Nordic Council of Ministers

Nordic Working Paper

Nordic NAM Training and Networking Event

Report prepared by:
Elina Ekokoski, Tomi Kaartinen, Pauli Kärkkäinen, Marianne Moilanen, Eeva Rissanen, Jukka Sund

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Nordic Council of Ministers
Nordens Hus
Ved Stranden 18
DK-1061 Copenhagen
www.norden.org

Nordic NAM Training and Networking Event - a report

Abstract

New Approach Methods (NAMs) are increasingly integrated into chemical legislation and regulators are already encountering NAM data in their assessments. The Nordic NAM Training and Networking Event was organized to enhance regulators' skills and understanding of NAMs. The event brought together European and Nordic regulators to build capacity in assessing and interpreting NAM data. Day 1, streamed online, provided European regulators with the latest updates on NAMs within different regulatory frameworks, while Day 2 offered in-depth, on-site training specifically for Nordic regulators. The on-site training focused on practical application and hands-on assessment of NAM data, namely on skin sensitivity and bioaccumulation. The event underscored the importance of collaboration, continuous learning, and knowledge sharing to prepare regulators for emerging NAM methodologies and regulatory challenges.

1 Preface

While the overall goal of EU chemicals legislation is to protect human health and the environment, the protection of animals used for experimental and scientific purposes including the aim for animal-free testing and assessment regime is expressed in different pieces of legislation (e.g. REACH Regulation[1], article 13; Cosmetic Product Regulation[2], article 18; Directive 2010/63/EU[3]). Furthermore, the European Commission's Chemicals Strategy for Sustainability (CSS) specifically states the willingness to move away from animal testing[4]. There is also a great pressure from the European public to reduce and replace animal testing overall. Recently, more than 1.4 million citizens signed a European Citizens' Initiative ´Save cruelty-free cosmetics – Commit to a Europe without animal testing´. As a response to this Initiative the European Commission expressed its commitment to develop a ´Roadmap Towards Phasing Out Animal Testing for Chemical Safety Assessments´[5]. The roadmap, planned to be published by 2026, will outline milestones and specific actions, to be implemented in the short to longer term to reduce animal testing, and it will serve as a guiding plan for accelerating the path towards replacing, reducing and refining animal testing for the safety assessments of chemicals.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, Evaluation, Authorisation and Restriction of Chemicals (REACH

[2] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

[3] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

[4] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM(2020) 667 final

[5] Commission Communication replying to the European Citizens' Initiative (ECI) 'Save cruelty-free cosmetics – Commit to a Europe without animal testing' (COM (2023) 5041)

New approach methods (NAMs) are defined as any technology, methodology, approach, or combination that can provide information on chemical safety to replace and reduce the traditional animal testing. Examples of NAMs are *in vitro* (e.g. omics, cell-based, tissue-based, etc.) assays, *in silico* (e.g. [Q]SARs) models), and other biotechnological and computational approaches. Before any NAM is used to assess safety, the validity and reliability of the method must be established. The method or a combination of methods should be equally or more informative than existing animal guideline study designed to address the corresponding endpoint. Hence, the Organisation for Economic Co-operation and Development (OECD), which develops internationally agreed test method guidelines for testing chemicals, has recently initiated several actions to further facilitate swift validation and acceptance of new test methods[6] . There are also initiatives in the EU to enhance method development and validation of new methods to be used as alternatives to animal testing.

As NAMs are increasingly integrated into chemical legislation, regulators are already encountering NAM data in their assessments. Currently the Cosmetic Products Regulation is the most advanced EU legislation regarding use of NAMs since animal testing is banned and therefore use of alternatives is a must. The forthcoming revision of the key EU chemicals regulation, REACH, is anticipated to amend the information requirements more towards NAMs. The CLP regulation[7] which eventually will utilize the new data coming from NAMs will also give these approaches a more prominent role. The classification criteria of the CLP regulation are based on the United Nations Globally Harmonized System for Classification and Labelling of Chemicals (GHS). In GHS, an ongoing work of updating and incorporating classification criteria to use of data derived from NAMs[8] will eventually be reflected in CLP. In conclusion, there are many actions and incentives at the EU and at global level to move away from using vertebrate animals in chemicals testing.

The above-mentioned actions mean that regulators will have to assess NAM-based data already now and the role of NAMs in chemicals regulation is becoming increasingly important. This presents both an opportunity and a challenge for regulators, as many of them lack the confidence in interpretation of NAM-based data. There is also a concern that hazard and risk assessors do not have the required skills to assess NAM-based data. The Finnish Safety and Chemicals Agency (Tukes) launched an internal survey on the depth of the knowledge of NAMs in the beginning of 2023, in which ninety percent (90 %) of the respondents wanted training on NAMs. A need for training was also raised in a recent NAM workshop in 2023: Towards an animal free regulatory system for industrial chemicals, organized by the European chemicals agency (ECHA)[9].

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[6] E.g. Guidance Document 34 on the "Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment": Project 5.7 in the Work plan for the OECD Test Guidelines Programme (TGP), led by EC (Joint Research Centre), United States and the Netherlands; Webinar Series on Testing and Assessment Methodologies, OECD Webinar | Training and orientation on validation of methods at the OECD - YouTube, OECD Chemical Safety and Biosafety

[7]Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures

[8] In its 30th session the Sub-Committee of experts on the Globally Harmonized System of Classification and Labelling of Chemicals decided to start discussing the use of non-animal testing methods for the classification of health hazards on the initiative of the experts from the Netherlands and the United Kingdom. The item has been kept in the work programme since then. https://unece.org/DAM/trans/doc/2015/dgac10c4/ST-SG-AC10-C4-2015-13e.docx

[9] https://echa.europa.eu/documents/10162/17220/nams_ws_june2023_en.pdf/06b8bc28-c563-3a36-cfa9-0fa5453b88a7?t=1695620290072

To address some of the identified needs, Tukes organized a Nordic NAM Training and Networking Event in October 2024 in collaboration with colleagues from European Chemicals Agency (ECHA). This two-day event was designed for regulatory professionals, focusing on building knowledge and practical skills necessary for integrating NAMs into regulatory decision-making. The further aim of the Event was to raise of the awareness of NAMs which can promote better use of NAM data and the regulatory acceptance of NAMs.

This report captures the insights, discussions, and outcomes of the event, underscoring the shared commitment across the Nordic countries to advance NAM expertise and readiness.

2 Event summary and outcomes

2.1 Objectives and outlines of the event

Objectives

The objectives of the event were on one hand to increase knowledge on NAMs via a series of presentations on NAMs and their role in current chemical legislation and possible future use. On the other hand, the event also aimed to build up confidence on the use of NAM based data via hands-on training on selected endpoints. An essential aim was also to enhance networking, collaboration and information sharing regarding NAMs among the Nordic regulators, possibly leading to the formation of a Nordic regulatory community of practice in NAM.

Outlines of the event

The event was organized on the 15-16th of October 2024 in Helsinki, Finland. The event consisted of two days: the first day was dedicated to oral presentations which provided a global perspective on the integration of NAMs within different regulatory frameworks on chemicals, development of NAMs, and on a future lookout. The speakers represented different EU and international bodies, member state regulators and researchers.

Although the initial plan was to arrange the event solely for the Nordic regulators, it was eventually decided that the first day should be streamed to all interested EU regulators. Over 150 participants followed the sessions, underscoring the broad interest and relevance of NAM developments across Europe. The second day of the event concentrated on interactive, hands-on training, specifically designed to build practical skills for Nordic regulators. A total of 30 participants from Norway, Denmark, Sweden, and Finland attended. The participants were divided into parallel training sessions for human health and environmental assessments, allowing each group to focus on topics directly relevant to their specialized regulatory responsibilities.

