

European Chemicals Agency

# IUCLID 6 plugins survey

Final report

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IUCLID 6 is developed by the European  
Chemicals Agency in association with the OECD



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## FOREWORD

In autumn 2014, a total of 203 IUCLID users responded to a survey performed in support of the development of the plugins for the upcoming new IUCLID version, IUCLID 6. The survey focused on the plugins that are related to the preparation of dossiers under REACH, CLP and BPR, namely the Dissemination, the Fee calculation, the Report generator and the Validation assistant plugins.

The questions included in the survey aimed at:

- Obtaining a general understanding of the frequency of use and user satisfaction of the different plugins,
- Establishing the support of the user community for a number of previously collected improvement proposals,
- Collecting additional user requirements for the plugins.

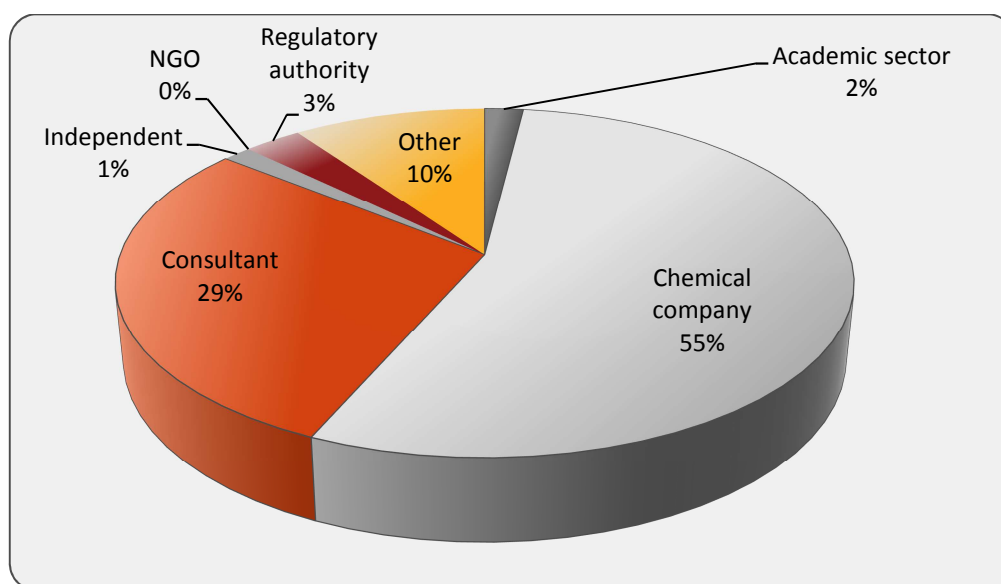
In the following report, unless stated otherwise, the number of respondents for a question is the maximum number of 203. When interpreting the results, it is to be noted that not all plugins are relevant for all IUCLID users.

## 1. GENERAL INFORMATION ON THE USE OF IUCLID

The survey was initiated with a set of general questions to characterise the group of respondents. The information was collected to be able to analyse the responses related to the IUCLID plugins in a more meaningful way.

### 1.1. Background of respondents

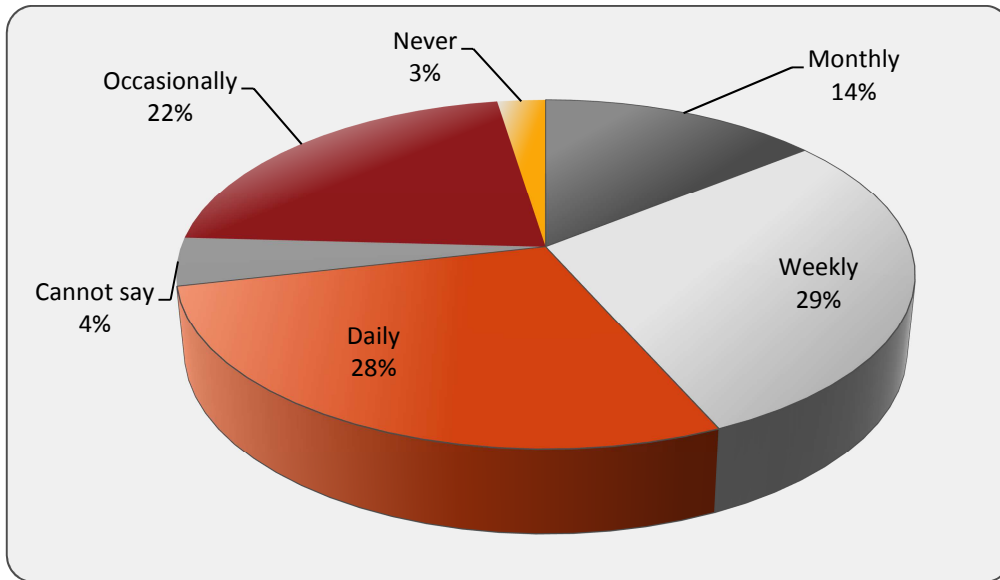
As expected, the vast majority of the survey respondents are coming from the industry (55%) and consultancy (29%) sectors as they are the primary providers of IUCLID information. The regulatory authorities (3%) and academic sector (2%) are also represented in this survey.



**Figure 1.** Background of survey respondents

## 1.2. How often respondents use IUCLID

Over half of the survey respondents are active IUCLID users: 28% state to use IUCLID on a daily basis and 29% on a weekly basis. A total of 7% have never used the software, or cannot specify their frequency of use.



