Survey after the webinar session "How to submit a CLH dossier?", 26 May 2021

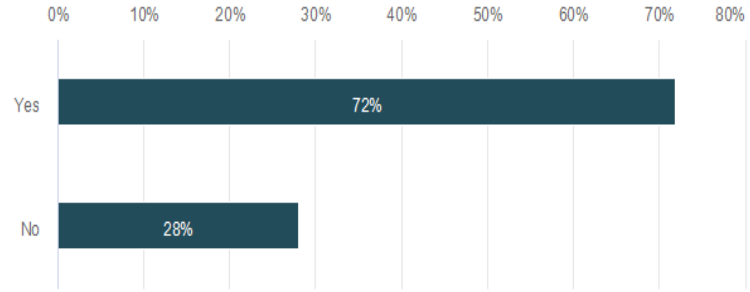
Disclaimer: ECHA conducted a survey following the webinar on how to submit a CLH dossier of May 2021. The results are included below, they incorporate also the comments provided during the survey by the responders which are made available in the tables below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table but not published on the website due to Intellectual Property Rights or confidentiality. ECHA accepts no responsibility or liability for the content of this document.

Total number of respondents: 27

General

1. Have you been involved in the preparation of CLH dossiers?

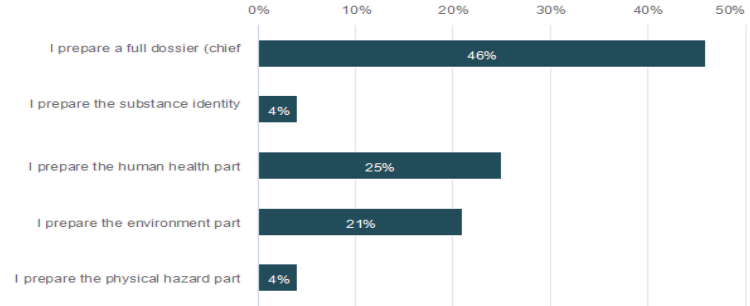
Number of respondents: 25



	n	Percent
Yes	18	72.0%
No	7	28.0%

2. Do you work on the full dossier or a specific part of the dossier?

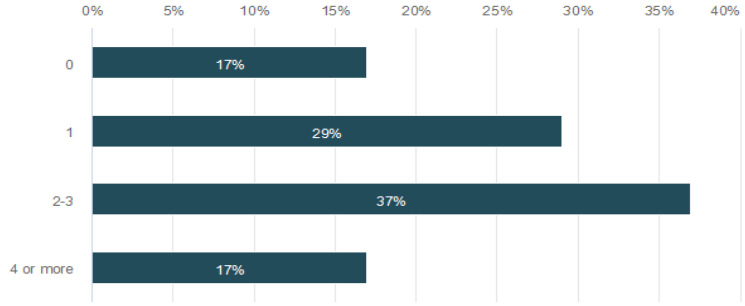
Number of respondents: 24



	n	Percent
I prepare a full dossier (chief editor)	11	45.8%
I prepare the substance identity part	1	4.2%
I prepare the human health part	6	25.0%
I prepare the environment part	5	20.8%
I prepare the physical hazard part	1	4.2%