At the end of the second day, a short brainstorming session was held to discuss and find ways how the Nordic countries could operate together in this field, to foster networking, collaboration, and information sharing.

2.2 Summary of the presentations on day 1

Presentations began with a keynote speech on the EU Commission's roadmap for phasing out animal testing in chemical safety assessments. Experts from ECHA, European Food Safety Authority (EFSA), and other key organizations highlighted their ongoing NAM-related initiatives. Participants gained insights into global efforts, such as the ongoing work at the GHS on non-animal methods in health hazard classification, and updates from the OECD on NAMs in Test Guidelines. The day also covered practical experiences of performing risk assessments with NAMs and a forward-looking session on the future regulatory framework for chemicals in the EU, titled "Chemicals 2.0." Together, these presentations provided participants with essential knowledge and context for the role of NAMs in Europe's evolving regulatory landscape.

Abstracts of each presentation are given below and arranged according to the allocated session.

Keynote

EU Commission Roadmap towards phasing out animal testing for chemical safety assessment, Georg Streck, European Commission, DG GROW

On 25 July 2023, the European Commission published a Communication C(2023)5041, with which it committed to develop a roadmap towards ultimately phasing out animal testing for chemical safety assessments and applicable to all relevant pieces of chemical legislation. The purpose of the roadmap is to provide guidance and a framework on how to reach this goal, including to define the required organisational structures and to mobilize funding. Elements of the roadmap have already been described in the Commissions Communication.

For some areas of (eco-)toxicological concern, short-term solutions are available, which are ready to be taken up in regulation. Some methods or approaches might need to be further developed, and the roadmap should provide guidance on how to prioritise the development needs. In other areas of concern, where simple replacements are not possible, it will rather be necessary to build a new system of regulatory assessment approaches, based on information animal-free methods can provide. While the ultimate goal is to replace all animal testing for chemical safety assessments, reducing or refining might be solutions until replacement approaches are available.

The roadmap will also seek solutions of how to accelerate the validation or standardization of methods or how to make use of qualifications. Furthermore, the roadmap is analysing the need and feasibility of (an) expert scientific committee(s) to provide advice on the development and regulatory application of non-animal methods.

The input from stakeholders is vital for developing the roadmap. The presentation will therefore outline how stakeholders can get involved in the shaping the path towards phasing out animal testing for chemical safety assessments.

Overview session

Towards an animal testing-free regulatory system for industrial chemicals: NAMs at ECHA, Mounir Bouhifd, European Chemicals Agency (ECHA)

The European Chemicals Agency (ECHA) is actively promoting use of New Approach Methodologies (NAMs) to advance regulatory acceptance. Despite the current regulatory framework's reliance on traditional animal testing, ECHA is tackling the regulatory challenges by integrating NAM based tools and data for hazard identification and characterisation toolbox.

This presentation will provide an overview of ECHA's approach to NAMs. We will discuss the regulatory and scientific challenges, such as the complexity of developing one-to-one replacements and the need for policy changes. Additionally, we will have a look at existing short-term opportunities for better integration of NAMs and outline the long-term vision for achieving full replacement through scientific advancements and policy evolution.

EFSA activities on NAMs, Sofia Batista Leite, European Food Safety Authority (EFSA)

EFSA, the European Food Safety Authority has the particularity of having several different scientific and regulatory areas under its remit. Many regulations specifically require the use on animals as part of the risk assessment. Still, in order to complement the knowledge and reduce animal use, EFSA has been for several years investing and exploring the potential of NAM. This talk will give an overview of EFSA approach regarding NAMs with some updates on the latest activities.

Regulatory session

Overview of on-going work at GHS-level on the use of non-animal methods in health hazard classification, Erika Witasp Henriksson, Swedish Chemicals Agency (KemI)

Data generated from in vitro test methods (validated and pre-validated) can be used under REACH provided that the information for the hazard endpoint is sufficient for the purpose of classification and labelling and/or risk assessment. Such information can be used either as stand-alone to fill in a data gap or as part of a Weight of Evidence approach. The lower tier information requirements in REACH, e.g. skin irritation/corrosion, eye irritation/severe eye damage, and skin sensitization, are already based on non-animal methods with stepwise integrated approaches (IATA) or mechanistic principles (AOP).

Although non-animal test methods are continuously developing and new in vitro methods become available, it is difficult to connect the outcome of the in vitro test with the CLP classification criteria. With the exception for the hazard class of Germ cell mutagenicity there are no clear criteria for the results from *in vitro* tests for health hazard classification in CLP. However, it is possible to use *in vitro* data and data derived from non-test methods as a basis for hazard assessment in a Weight of Evidence approach.

In 2015, work was initiated at the GHS level by the Netherlands and the UK to review international efforts to facilitate non-animal methods for classification and discuss how to incorporate these in GHS, and by way of consequence in CLP. For this purpose, an informal working group on facilitating the use of data from non-animal test methods in GHS classification was established.

Following a step-wise approach by selecting one hazard class at a time the working group has made great progress and revised the Skin corrosion/irritation chapter 3.2 (published in GHS revision 8), Eye corrosion/irritation chapter 3.3 (published in GHS revision 10) and the Skin sensitization chapter 3.4 for

substance criteria (published in GHS revision 10) and mixture criteria (will be published in GHS revision 11) to better reflect the increased capability, availability and utility for classification of *in chemico*/*in vitro* test methods, defined approaches, and non-test methods including computer models and read-across. The amendments have also included the development of adapted tiered approaches including more Weight-of-Evidence evaluation.

Currently, work is ongoing by the Commission to amend the CLP Regulation, Annex I with GHS revisions 8-10 including the provisions for the use of non-animal methods for classification of health hazards.

New approach methods in OECD Test Guidelines and beyond, Anne Gourmelon, OECD

The content of my presentation shows how OECD Test Guidelines, that have traditionally been about describing lab procedures, are evolving with the science and biotechnology revolution to adapt and propose solutions to regulatory needs. NAMs are innovative methods that deviate from traditional approaches, including non-animal methods and faster, more efficient testing techniques. The OECD Chemicals Programmes focus on hazard assessment, including read-across, (Q)SARs, and grouping, as well as IATA case studies and the Test Guidelines Programme.

Currently, there are over 160 OECD TGs, with 38 incorporating non-animal approaches, such as skin irritation, eye irritation, skin sensitisation, genotoxicity, and immunotoxicity. The evolution of Test Guidelines has been driven by advancements in science and biotechnology, leading to a shift from in vivo methods to NAMs. Examples include the evolution of eye irritation and skin sensitisation TGs to include various *in vitro* and *in chemico* methods.

Experiences in performing risk assessment with NAMs, Qasim Choudry, Scientific Committee on Consumer Safety (SCCS)

The Cosmetic Product Regulation (EC) No 1223/2009 is the first EU regulatory framework to have placed a complete ban on animal testing and marketing of cosmetic products tested on animals since March 2013. Data from animal studies can still be used to support safety of a cosmetic ingredient, if the tests have been carried out before 11 March 2013, or to meet requirements of another (non-cosmetic) regulation. The evidence for safety of new cosmetic ingredients needs to come from animal-free alternative methods thus making the use of NAMs imperative.

The Scientific Committee on Consumer Safety (SCCS) evaluates and gives scientific advice at the request of the Commission on substances in cosmetic products that may be prohibited or restricted, or their use is allowed as colourants, preservatives or UV-filters. In the evaluations SCCS has faced the question whether NAMs data give a risk assessor the same level of confidence for the safety of a chemical as the data from a traditional in vivo test. Over the years, the answer has gradually moved from ‘unlikely’ to ‘maybe’/ ‘potentially’ to ‘likely’ for some endpoints such as skin irritation/corrosion, skin sensitisation, phototoxicity and mutagenicity/genotoxicity. However, complex endpoints are a challenge, such as sub chronic/chronic repeated dose toxicity, reproductive/ developmental toxicity, non-genotoxic carcinogenicity and endocrine disruption.