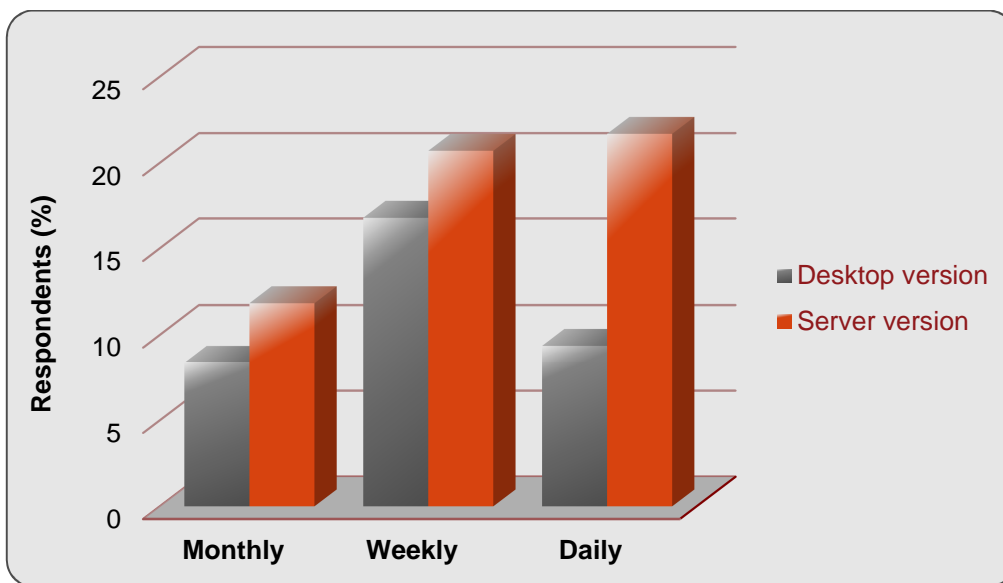
**Figure 2.** Frequency of IUCLID use by survey respondents

### 1.3. Type of IUCLID installation

The IUCLID software is available in two types:

- The *desktop version* (workstation version) is installed directly on a desktop computer or laptop. Any information in the desktop version of IUCLID is only accessible on that computer.
- The *server version* (distributed version) runs on a company or organisation server. The data in this IUCLID version can be accessed simultaneously by several users.

Of the IUCLID users responding to the survey, 34% use the desktop version on a regular basis, while 54% use the server version regularly. Figure 3 shows a more detailed breakdown of the frequency of use of the two types of installations.



**Figure 3.** Frequency of use of the different types of IUCLID installation

## 2. IUCLID PLUGINS

The second part of the survey consisted of plugin-specific questions, mapping the frequency of use of the various plugins, collecting opinions on their features and suggestions for further improvements.

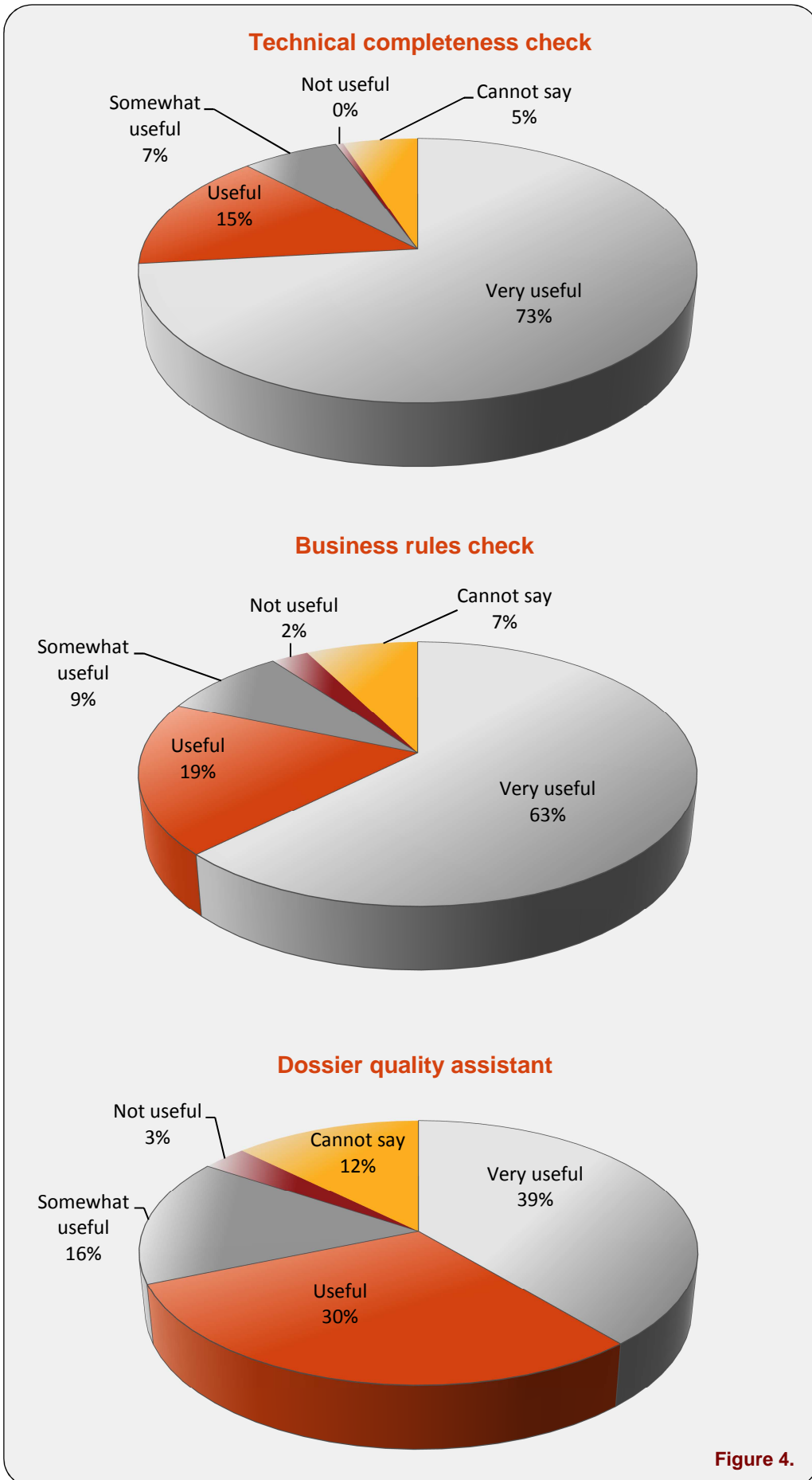
### 2.1. Validation assistant

#### 2.1.1. Usefulness of different modules

The Validation assistant allows IUCLID users to validate the content of their REACH registrations, PPORD notifications and other REACH and CLP dossiers before submitting them to the European Chemicals Agency (ECHA). The Validation assistant currently supports the following types of checks:

- The *technical completeness check* (TCC),
- The verification of those *business rules* that only rely on information from the IUCLID dossier,
- The check for common shortcomings and inconsistencies to improve the quality of a dossier (*Dossier quality assistant* module).

In the survey, respondents were first requested to rate the usefulness of the different modules of the Validation assistant. Of the 198 respondents who indicated to use the IUCLID software, 88% find the technical completeness check module of the Validation assistant to be useful or very useful. Likewise, 82% find the business rules check useful or very useful. The Dossier quality assistant is perceived to be useful or very useful by 69% of the 198 respondents. A more detailed breakdown of the answers can be found in Figure 4.



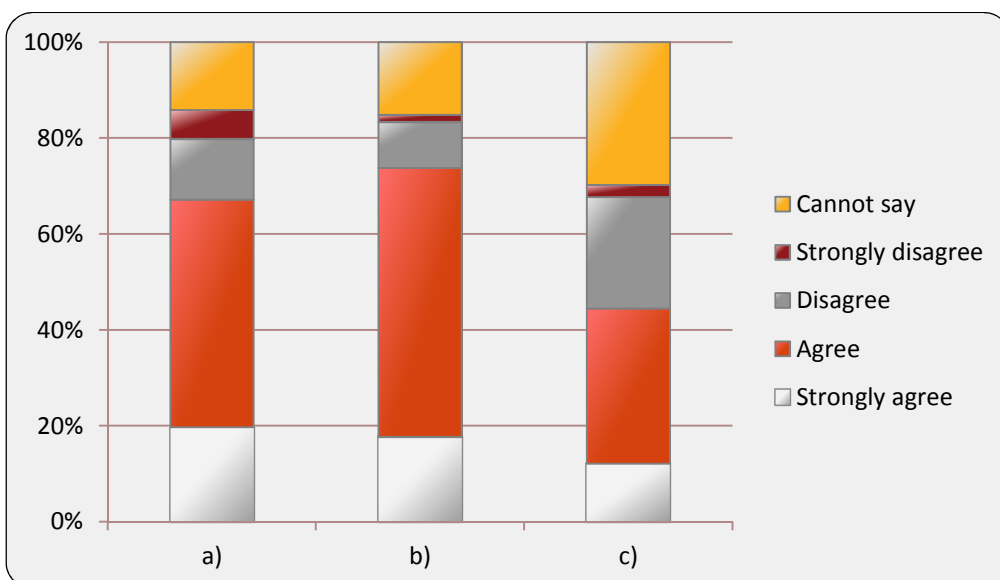


### 2.1.2. Support for three improvement proposals

Respondents were subsequently requested to give their opinion on three improvement proposals related to the Validation assistant. These proposals had previously been raised to the IUCLID team by individual stakeholders and the aim was to ensure that such modifications would be supported by a wider community of users. The suggested improvements were as follows:

- a) Improve the display of the validation result by removing the separate header shown for each rule,
- b) Improve checking of substance datasets by including the option to validate only the information flagged with specific regulatory programme flags (e.g. EU REACH). Indeed, the raw data set may contain information which will not be included in the final dossier (e.g. corresponding to other legislations) and its verification by the tool may therefore be confusing,
- c) Implement a possibility to simultaneously validate multiple dossiers ('batch mode' validation).

Of the 198 respondents who indicated to use the IUCLID software, 67% support the proposal to remove the separate rule header in the validation results display and 73% agree with the possibility to validate raw data information by regulatory programme flags. The usefulness of batch validation of dossiers is signalled by 44% of the respondents.



**Figure 5.** Breakdown of replies to the three improvement proposals consulted on

### 2.1.3. Main conclusions

Most respondents find the Validation assistant very useful, in particular to verify information that is mandatory for a successful submission of dossiers to ECHA. This is a clear indication for ECHA to continue improving and maintaining the plugin.

The two improvement proposals which received strong support from the respondents will be prioritised for implementation in an upcoming version of the Validation assistant for IUCLID 6. The proposal for batch mode validation will be further discussed with the stakeholders.

The free comments provided by the respondents were mainly related to:

- Extend support to further types of dossiers and datasets
- Improve clarity of failure and warning messages, link messages to further information on the subject
- Promote interactiveness of the tool during editing of raw dataset

ECHA will take into account the improvements suggested by the respondents in the future development of the Validation assistant under IUCLID 6.