3. How many CLH dossiers do you / your organisation submit per year?

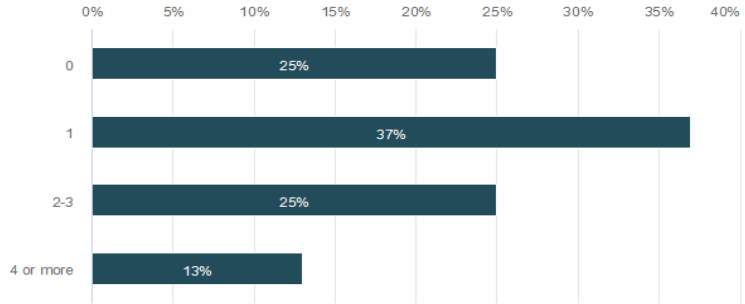
Number of respondents: 24



	n	Percent
0	4	16.6%
1	7	29.2%
2-3	9	37.5%
4 or more	4	16.7%

4. How many dossiers do you / your organisation plan to still submit in 2021?

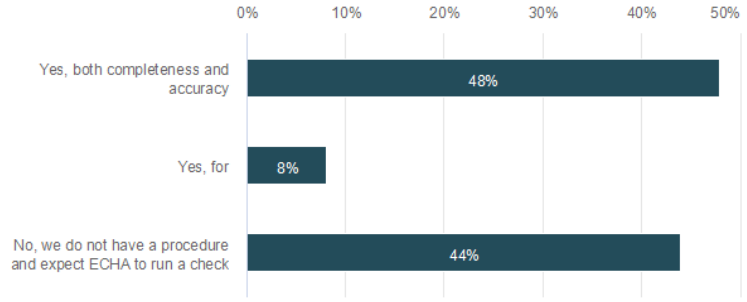
Number of respondents: 24



	n	Percent
0	6	25.0%
1	9	37.5%
2-3	6	25.0%
4 or more	3	12.5%

5. Does your organisation have a procedure for checking CLH dossiers for completeness and / or accuracy before submission to ECHA?

Number of respondents: 25



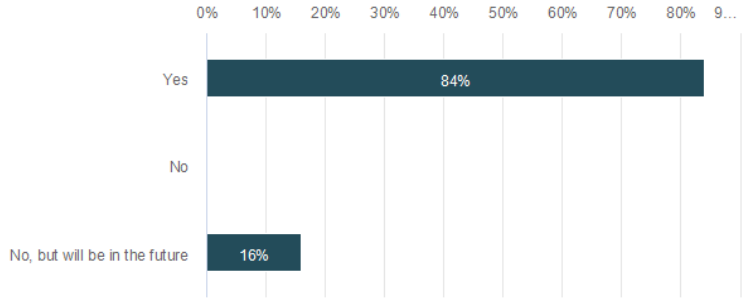
	n	Percent
Yes, both completeness and accuracy	12	48.0%
Yes, for	2	8.0%
No, we do not have a procedure and expect ECHA to run a check	11	44.0%

Answers given into text field:

Option names	Text
Yes, for	completeness according to the template
Yes, for	some parts

6. Are you / your organisation aware of the importance to submit a notification to Registry of Intentions prior submitting the CLH dossier?

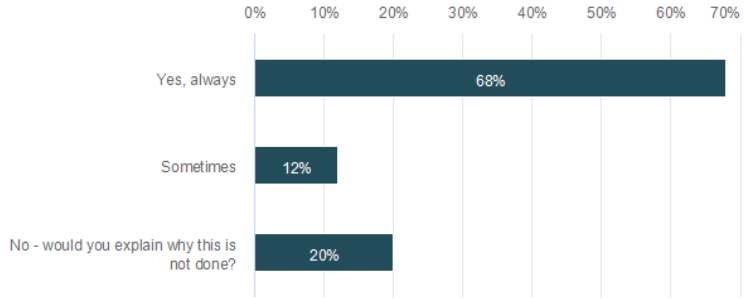
Number of respondents: 25



	n	Percent
Yes	21	84.0%
No	0	0.0%
No, but will be in the future	4	16.0%

7. Does your organisation regularly submit a notification to Registry of Intentions prior submitting the CLH dossier?

Number of respondents: 25



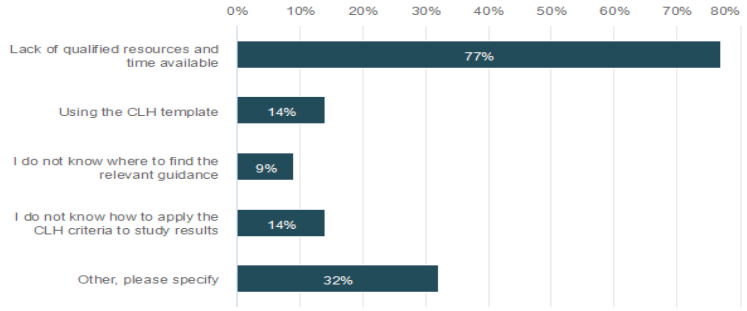
	n	Percent
Yes, always	17	68.0%
Sometimes	3	12.0%
No - would you explain why this is not done?	5	20.0%

Answers given into text field

Option names	Text
No - would you explain why this is not done?	Until now, no CLG dossier was submitted
No - would you explain why this is not done?	it is the duty of our client to submit the CLH dossier
No - would you explain why this is not done?	Not yet
No - would you explain why this is not done?	We are consultant, the decision comes from our customers.

