Mapping of Safe-by-Design Methods and Criteria

This document contains a summary of the results from the activities conducted in task 1.1 "Safe by design (SbD) methods and criteria" of the Work Package (WP) 1 of the IRISS Project entitled "International ecosystem for accelerating the transition to Safe and Sustainable-by-Design materials, products and processes". The contents of this summary have been restricted to only results of the survey conducted during task 1.1 since other results from the deliverable have been submitted to a scientific journal for publication and are therefore confidential as of September 2023. Nevertheless, the publication will be open access and uploaded to the IRISS website along with the other executive summaries as soon as possible.

A survey was conducted as a part of the assessment to understand the status of SbD application and competencies in both academia and industry. This survey was shared amongst academic partners involved in EU projects such as PARC and IRISS. Furthermore, the survey was shared with non-academic participants of the IRISS workshop, EUMAT stakeholders, and related EU Projects coordinators, who consented to receive the survey. Finally, the connections between companies and the organizations representing the value chains in IRISS (CEFIC, SusChem, CLEPA, EMIRI, ETP, EFCC, and IPC) were leveraged to source responses from the former. The survey was active and open to responses for around four months between mid-November 2022 and end-of-February 2023.

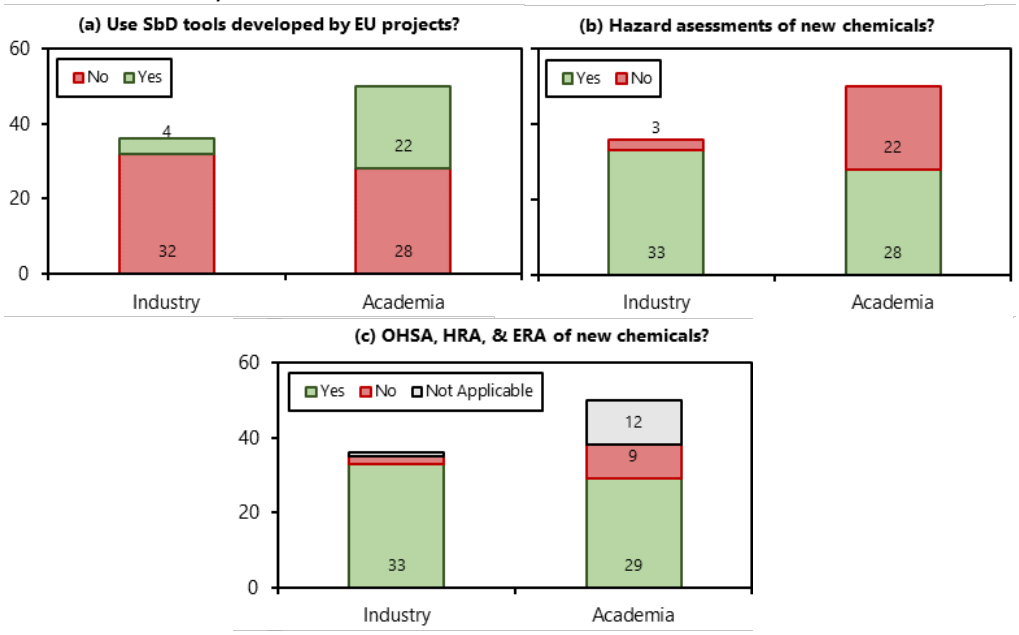

Figure 1 Survey results (n = 86) with classification based on the kind of respondents for (a) use of tools developed in EU projects; (b) hazard assessment of new chemicals; and (c) occupational health and safety assessment (OSHA), human risk assessment (HRA), and environmental risk assessment (ERA) of new chemicals

The SbD survey was answered by 86 respondents in total from academia and industry. Figure 1(a) and Figure 2 deal specifically with the responses related to the SbD tools used. As seen in Figure 1(a), a significant share of academic respondents use SbD tools developed within EU projects. In contrast, a minor set of respondents from the industry have applied SbD tools developed within EU projects. From the 26 total respondents in Figure 1(a) who claim to have used SbD tools from EU projects, Figure 2 highlights that the SbD tools proposed within the

Funded by the European Union

The project receives funding from the European Union's HORIZON EUROPE research and innovation programme under grant agreement n° 101058245. UK participants in Project IRISS are supported by UKRI grant 10038816. CH participants in Project IRISS receive funding from the Swiss State Secretariat for Education, Research and Innovation (SERI).