## 2.2. Dissemination plugin

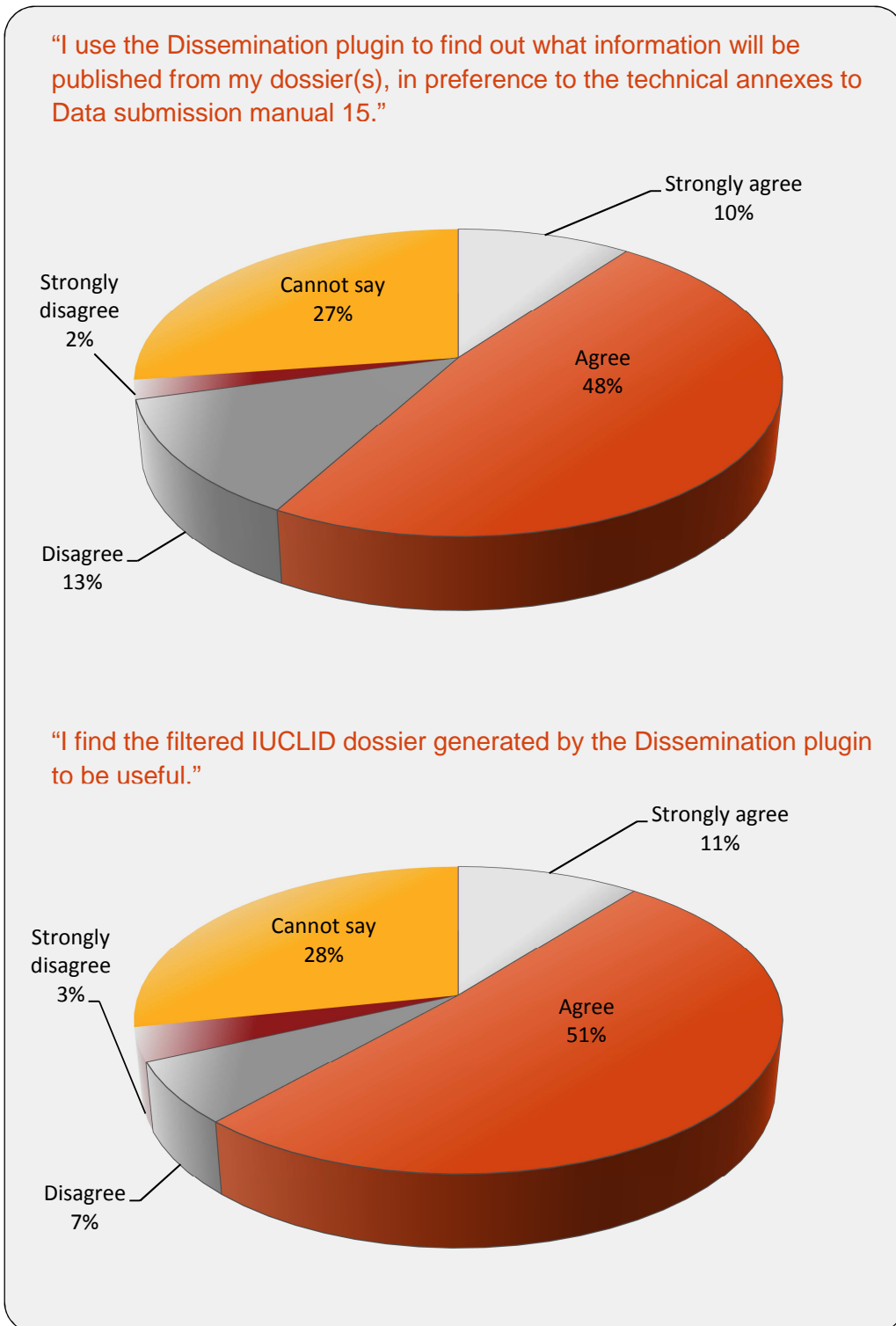
### 2.2.1. Usefulness of different features

The Dissemination plugin allows IUCLID users to verify which information will be published on the ECHA website before submitting their registration dossier to the Agency. The Dissemination plugin produces the following type of output:

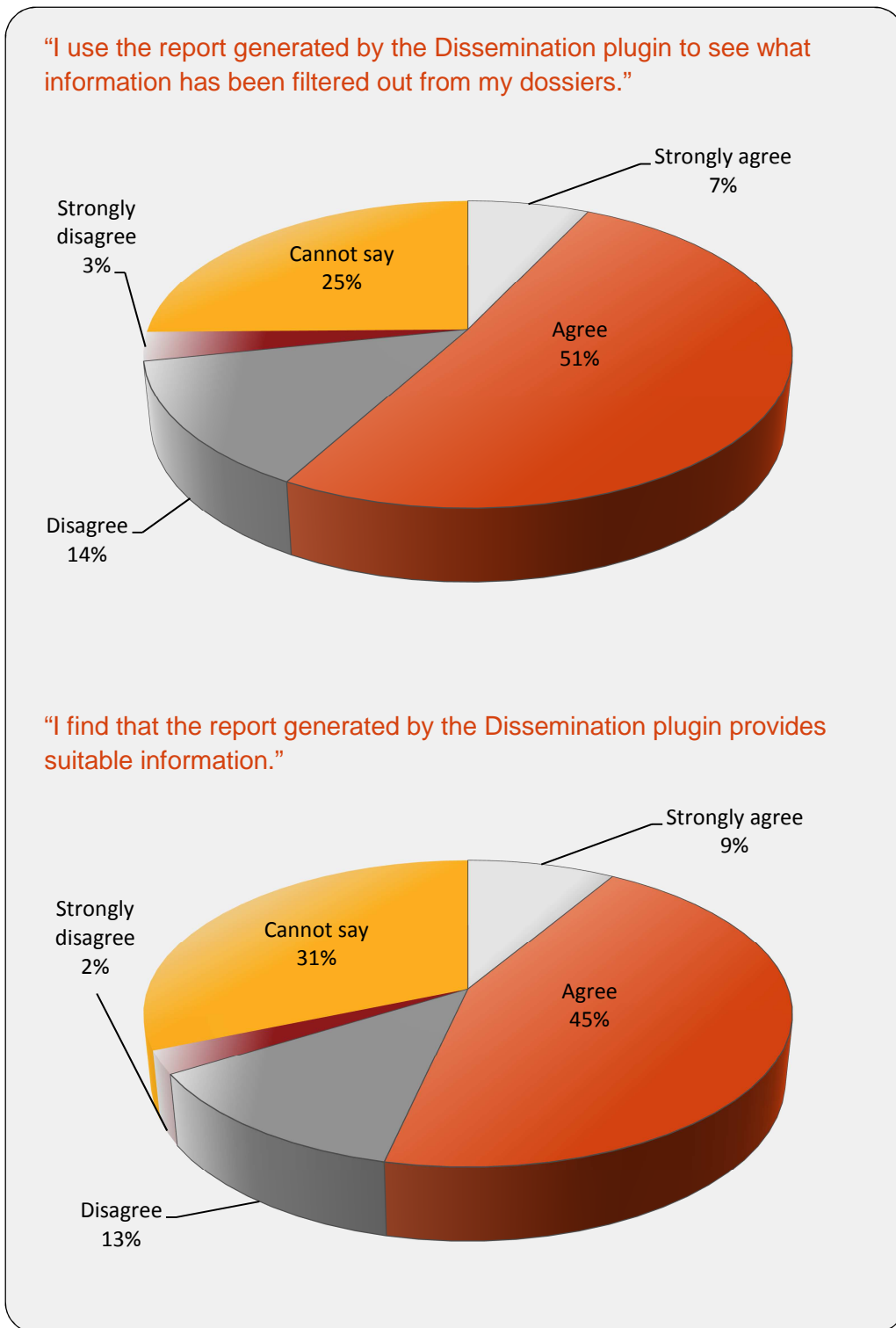
- The filtered dossier, representing the content of the IUCLID dossier that will be published on the ECHA website,
- A report that shows the content that has been removed compared to the original dossier.