8. What obstacles do you encounter when preparing the CLH dossier?

Number of respondents: 22, selected answers: 32



	n	Percent
Lack of qualified resources and time available	17	77.3%
Using the CLH template	3	13.6%
I do not know where to find the relevant guidance	2	9.1%
I do not know how to apply the CLH criteria to study results	3	13.6%
Other, please specify	7	31.8%

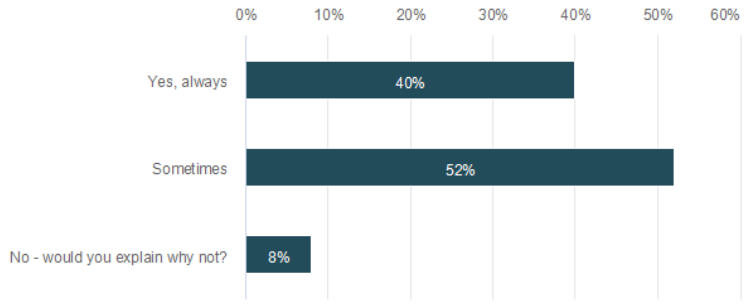
Answers given into text field

Option names	Text
Other, please specify	access to original studies
Other, please specify	limited access to the full study reports
Other, please specify	Lack of information or quality among the studies
Other, please specify	Based on our experience, we are of the opinion that clarification on the role of Annex I to the CLH report is required, particularly for substances subject to REACH. We note that in the questions and answers prepared by ECHA following the Webinar 'How to Submit a CLH dossier' (26 May 2021), ECHA indicated that 'Annex 1 was developed to facilitate using extracts from DARs, CARs and similar. If sufficient information is available in the report itself the annex is not needed'. Since it takes time to prepare

Option names	Text
	an Annex I report with detailed study summaries, further explanation from ECHA on when it is would be useful to prepare an Annex I report would be welcome. For example, if a CLH proposal is based on OECD guideline studies and if the study details (as outlined in section 2.10 of the Practical Guide "How to submit a CLH dossier") can be summarised in the CLH report, is there a need to also prepare an Annex I? The CLH template includes sub sections for "history of the previous classification and labelling" (section 3) and "Justification that action is needed at community level" (section 4). However, it is not clear where information on other relevant regulatory activities should be reported. For example, where CLH has been identified as an outcome of a substance evaluation under REACH, reference to the substance evaluation should be made in the CLH report. Consideration could be given to updating the template to include a separate section to report such relevant regulatory activities.
Other, please specify	template for group of substances is lacking
Other, please specify	Poor quality of data. Sufficient for risk assessment under BPR but not for classification.

9. Do you regularly engage in collaboration activities with other departments of your Competent Authority, e.g. between CLP and Biocides?

Number of respondents: 25



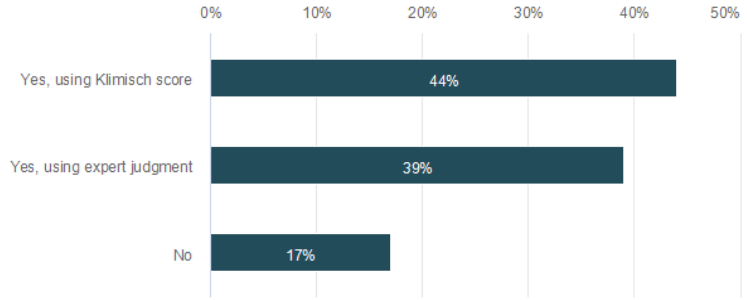
	n	Percent
Yes, always	10	40.0%
Sometimes	13	52.0%
No - would you explain why not?	2	8.0%

Answers given into text field

Option names	Text
No - would you explain why not?	Not needed

10. Do you regularly perform the reliability assessment of studies in the CLH dossier?

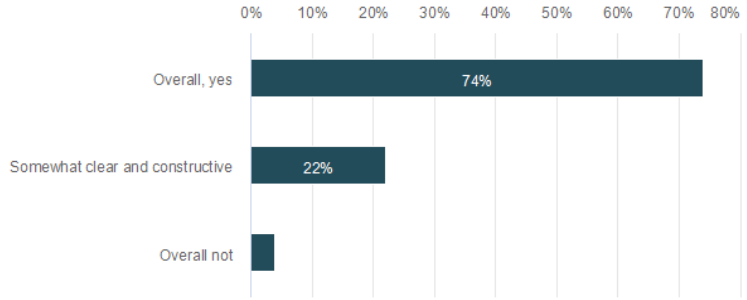
Number of respondents: 23



	n	Percent
Yes, using Klimisch score	10	43.5%
Yes, using expert judgment	9	39.1%
No	4	17.4%

11. If the CLH dossier did not pass the accordance check by ECHA and the CLH dossier is sent back to you for review, do you find the comments you received from ECHA clear and constructive?

