obligations)
121	**174**

ECHA considered that the 121 performed studies of "potential interest to NEAs" may be linked to potential non-compliance with the registrant's obligations, in accordance with Articles 10(a)(ix) or 22(1)(h) of the REACH Regulation, to submit a TP and await ECHA's decision before conducting a higher-tier vertebrate animal study.

In turn, such incompliances may be linked to other REACH provisions (e.g. Articles 12, 13 and 25(1)) (see chapter 2 of "Survey results (2015)" report).

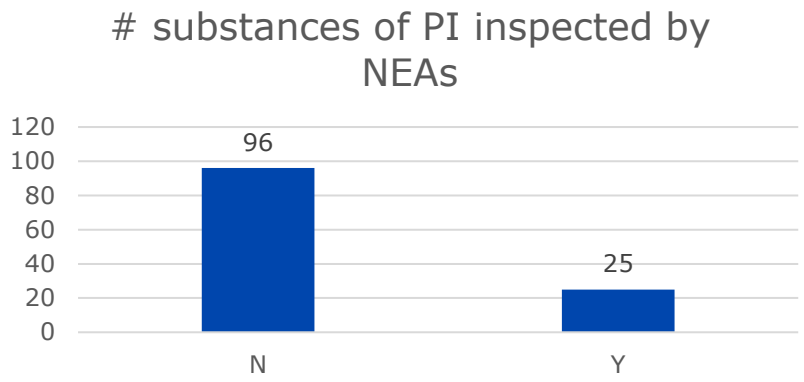
The 121 studies are mainly those where registrants have not provided reasons for submitting the tests (36), or provided complex (or unclear) responses to the survey (50). ECHA also added the studies (4) where registrants claimed "responsible care" as a reason, since this does not appear to be a legitimate reason to omit the testing proposal evaluation procedure laid out in REACH.

Finally, ECHA considers a possible breach of REACH obligations if the legal entity (e.g. other than the lead registrant) performing the test may also have had legal registration obligations under REACH (and therefore also needed to submit testing proposals) within the EU (31 studies).

The 121 studies were submitted by lead registrants (including the studies performed by other legal entities) located in 15 different MSs: Belgium (13), Czech Republic (2), Denmark (2), Estonia (1), Finland (2), France (12), Germany (56), Hungary (1), Ireland (2), Italy (2), the Netherlands (15), Poland (2), Slovakia (1), Spain (5) and the United Kingdom (5).

3. Reporting on enforcement activities

- By April 2017, ECHA received feedback on enforcement activities from 7 NEAs (CZ, FI, DE, IE, IT, NL, PL) which represents 47 % of the Member States contacted. Eight other NEAs provided no response (BE, DK, EE, FR, HU, SK, ES and UK). 6 NEAs (but DE) reported on 25 of the 121 studies, which represents 20.7 % of the total number of studies of potential interest ("PI").



- DE NEA noted that German companies were contacted but none provided further explanations regarding their potential violations of Articles 10(a)(ix) and 22(1)(h) of REACH. DE NEA added that the German national laws do not allow sanctions in relation to these specific REACH violations, and that the animal tests performed in Germany would be punishable if they contravene the national animal protection act. However, this national legislation would not apply to tests conducted in laboratories outside of Germany.

4. Conclusions from enforcement activities

Out of the 25 reported inspections related to substances and studies, which could be of potential interest ("PI"), in 92 % (23/25) of "PI" cases, the NEAs reported that they had not identified an incompliance in respect to possible failures to submit a testing proposal and await ECHA's decision.

In addition, the NEAs reported the following:

- One confirmed violation of Article 12(1)(d) (also related to the obligation to submit a testing proposal);
- One non-concluded inspection, as the legal liability is part of another MS (cooperation initiated).

Finally, one NEA considered and confirmed that there was no violation of Article 25(1) found.

Two NEAs (CZ and NL) conducted additional inspections of 12 studies of low priority (labelled as "L"), and reported that no violation of national law could be identified (except in one case, which may have been subject to enforcement action, if proceedings had started within three years of the offense).

The appendix below lists the case-specific outcome reported.

APPENDIX: List of substances for which national enforcement authorities conducted inspections and assessed incompliance (as a follow-up of ECHA's Survey analysis – July 2015)

Registered Substance EC Number	IUCLID section	Study type	Categories of explanations	Incompliance according to national inspection
200-872-4	7.6.2	*In vivo* GenTox	Conducted by a different LE	N
200-939-8	7.6.2	*In vivo* GenTox	Conducted by a different LE	N
222-695-1	5.3.1	BCF- fish	No explanation provided	N
222-695-1	7.8.2	PNDT	No explanation provided	N
222-695-1	7.8.2	PNDT	No explanation provided	N
222-695-1	7.5.1	RDT 90 Oral	No explanation provided	N
222-695-1	7.6.2	*In vivo* GenTox	No explanation provided	N
223-989-2	7.6.2	*In vivo* GenTox	No explanation provided	Cooperation needed
231-609-1	6.1.2	Fish	Complex explanations	Y
232-734-4	7.5.1	RDT 90 Oral	Conducted by a different LE/ other regulatory purposes	N
235-627-0	7.5.1	RDT 90 Oral	Complex explanations	N
237-864-5	7.5.1	RDT 90 Oral	Complex explanations	N
239-407-5	7.5.1	RDT 90 Oral	Complex explanations	N
239-407-5	7.8.1	Repro 1Gen	Complex explanations	N
248-227-6	7.6.2	*In vivo* GenTox	No explanation provided	N
297-049-5	7.5.1	RDT 90 Oral	No explanation provided	N
500-655-7	5.3.1	BCF- fish	Complex explanations	N
618-882-6	7.5.1	RDT 90 Oral	Conducted for other regulatory purposes	N
627-071-6, 627-083-1	5.3.1	BCF- fish	Conducted by a different LE/ other regulatory purposes	N
627-071-6, 627-083-1, 605-717-8	7.5.1	RDT 90 Oral	Conducted by a different LE/ Not a new test	N
700-459-3	7.6.2	*In vivo* GenTox	Conducted by a different LE	N
930-592-4	7.5.1	RDT 90 Oral	Complex explanations	N
931-257-5	7.5.1	RDT 90 Oral	No explanation provided	N
931-257-5	7.5.1	RDT 90 Oral *	No explanation provided	
939-180-9	7.6.2	*In vivo* GenTox	No explanation provided	N

* Duplicate noted during finalisation of the report.

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