In the survey, respondents were requested to rate the usefulness of the different features of the Dissemination plugin. Of the 198 respondents who indicated to use the IUCLID software, 58% indicate that they prefer to use the Dissemination plugin to find out what information from their dossiers will be published on the ECHA website rather than the technical annexes to Data submission manual 15 (Figure 6). 62% find the filtered IUCLID dossier generated by the Dissemination plugin to be useful.

Furthermore, 58% of the respondents indicate to use the report generated by the Dissemination plugin to see what information has been filtered out from their dossiers, and 54% find the report to provide suitable information (Figure 7).



**Figure 6.** Breakdown of replies to questions on usefulness of Dissemination plugin and filtered dossier



**Figure 7.** Breakdown of replies to questions related to the filtering report of the Dissemination plugin

### 2.2.2. Main conclusions

The majority of the survey respondents indicate to use the Dissemination plugin. The tool is not only used for viewing the information to be published on the ECHA website, but also to prepare information for communication with downstream users and customers.

The filtered IUCLID dossier generated by the plugin was considered especially useful, and a good way to share data within a SIEF without disclosing confidential information, for example.

As an area of improvement, the respondents unanimously highlighted the user-friendliness of the plugin, particularly:

- The filtered dossier (format improvements)
- The report indicating what information has been filtered out (structure improvements)

ECHA will explore the possibilities to improve the user experience of the Dissemination plugin.

As a matter of priority the plugin will be adapted to support filtering of BPR biocides active substance and biocidal product dossiers.

## 2.3. Report generator

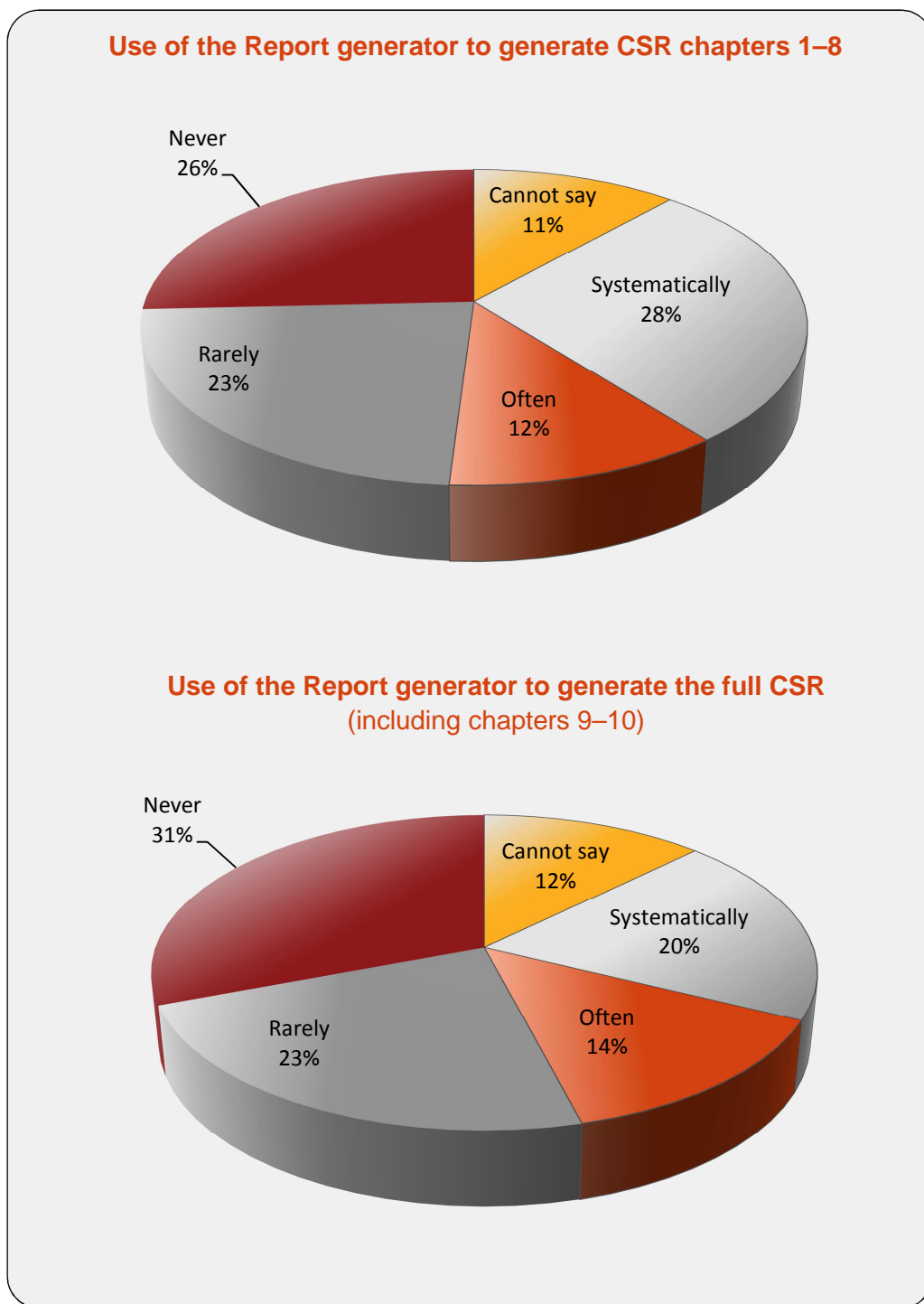
The Report generator allows IUCLID users to generate reports from the information contained in IUCLID dossiers and datasets. The Report generator can currently be used to generate the following types of reports:

- The REACH Chemical safety report (CSR). Chapters 1 to 8 are generated based on the information stored in a IUCLID dataset or dossier. In addition, chapters 9–10 can be generated by importing the corresponding assessment carried out with ECHA's Chemical safety assessment and reporting tool Chesar,
- The summary of product characteristics (SPC) document for BPR biocidal product authorisation applications.

### 2.3.1. REACH Chemical safety report

In the survey, respondents were first requested to indicate how often they use the Report generator to generate the CSR. Of the 198 respondents who indicated to use the IUCLID software, 40% indicate to use the Report generator often or systematically to generate chapters 1 to 8 of the CSR. Furthermore, 34% of respondents often or systematically create the full CSR, including chapters 9–10, with the Report generator. A more detailed breakdown of the answers can be found in Figure 8.

When interpreting the respondents' indications of the frequency of use of the Report generator in preparation of CSRs it should be noted that the Chemical safety report is not required for all types of REACH registrations and that it can be prepared in a joint manner by registrants of the same substance. Hence it is expected that not all registrants will have needed to prepare a CSR for their registration dossier. The further analysis of the responses regarding the generation of CSRs will focus on the replies from respondents who indicated to use the module (Figure 8). **Figure 4.**



**Figure 8.** Breakdown of replies on use of the Report generator to generate REACH Chemical safety reports

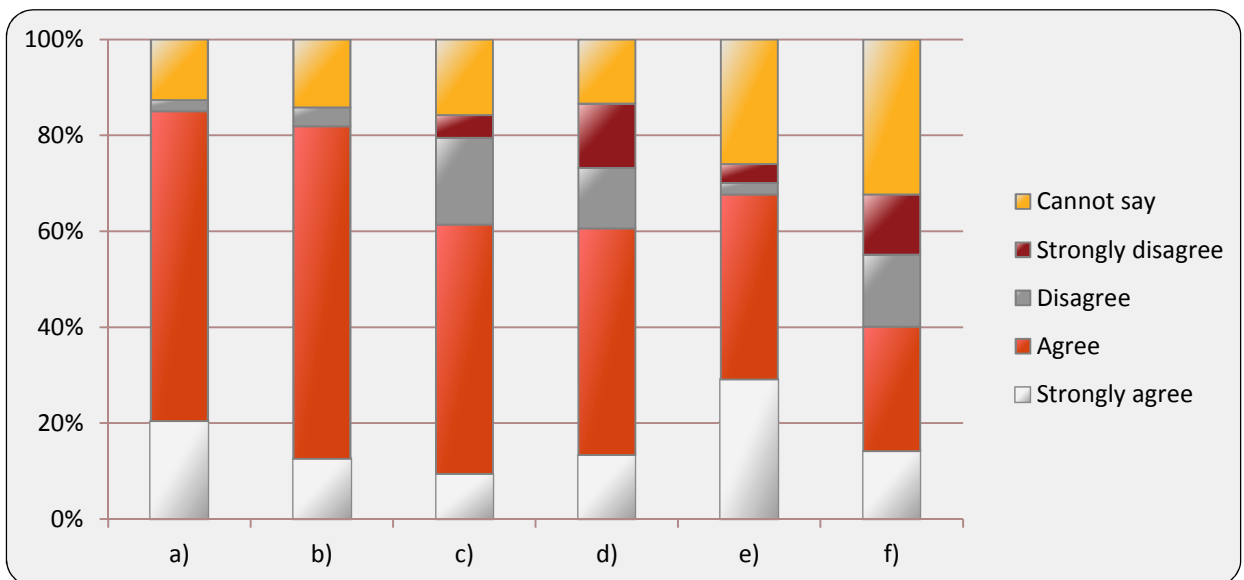


Respondents were subsequently requested to give their opinion on the following statements related to the use of the Report generator in generating the CSR:

- a) I find the Report generator wizard, which pops up when running the plugin, clear and self-explanatory
- b) I find the presentation (layout) of the information in the CSR sections 1-8 useful
- c) All relevant IUCLID information is captured by the plugin for sections 1-8 of the CSR and I do not need to manually edit it
- d) The table of contents is automatically included in the generated .rtf-file and I do not have to update it manually
- e) I find it convenient to be able to generate the full CSR including the Chesar file with the Report generator
- f) I would prefer to be able to generate the full CSR in Chesar

Of the 127 respondents who indicated to use the Report generator in the preparation of their CSR, over 80% find the Report generator wizard easy to use and the layout of the information in the CSR sections 1–8 useful. Around 60% of these 127 respondents indicate that they do not need to further edit the CSR sections 1–8 or the table of contents after generating the CSR with the Report generator.