Number of respondents: 23



	n	Percent
Overall, yes	17	73.9%
Somewhat clear and constructive	5	21.7%
Overall not	1	4.4%

12. If you answered one of the two latter options, how could ECHA improve the feedback given?

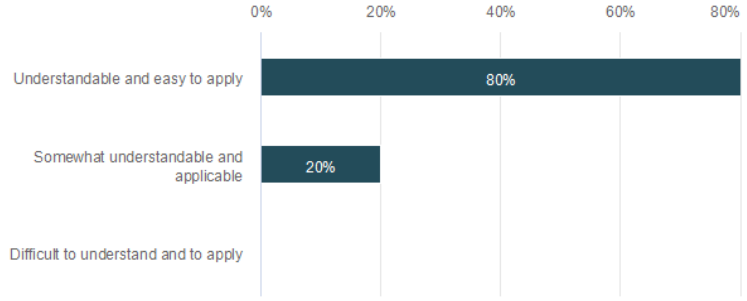
Number of respondents: 5

Responses - how could ECHA improve the feedback given?
Not yet received
There is not always consistency in the comments provided by ECHA with different substances.
We note that the accordance check results contain “required information/revisions” and “recommended information/revisions”. We understand that the “required” amendments are needed in order for the CLH proposal to pass the accordance check. However, it is not clear whether the dossier submitter should also make the recommended amendments in order to pass accordance check. Therefore, the purpose of the recommended amendments, and ECHA’s expectations for them, could be further clarified. While we have found some of the “recommended” feedback in the accordance check useful, other feedback appears to be based on the preference of the ECHA dossier manager on how aspects should be reported or their preferred wording, rather than correcting an inaccuracy or highlighting the need for clarifications. For example, requests to include the view of the dossier submitter on a point when this is already included in a subsequent paragraph in the CLH report or including editorial amendments which do not fundamentally change the meaning or clarity of the statement. Increased harmonisation of the recommended feedback could be considered to ensure consistency for dossier submitters. We prepared our CLH proposals using recent CLH submissions for REACH substances from other Member States, which addressed similar hazard classes to our proposals, as a guide. We found that we failed the accordance check on issues that were present in the other successful proposals. Therefore, we have found it difficult to predict issues which would be identified in accordance check.
Varies between dossier managers. Often clear and constructive but in many cases comments seem to reflect personal preference in terms of writing rather than what is actually needed for the understanding.
careful use of "recommended" and "required" recommendation

Practical Guide 'How to submit a CLH dossier'

13. Overall, did you find the Practical Guide:

Number of respondents: 25



	n	Percent
Understandable and easy to apply	20	80.0%
Somewhat understandable and applicable	5	20.0%
Difficult to understand and to apply	0	0.0%

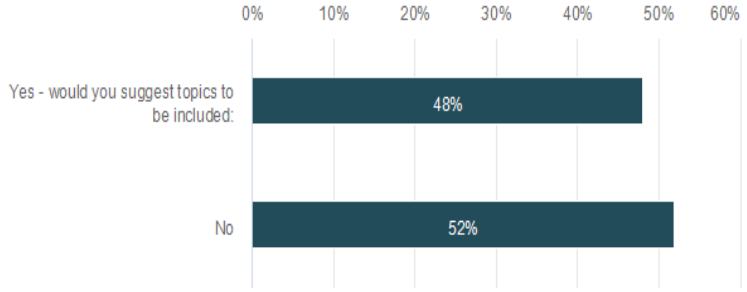
14. If you answered one of the two latter options, please specify what are the difficulties in understanding the content and how to apply the advice and guidance

Number of respondents: 2

Responses
In general we found the practical guide understandable and applicable. However, in the first instance, we would rely on the CLP Regulation and Guidance on the Application of the Criteria. While some of the topics are well covered, others are only briefly discussed and the reader is then referred to other guidance. Some of the points may have been better addressed in an updated annotated CLP report template. We found Table 3 in the practical guide difficult to follow and we are unclear as to what message this table is trying to convey.
We are involved in CLH for PPP and the information are not completed yet. Templates specific for PPP could not be identified.