Another question has been whether to accept data from non-validated methods although the methods may still be scientifically valid. On a case-by-case basis, the SCCS has considered data from those methods. However, a single NAM is unlikely to provide sufficient evidence for safety and thus a weight of evidence (WoE) based on a combination of NAMs is required for safety assessments. The WoE is further strengthened where NAMs are aligned with an AOP and address one or more key events.

In summary, in the SCCS evaluations *in chemico* information has been used routinely, *in silico* (Q)SAR models and read-across data have been used increasingly, and *in vitro* test data have been used in virtually all cases. The most desirable format is where data from different NAMs have been integrated in a weight of evidence. A few structured frameworks exist for the integration of NAMs data such as Defined Approach (DA) for skin sensitisation.

There are new concepts under development for cosmetics safety evaluation such as new generation risk assessment (NGRA) which is based on *ab initio* approach that combines *in silico* modelling/read-across, mode of action, systemic bioavailability/biokinetics, targeted *in vitro* testing, and the plausibility toxicological effects through *in vitro*/*in vivo* extrapolation.

Future opportunities

Towards a future regulatory framework for chemicals in the European Union – Chemicals 2.0, Elisabet Berggren, European Commission, DG JRC

There is a need to make the European regulatory framework on chemicals more effective and to better protect people and the environment, but there is also a desire to make it more effcient and cost-effective, by harmonising assessment practices across sectors and avoiding the need for unnecessary testing. At the same time, there is a political commitment to phase out animal testing in chemical safety assessments. However, the roadmap to phase out animal testing could also be the transition pathway to a more efficient, effective and sustainable regulatory ecosystem. Central to our proposal is a framework based on biological reasoning in which biological questions can be answered by a choice of methods, with non-animal methods progressively becoming the only choice. Chemicals safety assessment could be informed by currently accepted protection levels, rather than their ability to predict outdated animal tests.

Performance expectations of new approach methods (NAMs) based on variability and concordance of existing models, Katie Paul Friedman, U.S. Environmental Protection Agency (US EPA)

Use of new approach methods (NAMs), including high-throughput, in vitro bioactivity data, in setting a point-of-departure (POD) will accelerate the pace of human health hazard assessments. In this presentation, efforts to demonstrate a NAM-based POD (POD-NAM), particularly through two case studies within the Accelerating the Pace of Chemical Risk Assessment, will be summarized. Further, the results of these POD-NAM development exercises will be put into the context of what we know about the variability in animal studies used to benchmark POD-NAM performance. In short, we find that a POD-NAM can be developed based on a battery of in vitro assay data that is typically within a factor 2 log10-mg/kg/day of traditional animal-based POD values for our latest case study. What we need and what we expect from a POD-NAM will be discussed broadly, underscoring how traditional PODs and POD-NAM are both used in a protective context, and are then complemented with targeted information for additional hazard considerations.

2.3 Summary of the hands-on training on day 2

The second day of the event shifted from presentations to interactive, hands-on training, specifically designed to build practical skills for Nordic regulators. The participants were divided into parallel training sessions for human health and environmental assessments, allowing each group to focus on topics directly relevant to their specialized regulatory responsibilities.

Human health training session

The human health training session concentrated on skin sensitisation as the endpoint. Expert Laura Rossi from ECHA acted as the trainer and gave first an introductory presentation on the developments in the in vitro/in chemico methods for skin sensitisation including the key events (KE) in question for the respective method. These included methods for peptide binding as the KE (DPRA, kDPRA), inflammatory responses in keratinocytes (KeratinoSens, LuSens, EpiSensA), or activation of dendritic cells (h-CLAT, U-SENS, GARD, IL-8 Luc). For each method acceptance criteria, limitations and prediction models were described. It was also pointed out that not all are stand-alone methods. An overview and background of defined approaches (DA) were also given, and of those DAs that have been approved for skin sensitisation (2 out of 3, ITS 1 and ITS 2), including their application rules and predictive capacity. Hands-on exercises followed with case studies using anonymised real-world REACH registration data to evaluate whether conclusions of the results could be agreed, whether based on in vitro data performance of an in vivo LLNA test was justified, or whether it was possible to conclude on skin sensitisation potential based on the data provided.

Environmental training session

The environmental session of the training focused on in vitro bioaccumulation assessment and the prediction of bioconcentration factors (BCF) using in vitro-in vivo extrapolation (IVIVE) and regression models. Expert Heike Laue from Givaudan acted as the trainer. The session began with a lecture on the importance of biotransformation rate determination and an overview of the OECD TG 319 A/B methods. A hands-on exercise followed, where participants worked with in vitro data to calculate biotransformation rates. The regulatory section introduced IVIVE and regression models for BCF prediction, demonstrating their regulatory applications. In the final hands-on training session, participants used case studies with real data (biotransformation rates, log Kow) to practice BCF predictions using spreadsheet with different models. The training concluded with a checklist-based evaluation of OECD TG 319 A/B data quality, enabling participants to assess real data from ECHA registration dossiers.

Assessment of pre- and post-training knowledge

To get a picture of the baseline knowledge, the skills and confidence of the Nordic participants in using NAM-based data in practice, a pre-training survey was carried out. The survey was repeated after the training.

Pre-Training Knowledge Assessment

The pre-training questionnaire results provide baseline assessment of participants' knowledge and confidence levels in applying NAMs across key regulatory areas. These responses revealed diverse levels of familiarity with NAMs and highlighted areas requiring additional focus during the training. Pre- and post-training questionnaire results can be found in Appendix 2 with the exclusion of open-ended questions.

The responses to questions about general confidence in applying NAM concepts ranged significantly, with some participants expressing moderate confidence while others reported minimal familiarity or no prior experience. When asked specifically about using NAMs for skin sensitization assessments, many participants rated their confidence and knowledge at the lower end of the scale, typically describing their familiarity as "low" or "basic". The questionnaire also asked participants' confidence and knowledge in using NAMs for bioaccumulation assessments, specifically in predicting bioconcentration factors (BCFs) using in vitro data. Here again, responses predominantly reflected low confidence and limited knowledge. Responses indicate that many participants have had limited experience with the in silico tools and computational softwares commonly used in NAM-based assessments. For example, while some participants have worked with tools like R or the Episuite BCFBAF model, the majority reported little to no experience with these or similar tools.

The pre-training questionnaire results highlight varying levels of familiarity and confidence in applying NAMs, with many participants expressing limited experience prior to the NAM workshop.

Post-Training Knowledge Assessment

The comparison of the pre- and post-training questionnaires provides a clear picture of the training's effectiveness, highlighting changes in participants' confidence, knowledge, and readiness to apply NAMs in their regulatory roles. The comparison of pre- and post-training surveys highlights significant improvements in participants' confidence, knowledge, and ability to apply NAMs in regulatory work.

Key Findings:

- Confidence growth: Participants entered with low-to-moderate confidence, particularly in complex NAM applications, but post-training many participants reported feeling "somewhat confident" to "confident" in using NAMs after the training. Participants attributed this boost in confidence to the hands-on sessions and practical use of real NAM data.
- Knowledge gains: Many participants had limited prior experience with using NAMs for predicting bioaccumulation and skin sensitization potential. Post training, knowledge ratings of participants shifted towards "moderate" to "good" for predicting bioconcentration factors (BCFs) and skin sensitization potential.
- Practical relevance: The post-training responses indicate that the training met expectations, with participants rating it as "relevant" to "very relevant" to their work.
- Satisfaction & future training needs: Participants expressed high satisfaction with the training's structure, content, and practical relevance. They valued the hands-on exercises, real-world case studies, and the opportunity to work with actual NAM data, with requests for more in-depth content on topics like EDs, toxicokinetics, eye irritation, fish acute toxicity and computational methods (QSAR/in silico). Many participants suggested training materials and background documents to be provided earlier to allow sufficient preparation time. Also, more topics relevant for the environment was suggested.