Gov4Nano and NanoReg2 projects are popular amongst academic practitioners. However, the majority of academic respondents along with the industry respondents have used the SbD tools developed within EU projects that were not explicitly listed in the survey. Hence, it is necessary to further investigate these other popular SbD tools from EU projects that were not specifically mentioned in the survey to further promote the use of SbD tools from EU projects in industry.

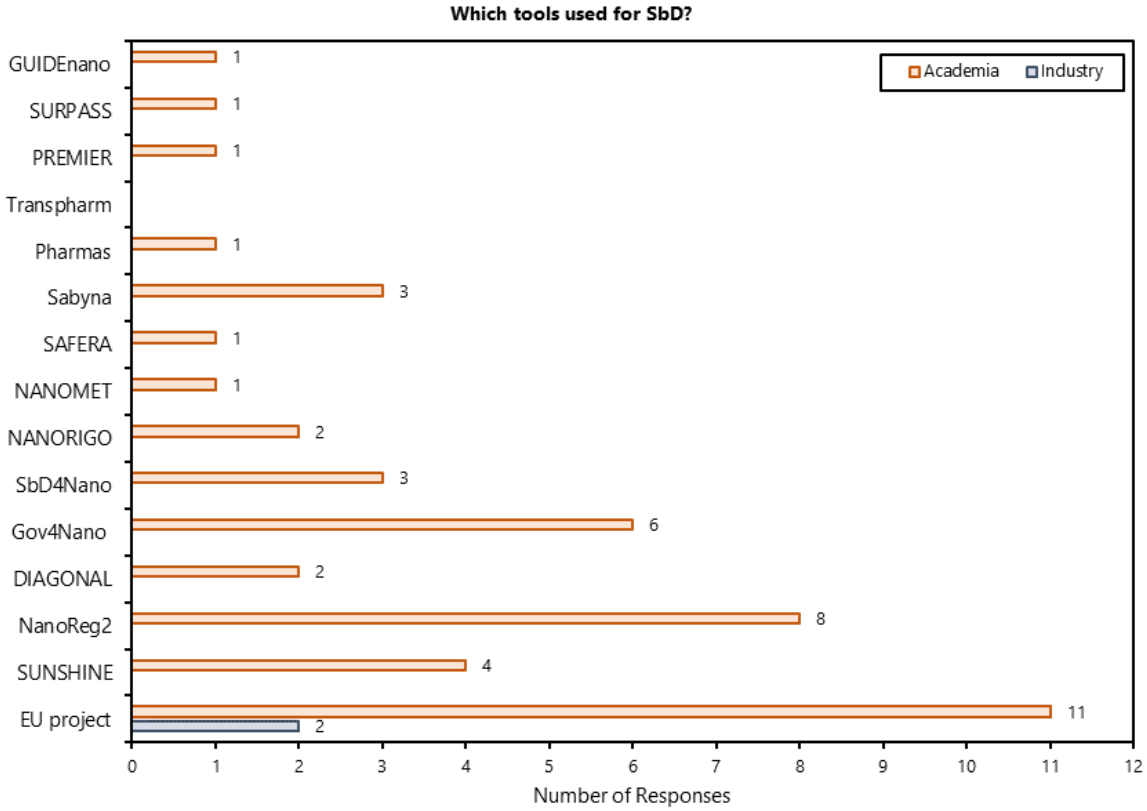

Figure 2 Responses (n = 26) classified based on the respondents and showing the SbD tools they use; here 'EU project' was offered as an option so that the respondents could specify a specific SbD approach that was excluded from the provided list, however, the respondents selecting this option never provided the names of these alternative approaches