15. Do you think the guide is missing important topics?

Number of respondents: 25



	n	Percent
Yes - would you suggest topics to be included:	12	48.0%
No	13	52.0%

Answers given into text field

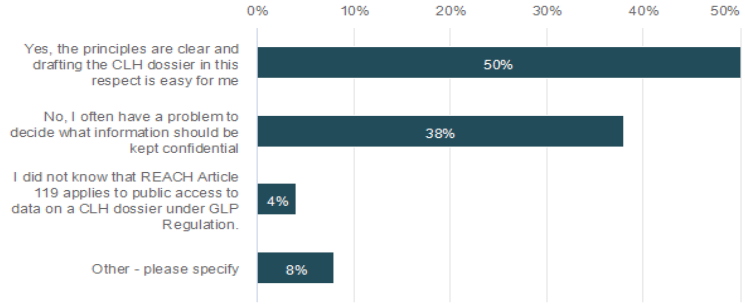
Option names	Text
Yes - would you suggest topics to be included:	Sanitisation rules
Yes - would you suggest topics to be included:	more information on grouping and read-across would be appreciated
Yes - would you suggest topics to be included:	• It would be useful to clarify under what conditions ECHA expects a dossier submitter to prepare an Annex I to the CLH report. Also, if Annex I to the CLH report is prepared, is it acceptable not to repeat aspects of the study design in the CLH report. From our experience, it is not clear as to whether RAC reviews only the CLH report, or both documents. As the dossier submitter spends a considerable amount of time and resources drafting Annex I to the CLH report, further clarity on the use and applicability of this document would be beneficial. • Section 2.10 describes the “scientific details needed”. It provides a set of bullet points covering what a study summary should report. It is not clear whether it is expected that all these details should be included in the CLH report or whether it is acceptable to provide details of the study conditions for example in Annex I. • Section 2.8.1 could be amended (or a new section developed) to provide an example of how ECHA wishes dossier submitters to reference study summaries taken from the disseminated REACH registration dossier, both in the summary tables and the reference list. By providing an example, this would ensure consistency between CLH proposals and avoid confusion. This point is briefly covered in the questions and answers prepared by ECHA following

Option names	Text
	the Webinar 'How to Submit a CLH dossier' (26 May 2021) but could be expanded.
Yes - would you suggest topics to be included:	In section 2.7 we would like to have more information on to what extent data should be presented (not key data) in the report, in particular for data rich substances
Yes - would you suggest topics to be included:	We would like to have information on to what extent data should be presented (especially for non-key data) in the report in particular for data rich substances.
Yes - would you suggest topics to be included:	Section 2.7 should clearly state to what extent data apart from key data should be presented.
Yes - would you suggest topics to be included:	intellectual property regulations - potential conflicts with disclosure of the information
Yes - would you suggest topics to be included:	For PPP, the link with IUCLID. Should come in October.
Yes - would you suggest topics to be included:	SID: ID in Annex VI, ID in registration dossiers vs. ID in AS dossiers
Yes - would you suggest topics to be included:	Reliability evaluation of studies (registrants vs authority)
Yes - would you suggest topics to be included:	To what extent there is a need to consider in-situ ingredients (e.g. biocidal active substances) or reaction products when classifying substances?

Confidentiality

16. A CLH proposal is always published. Are the confidentiality rules (REACH Article 119) sufficiently clear to you?

Number of respondents: 24



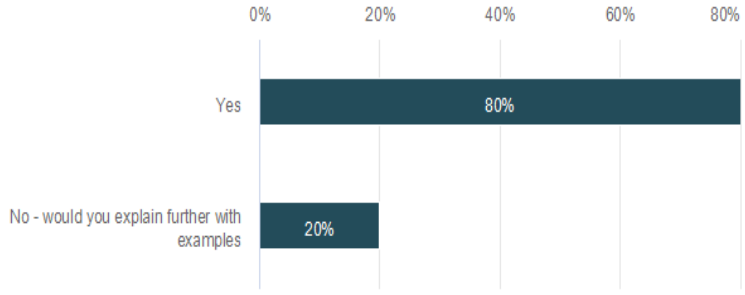
	n	Percent
Yes, the principles are clear and drafting the CLH dossier in this respect is easy for me	12	50.0%
No, I often have a problem to decide what information should be kept confidential	9	37.5%
I did not know that REACH Article 119 applies to public access to data on a CLH dossier under GLP Regulation.	1	4.2%
Other - please specify	2	8.3%