  These findings confirm that the training was effective in delivering practical, applicable skills for daily regulatory purposes while fostering a stronger Nordic regulatory community for ongoing collaboration for NAMs.

2.4 Future Nordic collaboration

At the end of day 2, a brainstorming session was arranged on how Nordic collaboration in NAMs could be arranged in the future. The discussion was facilitated by Jukka Sund and Miia Häkkinen, Tukes.

Nordic regulators suggested various strategies to strengthen cooperation and support training in NAMs. Many expressed a strong interest in advanced learning opportunities, such as case-based modules and targeted practical workshops, which would enable them to deepen their expertise. The feedback indicated a desire for establishing a Nordic regulatory community of practice around NAMs, fostering an environment for sustained knowledge sharing and support.

Key ideas included:

- Regular Training and Updates: Nordic regulators emphasized the importance of frequent hands-on training sessions, similar to the current event, to build practical skills and keep regulators updated on newly validated NAMs, including areas like QSAR and ToxCast.
- Knowledge Sharing and Expert Networks: Nordic regulators recommended establishing a collaborative network or expert group to share knowledge, discuss new developments, and support each other in interpreting NAM data. Suggestions included an email list or an online platform for regular communication and resource sharing.
- Case Studies and Practical Examples: Nordic regulators found case studies and practical exercises highly beneficial. They proposed more sessions with real-world examples, checklists, and case materials, especially on specific NAMs like eye irritation, to solidify learning and provide practical reference materials.
- Inter-Nordic Collaboration and Expertise Exchange: Leveraging the diverse expertise across Nordic countries was highlighted as a valuable approach. They suggested a platform to facilitate collaboration on joint projects, which would enable regulators to share experiences, insights, and resources more effectively.
- Hybrid Training Options: Regulators also suggested offering both in-person and online training opportunities. This approach would facilitate broader participation and allow for stronger connections between colleagues across institutions and countries.

Overall, the regulators stressed the value of continuous learning, collaborative networks, and access to updated NAM resources to enhance the effectiveness of NAM training across the Nordic region.

3 Conclusions on the event

The Nordic NAM Training and Networking Event served several purposes: It provided European regulators with the latest updates on NAMs within different regulatory frameworks, while on-site hands-on training on NAMs in selected endpoints provided in-depth practice for Nordic regulators. The event also aimed to initiate a discussion on how Nordic regulators could co-operate or work together in this field in the future.

Throughout the event, several recurring themes emerged. A strong emphasis was placed on the importance of cross-agency collaboration to support NAM implementation, especially in addressing shared challenges related to data standardization and validation. Participants acknowledged that a collaborative, Nordic approach would be key to overcoming these obstacles. In discussing

implementation hurdles, participants frequently mentioned the need for standardized protocols and clearer guidelines for interpreting complex NAM data within regulatory frameworks. These shared insights pointed to the collective challenges faced across regulatory bodies and highlighted the value of joint solutions.

There was also a clear commitment among participants and organizers to continue NAM training. Many expressed a strong interest in advanced learning opportunities, such as case-based modules and targeted practical workshops, which would enable them to deepen their expertise. The feedback indicated a wish for establishing a Nordic regulatory community of practice around NAMs, fostering an environment for sustained knowledge sharing and support.

There have been two previous Nordic projects on NAMs namely Nordic Workshop on New Approach Methodologies (NAMs) for Grouping and Read-Across under REACH and CLP[10] and Workshop on alternative in vitro methods to vertebrate studies under CLP[11]. The aim of the present event was to continue to build confidence on NAMs by organising hands-on sessions where participants could learn how to assess data coming from NAMs.

According to the final questionnaire regarding the overall evaluation of the event, the training successfully met its primary objectives of skill-building, confidence enhancement, and practical application of NAMs in regulatory contexts. The success of this training demonstrates its value as a model for future NAM-focused initiatives aimed at advancing regulatory competence and fostering sustainable, animal-free approaches in chemical safety assessment.

4 Acknowledgments

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The event was planned and implemented by the following experts from Tukes: Jukka Sund, Elina Ekokoski, Eeva Rissanen, Tomi Kaartinen, Marianne Moilanen, Pauli Kärkkäinen, Paula Haapasola, Miia Häkkinen, Satu Hiltunen and Eeva Neuvonen. Experts Mounir Bouhifd and Laura Rossi from ECHA helped in planning the event and are greatly acknowledged.

The online studio session on the first day was arranged by Jönssi Oy. Their professional help is greatly appreciated.

[10] https://pub.norden.org/temanord2022-526/

[11] https://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A1754838&dswid=-6655

5 Appendices

5.1 Appendix 1

Agenda day 1

Opening		
10:00	10:10	Welcome Tiina PUTKONEN, Finnish Safety and Chemicals Agency (TUKES)
10:10	10:40	Housekeeping and aims of the training Jukka SUND, Finnish Safety and Chemicals Agency (TUKES)
10:40	11:20	Keynote: EU Commission Roadmap towards phasing out animal testing for chemical safety assessment Georg STRECK, European Commission (DG GROW)
11:20	11:50	Coffee break
Overview session		
11:50	12:20	Towards an animal testing-free regulatory system for industrial chemicals: NAMs at ECHA Mounir BOUHIFD, European Chemicals Agency (ECHA)
12:20	12:50	EFSA activities on NAMs Sofia BATISTA LEITE, European Food Safety Authority (EFSA)
12:50	13:50	Lunch

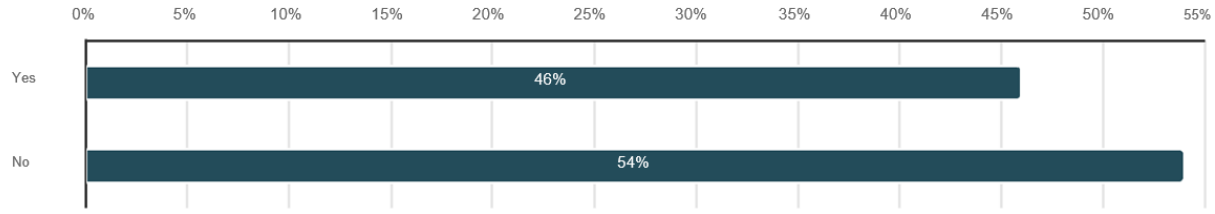
Regulatory session		
13:50	14:20	Overview of on-going work at GHS-level on the use of non-animal methods in health hazard classification Erika WITASP HENRIKSSON, Swedish Chemicals Agency (KEMI)
14:20	14:50	New approach methods in OECD Test Guidelines and beyond Anne GOURMELON, Organisation for Economic Co-operation and Development (OECD)
14:50	15:20	Experiences in performing risk assessment with NAMs Qasim CHAUDHRY, Scientific Committee on Consumer Safety (SCCS)
15:20	15:50	Coffee break
Future opportunities		
15:50	16:20	Towards a future regulatory framework for chemicals in the European Union – Chemicals 2.0 Elisabet BERGGREN, European Commission (DG Joint Research Centre / EU Reference Laboratory for alternatives to animal testing)
16:20	17:00	Performance expectations of new approach methods (NAMs) based on variability and concordance of existing models Katie PAUL FRIEDMAN, United States Environmental Protection Agency (US EPA)
Closing		
17:00	17:10	Wrap-up Jukka SUND, Finnish Safety and Chemicals Agency (TUKES)