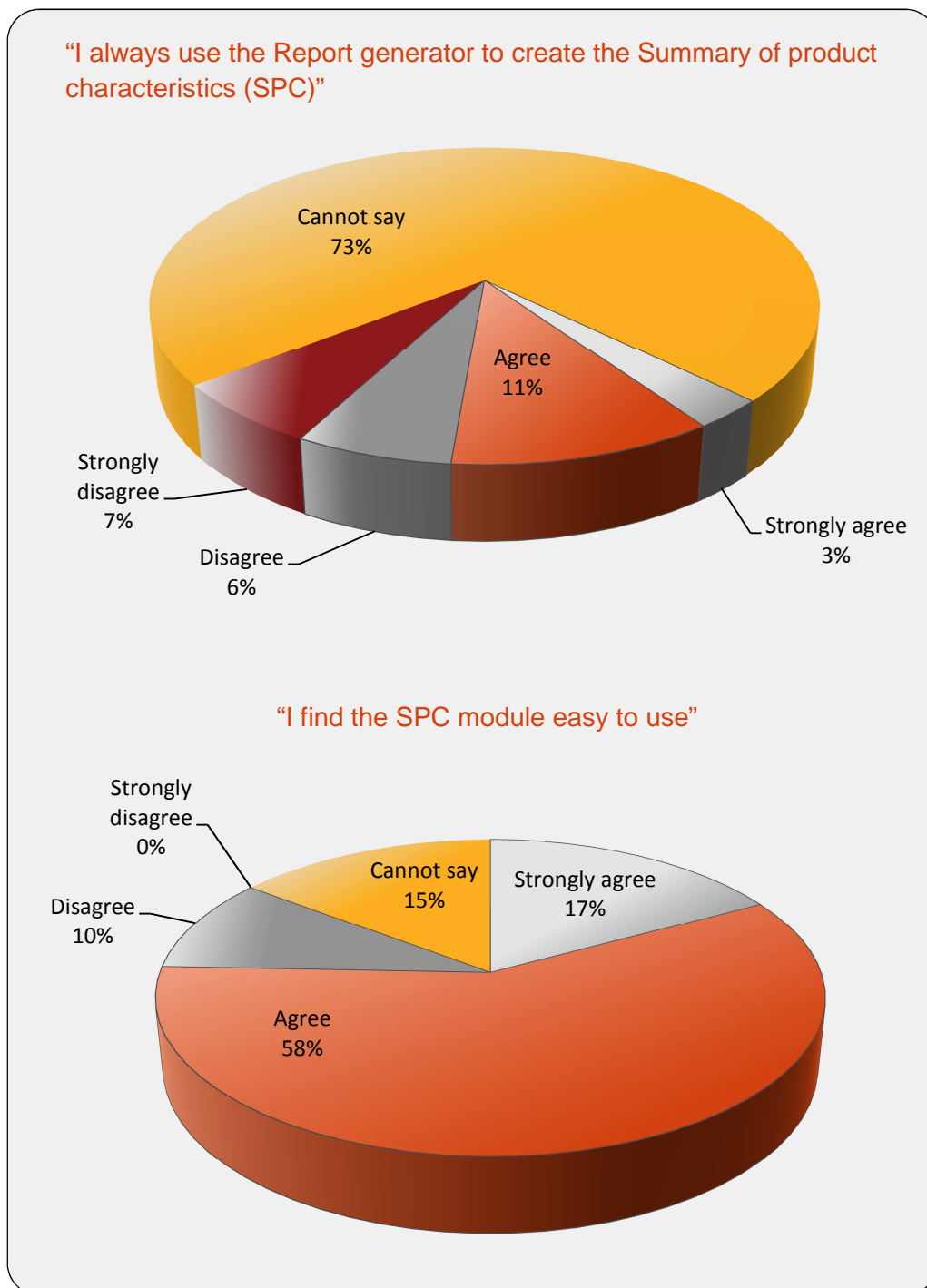
68% of respondents appreciate the possibility to integrate the Chesar file in the CSR created by the Report generator. On the question regarding the use of Chesar to generate the full CSR, response is mixed with ca. 40% in favour and ca. 30% against. A more detailed breakdown of the answers can be found in Figure 9.



**Figure 9.** Breakdown of rating of statements related to generation of CSR with the Report generator

### 2.3.2. BPR Summary of product characteristics

The EU Biocidal Products Regulation entered into operation on 1 September 2013. Hence, it is not surprising that of the 198 respondents who indicated to use the IUCLID software, only 14% had used the Report generator to create an SPC document (Figure 10). Nevertheless, of those respondents who indicated to have used the SPC module of the Report generator, 75% considered it easy to use.



**Figure 10.** Use of the Report generator to create the Summary of Product Characteristics (SPC)

On 3 December 2014, a new format for the summary of the characteristics (SPC) was introduced. The new SPC format is submitted with an online application called SPC Editor. Respondents of this survey were asked whether they would be interested to have the possibility to use the Report generator to extract SPC-relevant data in the new XML format for export to the SPC Editor. 79% of respondents who provided an opinion supported this proposal and consequently, on 24 March 2015 ECHA released a new version of the IUCLID 5 Report generator which is compatible with the SPC Editor. The feature will be maintained in the Report generator for IUCLID 6.

### **2.3.3. Main conclusions**

#### **2.3.3.1. CSR module**

40% of the survey respondents indicate to use the Report generator often or systematically in the generation of the Chemical safety report.