Answers given into text field

Option names	Text
Other - please specify	information from full study reports and unpublished studies
Other - please specify	Art 119 is clear, however distinction to copyright is difficult

17. Is it clear when authors' names of studies referred to in the CLH report need to be redacted?

Number of respondents: 25



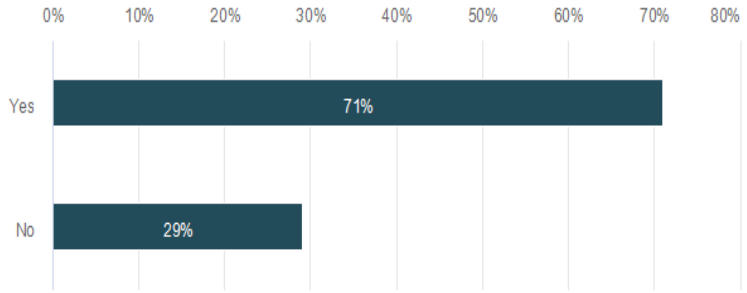
	n	Percent
Yes	20	80.0%
No - would you explain further with examples	5	20.0%

Answers given into text field

Option names	Text
No - would you explain further with examples	how to refer to study authors for unpublished studies in registrations
No - would you explain further with examples	If I understood correctly, redacting company name/testing laboratory is not meant (because not a natural person, such as study director of unpublished study).

18. Do you know for substance identity when impurities or constituents of a substance can not be claimed as confidential?

Number of respondents: 24

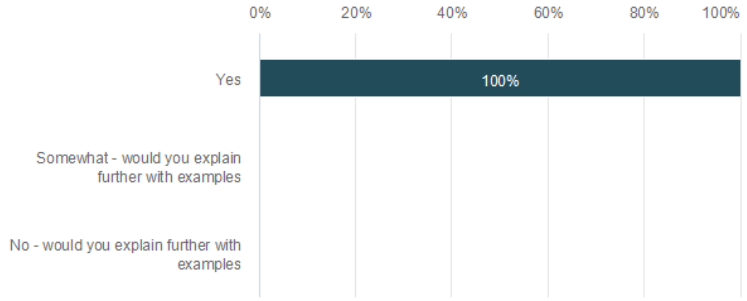


	n	Percent
Yes	17	70.8%
No	7	29.2%

Physical hazards

23. Is the section on the physical hazards in the Practical Guide clear?

Number of respondents: 5

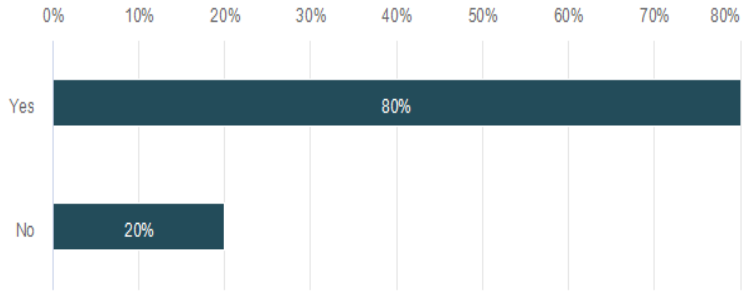


	n	Percent
Yes	5	100.0%
Somewhat - would you explain further with examples	0	0.0%
No - would you explain further with examples	0	0.0%