5.2 Appendix 2

Pre-training questionnaire

1a. Have you assessed NAM-based data before

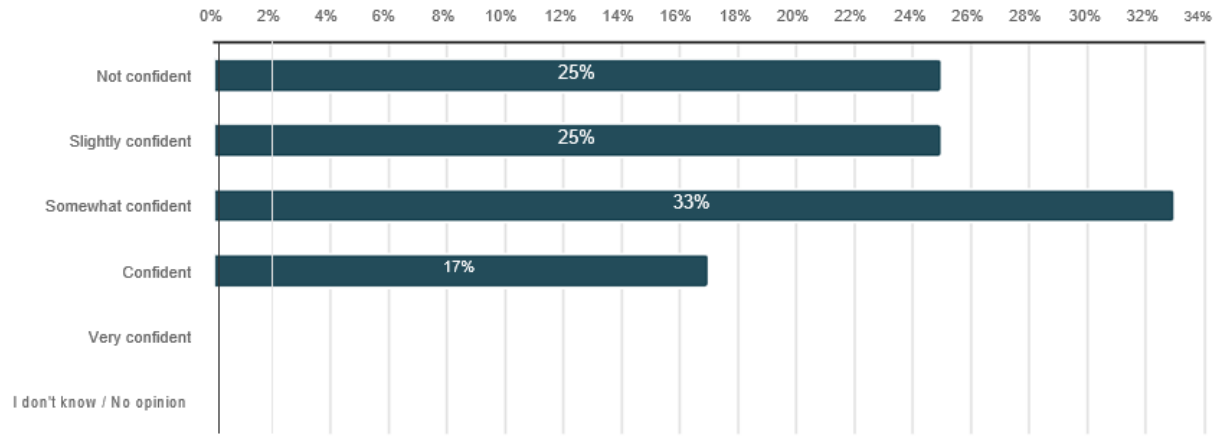
Number of respondents: 26



	n	Percent
Yes	12	46,2%
No	14	53,8%

1b. How confident are you in your ability to apply Non-Animal Methods (NAM) concepts?

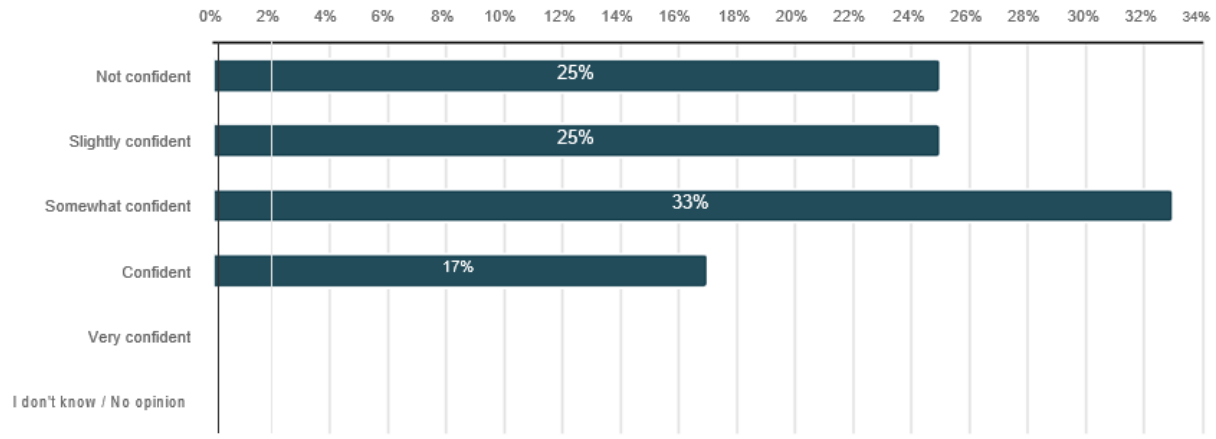
Number of respondents: 12



	n	Percent
Not confident	3	25,0%
Slightly confident	3	25,0%
Somewhat confident	4	33,3%
Confident	2	16,7%
Very confident	0	0,0%
I don't know / No opinion	0	0,0%

1b. How confident are you in your ability to apply Non-Animal Methods (NAM) concepts?

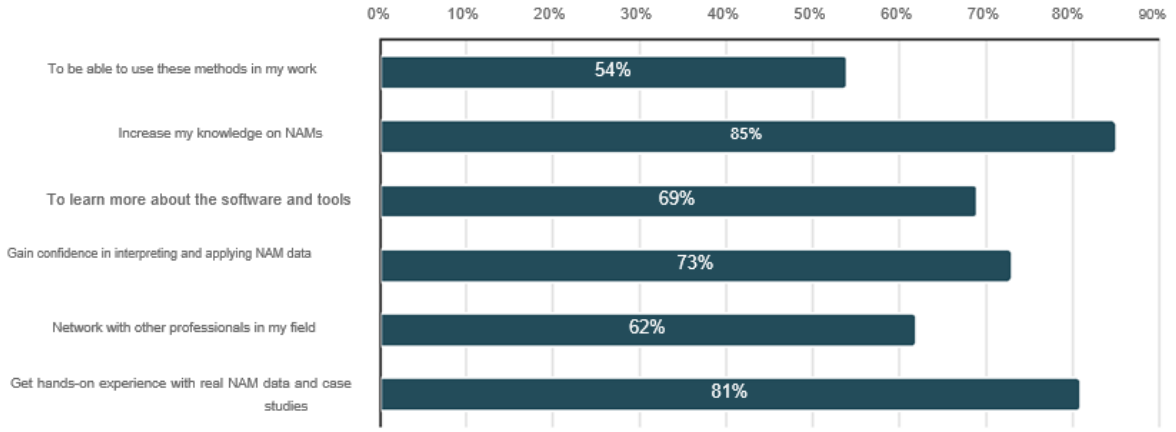
Number of respondents: 12



	n	Percent
Not confident	3	25,0%
Slightly confident	3	25,0%
Somewhat confident	4	33,3%
Confident	2	16,7%
Very confident	0	0,0%
I don't know / No opinion	0	0,0%

2a. What do you hope to achieve by the end of this training?

Number of respondents: 26 , selected answers: 110

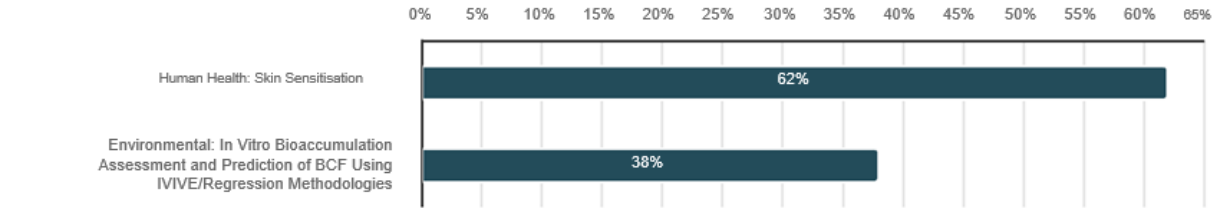


	n	Percent
To be able to use these methods in my work	14	53,8%
Increase my knowledge on NAMs	22	84,6%
To learn more about the software and tools	18	69,2%
Gain confidence in interpreting and applying NAM data	19	73,1%
Network with other professionals in my field	16	61,5%
Get hands-on experience with real NAM data and case studies	21	80,8%