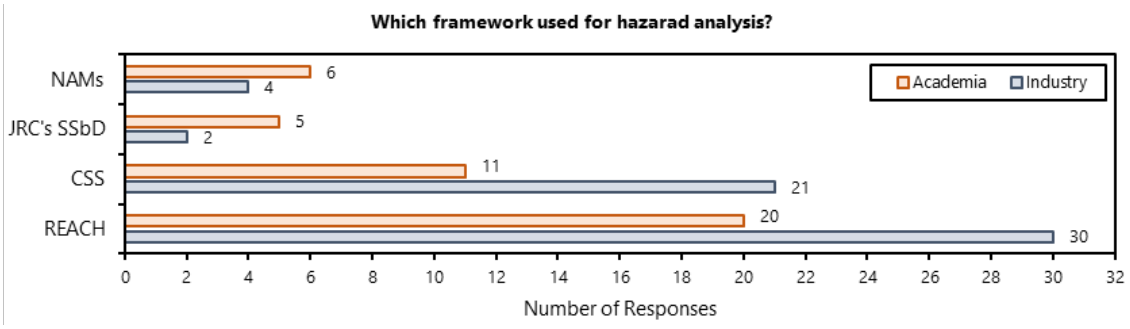

Figure 3 Responses (n = 61) classified based on the respondents and showing the hazard analysis tools they use; here NAMs refers to novel assessment methodologies and CSS refers to the EU's chemical strategy for sustainability

Funded by the European Union

The project receives funding from the European Union's HORIZON EUROPE research and innovation programme under grant agreement n° 101058245. UK participants in Project IRISS are supported by UKRI grant 10038816. CH participants in Project IRISS receive funding from the Swiss State Secretariat for Education, Research and Innovation (SERI).