No answers given into text field

26. Are you aware that all methods EU A.number do not provide a conclusive evidence for classification?

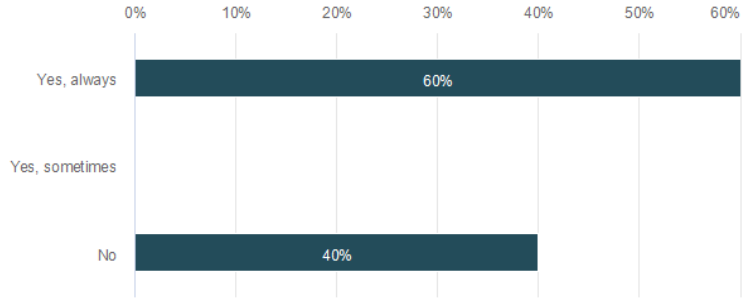
Number of respondents: 5



	n	Percent
Yes	4	80.0%
No	1	20.0%

27. Do you routinely use the screening procedures, if available, in the assessment of the physical hazard classes?

Number of respondents: 5

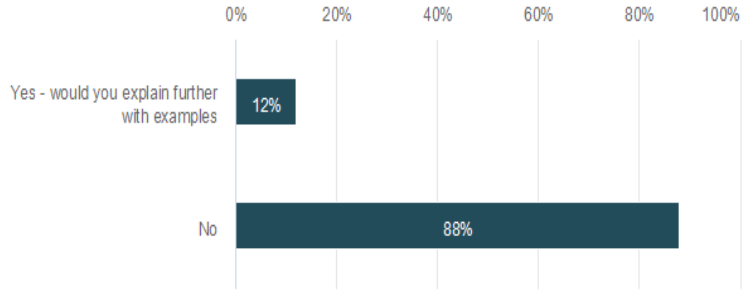


	n	Percent
Yes, always	3	60.0%
Yes, sometimes	0	0.0%
No	2	40.0%

Environment hazards

39. Do you have any comments on the section Environment Hazards in the Practical Guide?

Number of respondents: 8



	n	Percent
Yes - would you explain further with examples	1	12.5%
No	7	87.5%

Answers given into text field

Option names	Text
Yes - would you explain further with examples	Please clarify in section 5.2 whether the conclusion can also be “inconclusive”. (This conclusion may be relevant should the data e.g. show that there is high variability among species for this endpoint and it is not possible to draw a general conclusion).

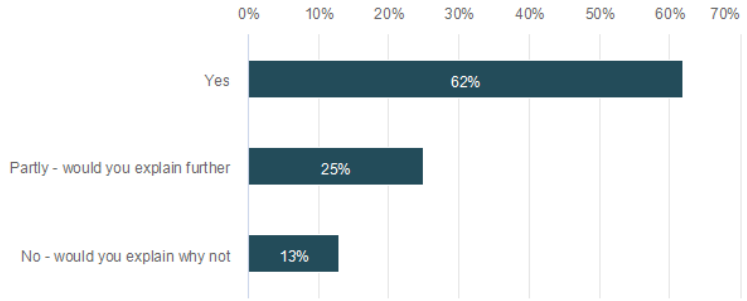
40. What are the most commonly faced issues/ problems you encounter when preparing your proposal for environmental hazards?

Number of respondents: 6

Responses
Data needed
For REACH registered substances the lack of full study reports or sufficient study summaries may make it difficult to assess the reliability of the studies. Overall study quality might be poor (eg. analytical verification lacking).
The availability of relevant and reliable information Level of detail reported in the robust study summaries in the REACH registration dossier The level of reporting required in the CLH report and Annex I
We would like to have information on to what extent data should be presented (especially for non-key data) in the report in particular for data rich substances.
Dealing with the Quality of the available studies to come to a robust conclusion for environmental classification of a substance.
I faced some problems on how to prepare the information about degradability

41. Has the Practical Guide addressed these considerations?

Number of respondents: 8



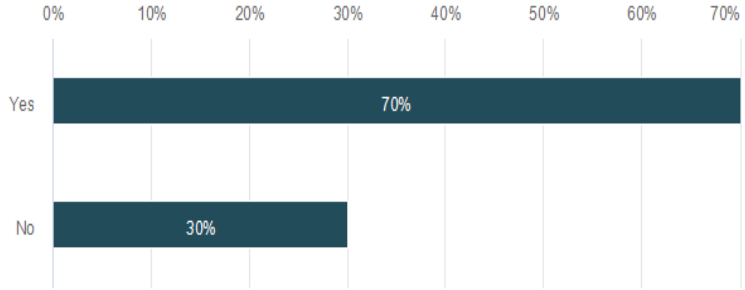
	n	Percent
Yes	5	62.5%
Partly - would you explain further	2	25.0%
No - would you explain why not	1	12.5%

Answers given into text field

Option names	Text
No - would you explain why not	The first two problems relate to the quality of information available and are outside of the scope of the Practical Guide. The Practical Guide could provide clarity on the type and level of reporting detail (e.g. information that should be reported in the tables, summaries, necessity to report purity) required in the CLH report, as it appears to vary between CLH dossiers. Equally, the dossier submitter spends a considerable amount of resources drafting Annex I to the CLH report. Further clarity on the use and applicability of this document would be beneficial.
Partly - would you explain further	Yes, some studies have had to be discarded.
Partly - would you explain further	Information on to what extent data should be presented (especially for non-key data) could preferably be included in section 2.7.