3. Training Session You Will Attend

Choose on

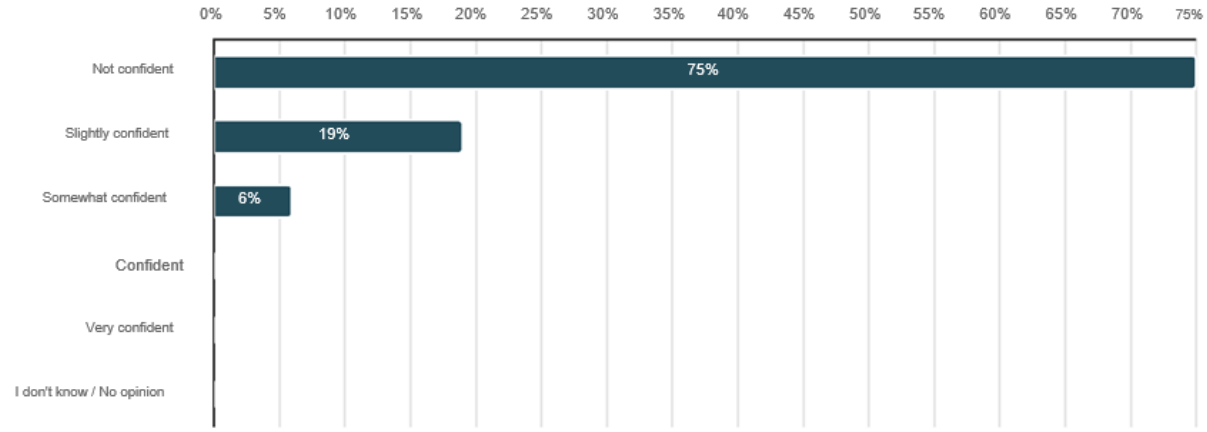
Number of respondents: 26



	n	Percent
Human Health: Skin Sensitisation	16	61,5%
Environmental: In Vitro Bioaccumulation Assessment and Prediction of BCF Using IVIVE/Regression Methodologies	10	38,5%

4a. How confident are you in using NAM-based methods and defined approaches for skin sensitisation assessments?

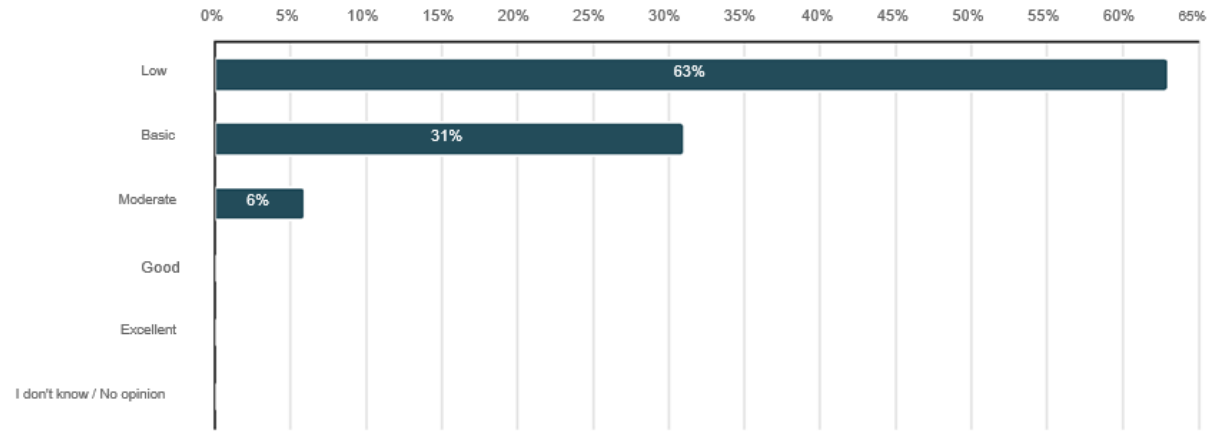
Number of respondents: 16



	n	Percent
Not confident	12	75,0%
Slightly confident	3	18,7%
Somewhat confident	1	6,3%
Confident	0	0,0%
Very confident	0	0,0%
I don't know / No opinion	0	0,0%

4b. Please rate your current knowledge on predicting human skin sensitisation potential using NAM data:

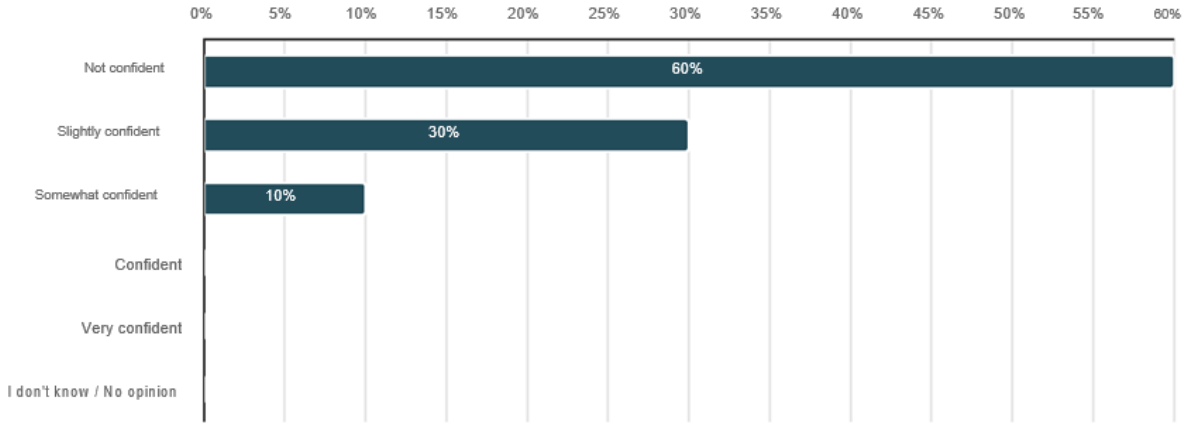
Number of respondents: 16



	n	Percent
Low	10	62,5%
Basic	5	31,2%
Moderate	1	6,3%
Good	0	0,0%
Excellent	0	0,0%
I don't know / No opinion	0	0,0%

5a. How confident are you in using (OR in evaluating?) in vitro biotransformation data for bioaccumulation assessment?

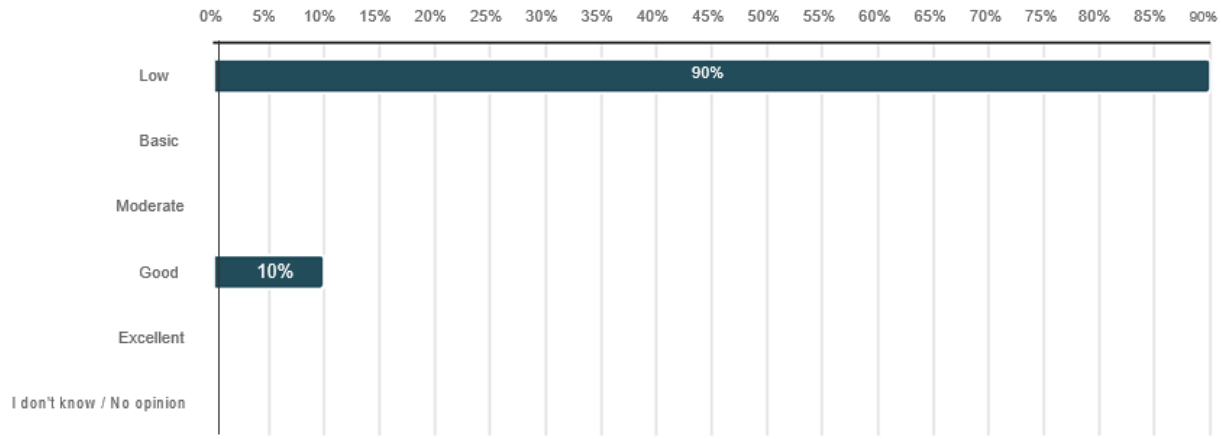
Number of respondents: 10



	n	Percent
Not confident	6	60,0%
Slightly confident	3	30,0%
Somewhat confident	1	10,0%
Confident	0	0,0%
Very confident	0	0,0%
I don't know / No opinion	0	0,0%