The majority of the users of the CSR module find it easy to use, and the generated structure clear. As areas of improvement the respondents highlighted the following:

- The table of contents cannot be updated effectively
- The occasional need to edit manually the CSR after the generation, to fix formatting issues or to add information that was not possible to report in IUCLID (e.g. attached tables to justify read-across, etc.)
- Too many repetitions in the information reported in the CSR.

With the IUCLID 6 version, ECHA will explore the possibilities to address the areas of improvement mentioned above.

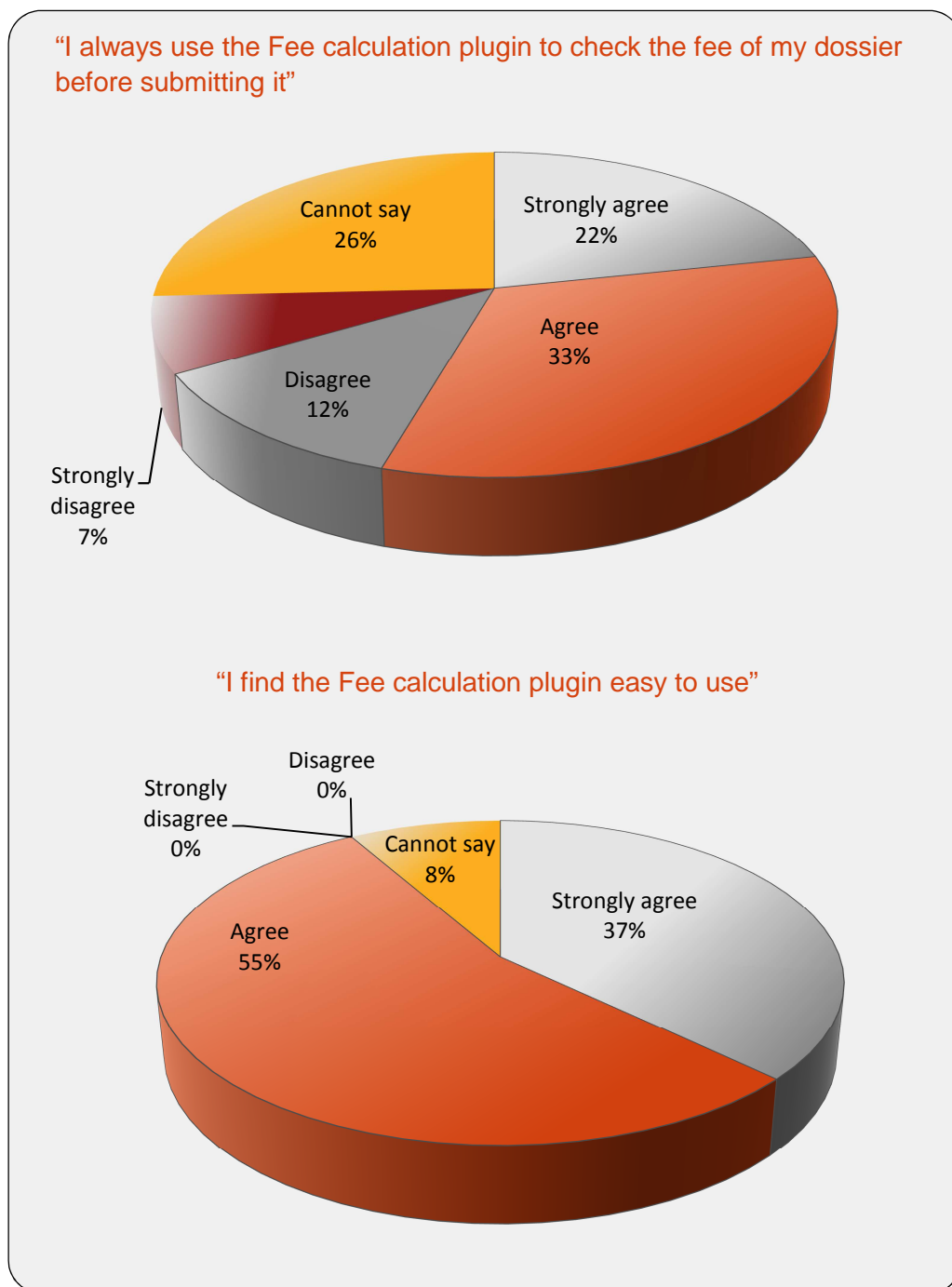
#### **2.3.3.2. SPC module**

The SPC module of the Report generator has not yet been widely used by the respondents, but was indicated as easy to use by those who used it.

With the new SPC format introduced at the end of 2014, the development of the SPC generation under IUCLID 6 will focus on maintaining and improving the extraction of information for import into the SPC Editor.

## 2.4. Fee calculation plugin

The Fee calculation plugin allows IUCLID users to predict the fee to be issued on their REACH registration and PPORD notification dossiers, before submitting them to the European Chemicals Agency. Of the 198 respondents who indicated to use the IUCLID software, 55% indicate to use the Fee calculation plugin to check the fee of their dossiers. Almost all respondents who indicated to have used the Fee calculation plugin (92%) considered it easy to use. A more detailed breakdown of the answers can be found in Figure 11.



**Figure 11.** Use of the Fee calculation plugin

### 2.4.1. Main conclusions

Around half of the survey respondents indicate to use the Fee calculation plugin. The tool is perceived as easy to use by nearly all respondents who stated to have used it.

As improvement suggestions the respondents listed:

- The extension of the plugin to other dossier types, such as Application for authorisation
- The possibility to check the fee already on the raw dataset, before dossier creation

The requirement for the Fee calculation plugin will also be considered as part of the development of new versions of the plugins for IUCLID 6.



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<http://iuclid.eu> and <http://iuclid6.echa.europa.eu>