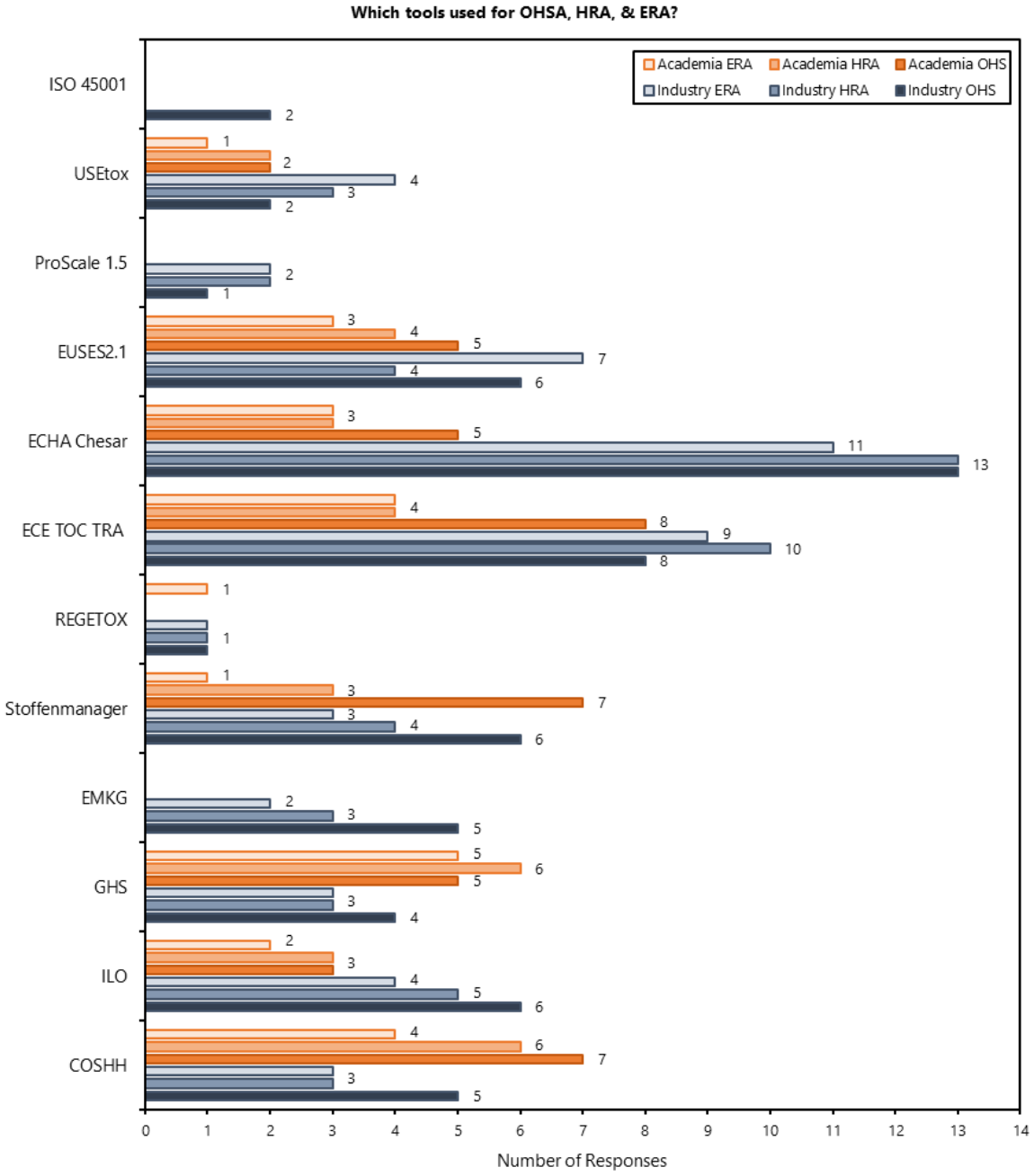

Figure 4 Responses (n = 62) classified based on the respondents and showing the respective tools they use for OHSA, HRA, and ERA

Apart from SbD tools, the results in Figure 1(b) and Figure 4 illustrate the results of the inquiry about hazard assessments. As seen in Figure 1(b), a significant share of both academic and industrial respondents performs hazard assessments. Industrial respondents also shared that it is mandatory in the EU to ensure compliance of their products with REACH, then the REACH framework is found to be the most prominent for hazard assessments in Figure 3. As seen in Figure 3, early-stage hazard assessments possible with Novel Assessment methodologies (NAMs) and the JRC's SSbD framework are found to be more popular amongst the academic respondents as compared to their industrial counterparts. Furthermore, conventional hazard assessment frameworks such as the EU Chemical Strategy for Sustainability (CSS) and REACH are more popular amongst respondents from the industry due to the legislative and policy push for the

Funded by the European Union

The project receives funding from the European Union's HORIZON EUROPE research and innovation programme under grant agreement n° 101058245. UK participants in Project IRISS are supported by UKRI grant 10038816. CH participants in Project IRISS receive funding from the Swiss State Secretariat for Education, Research and Innovation (SERI).

same. These results highlight the popularity of hazard assessment for compliance purposes and the need for incentivization of hazard assessments during early-innovation phases that would be rooted in novel assessment methodologies.

Finally, the results in Figure 1(c) and Figure 4 shed light on the current state of the safety pillars in the SSbD assessment in academia and industry. Again Figure 1(c) highlights the large share of industrial respondents involved in Occupational Health and Safety assessment (OSHA), Human Risk Assessment (HRA), and Environmental Risk Assessment (ERA) because OSH and risk assessments in manufacturing facilities are mandated by law to ensure safe working conditions for their employees. Academic respondents who claimed to perform safety assessments also stated that they offer OSHA, HRA, and ERA services to industrial partners. Figure 4 shows which tools compiled by the JRC are applied for what kind of safety assessments and by which kind of respondents. The popularity of the European Chemical Agency (ECHA)'s Chesar tool amongst industrial respondents due to REACH is evident in Figure 4. Apart from this, all other tools given in the SSbD framework for safety assessments seem to enjoy similar popularity and a good split in shares amongst industrial and academic institutions for all assessments: OSHA, ERA, and HRA. Two industrial respondents specifically mentioned that the ISO 45001 standard is a critical OSHA tool that was absent from the survey as it is currently not mentioned in the JRC's SSbD tool list. Another valuable aspect worth noting is that all the tools listed by the JRC as SSbD tools are conventional safety assessment tools that are typically applied during later stages of product development when sufficient data and expertise on the developed materials are available. The validity of these listed tools at lower technology readiness levels (TRLs) is unclear and therefore, so is their true utility as SSbD tools. It is however clear that the JRC's framework sufficiently captures the current state-of-art of compliance-stage tools as no other tools, except for ISO 45001, were recognized as missing from the list by the respondents.

Funded by the European Union

The project receives funding from the European Union's HORIZON EUROPE research and innovation programme under grant agreement n° 101058245. UK participants in Project IRISS are supported by UKRI grant 10038816. CH participants in Project IRISS receive funding from the Swiss State Secretariat for Education, Research and Innovation (SERI).

Disclaimer

Our partners:

Funded by the European Union

The project receives funding from the European Union's HORIZON EUROPE research and innovation programme under grant agreement n° 101058245. UK participants in Project IRISS are supported by UKRI grant 10038816. CH participants in Project IRISS receive funding from the Swiss State Secretariat for Education, Research and Innovation (SERI).