5b. Please rate your current knowledge on predicting bioconcentration factors (BCFs) using in vitro data as input for extrapolation models (e.g. IVIVE models):

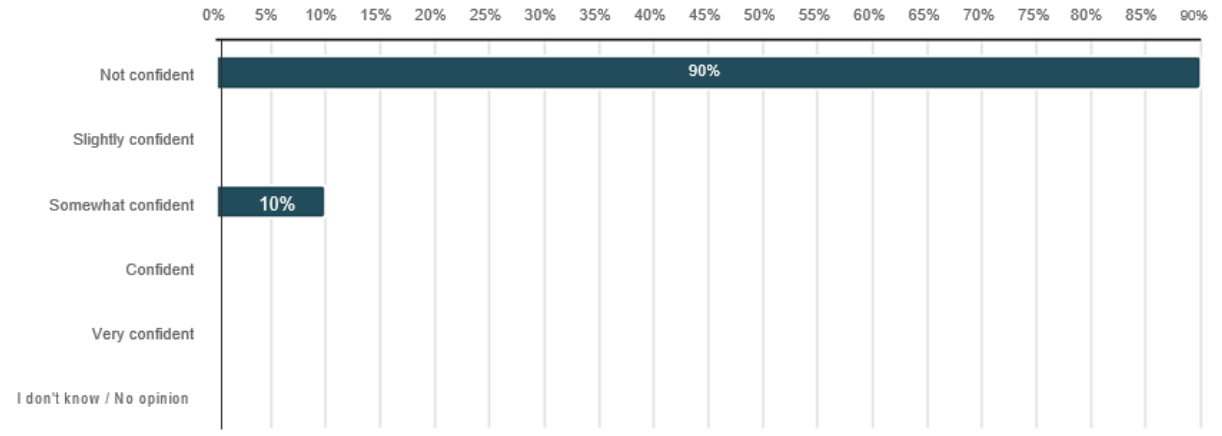
Number of respondents: 10



	n	Percent
Low	9	90,0%
Basic	0	0,0%
Moderate	0	0,0%
Good	1	10,0%
Excellent	0	0,0%
I don't know / No opinion	0	0,0%

5c. How confident are you in your ability to apply OECD TG 319 and IVIVE methodologies for regulatory applications?

Number of respondents: 10

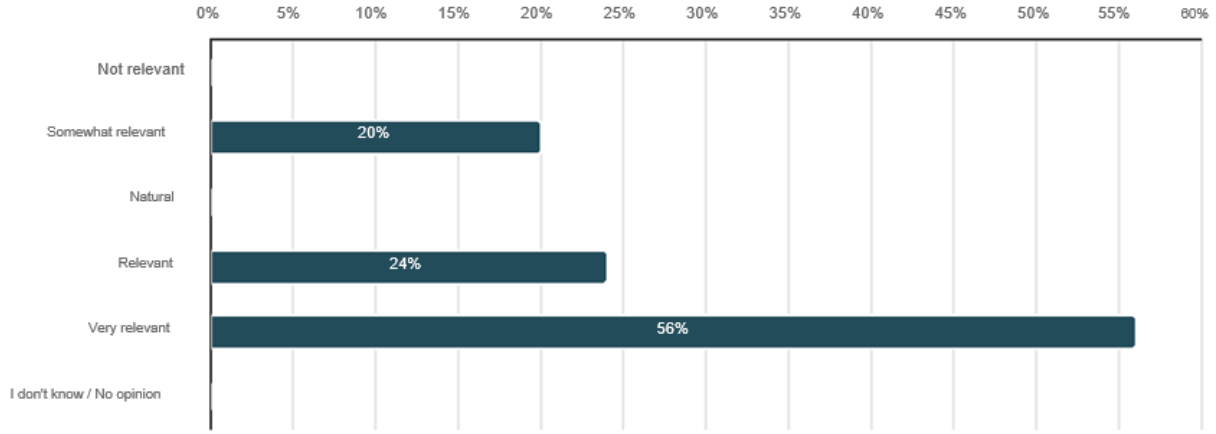


	n	Percent
Not confident	9	90,0%
Slightly confident	0	0,0%
Somewhat confident	1	10,0%
Confident	0	0,0%
Very confident	0	0,0%
I don't know / No opinion	0	0,0%

Post-training questionnaire

1a. How relevant was the hands-on training to your current work?

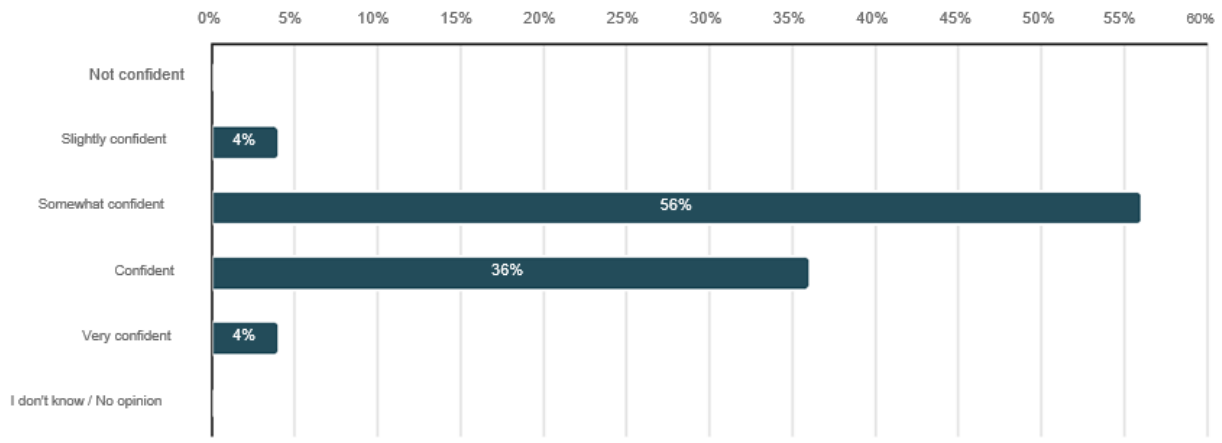
Number of respondents: 25



	n	Percent
Not relevant	0	0,0%
Somewhat relevant	5	20,0%
Natural	0	0,0%
Relevant	6	24,0%
Very relevant	14	56,0%
I don't know / No opinion	0	0,0%

1b. How confident are you in your ability to apply NAM concepts related to your selected training session after the training?

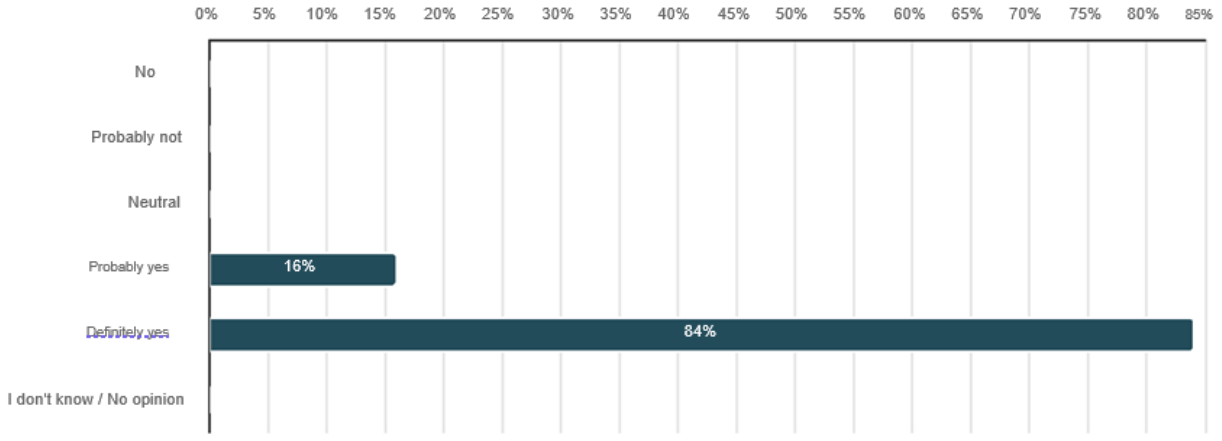
Number of respondents: 25



	n	Percent
Not confident	0	0,0%
Slightly confident	1	4,0%
Somewhat confident	14	56,0%
Confident	9	36,0%
Very confident	1	4,0%
I don't know / No opinion	0	0,0%

2a. Did the training meet your expectations in terms of content quality and practical applicability?