42. Is the difference between ready and rapid degradability sufficiently clear as described in the Practical Guide?

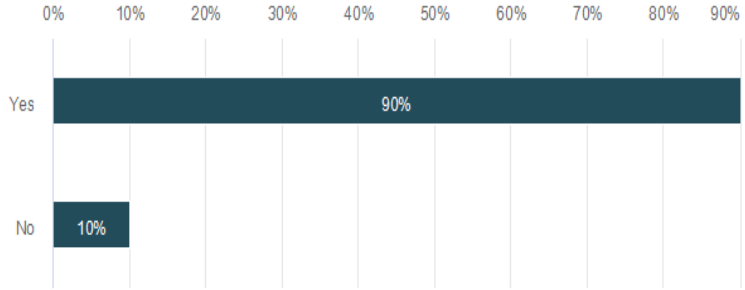
Number of respondents: 10



	n	Percent
Yes	7	70.0%
No	3	30.0%

43. Do you routinely report and consider information on degradation products in a CLH dossier?

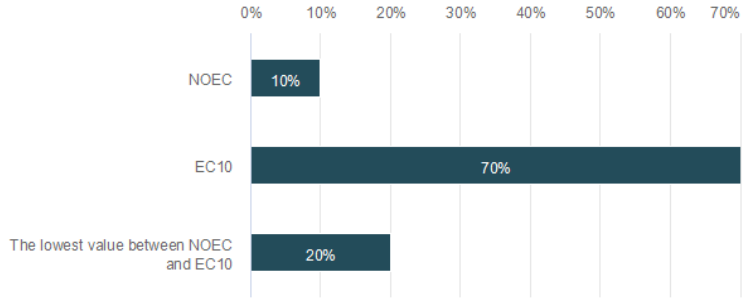
Number of respondents: 10



	n	Percent
Yes	9	90.0%
No	1	10.0%

44. If from a chronic study both NOEC and EC10 values are derived, which one do you routinely use for Aquatic Chronic classification?

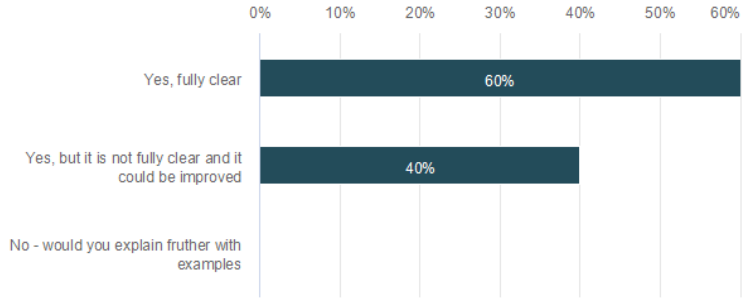
Number of respondents: 10



	n	Percent
NOEC	1	10.0%
EC10	7	70.0%
The lowest value between NOEC and EC10	2	20.0%

45. Is it clear to you under which conditions the “surrogate approach” [CLP Table 4.1.0 (b)(iii)] can be used to derive an aquatic chronic classification?

Number of respondents: 10

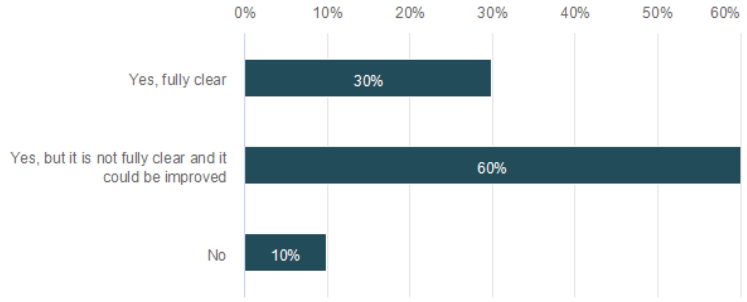


	n	Percent
Yes, fully clear	6	60.0%
Yes, but it is not fully clear and it could be improved	4	40.0%
No - would you explain further with examples	0	0.0%

No answers given into text field

46. Are you aware of the dedicated classification scheme available for metals and metal compounds?

Number of respondents: 10



	n	Percent
Yes, fully clear	3	30.0%
Yes, but it is not fully clear and it could be improved	6	60.0%
No	1	10.0%

47. If you answered one of the two latter options, would you explain further with examples

Number of respondents: 0