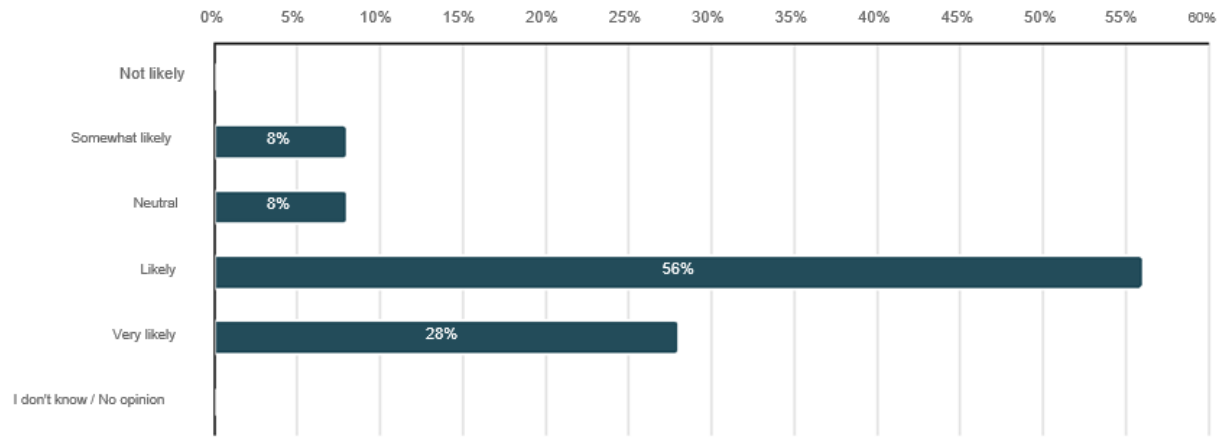
Number of respondents: 25



	n	Percent
No	0	0,0%
Probably not	0	0,0%
Neutral	0	0,0%
Probably yes	4	16,0%
Definitely yes	21	84,0%
I don't know / No opinion	0	0,0%

2c. How likely are you to apply what you've learned in your daily work?

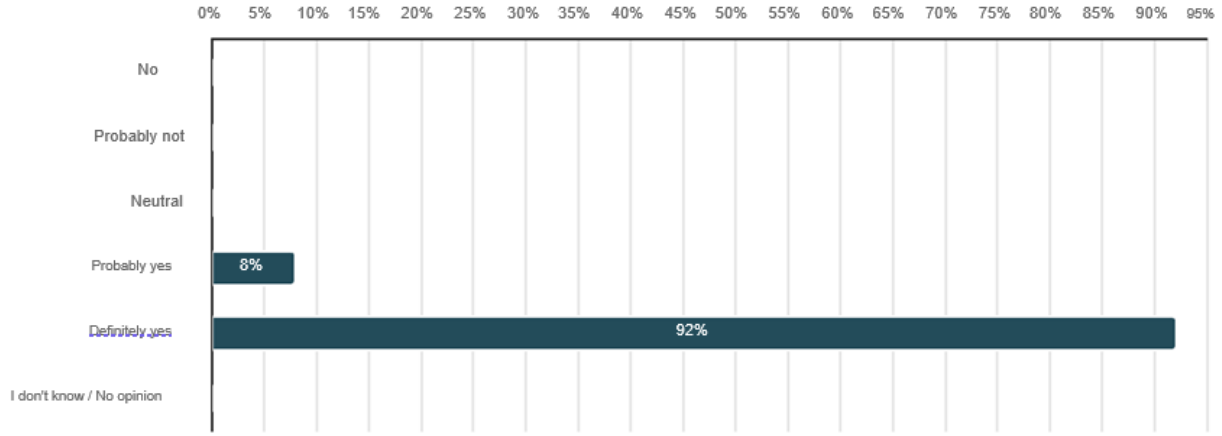
Number of respondents: 25



	n	Percent
Not likely	0	0,0%
Somewhat likely	2	8,0%
Neutral	2	8,0%
Likely	14	56,0%
Very likely	7	28,0%
I don't know / No opinion	0	0,0%

2d. Would you recommend this training to your colleagues?

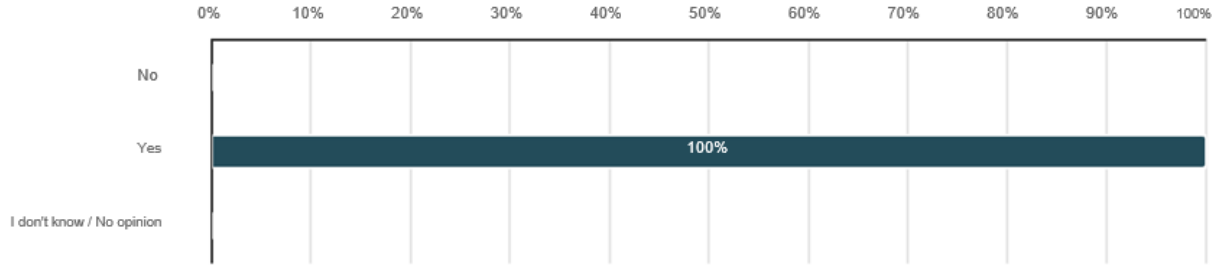
Number of respondents: 25



	n	Percent
No	0	0,0%
Probably not	0	0,0%
Neutral	0	0,0%
Probably yes	2	8,0%
Definitely yes	23	92,0%
I don't know / No opinion	0	0,0%

3a. Do you think similar NAM-related trainings should be arranged in the future as Nordic co-operation?

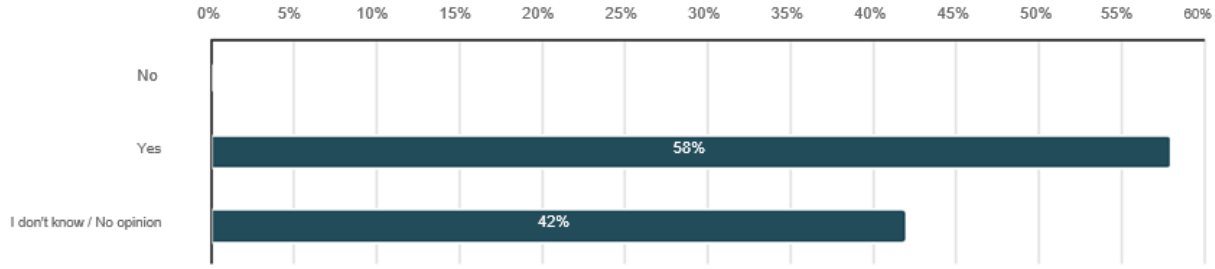
Number of respondents: 25



	n	Percent
No	0	0,0%
Yes	25	100,0%
I don't know / No opinion	0	0,0%

3c. Would you be interested in participating in a Nordic Regulatory Community of Practice focused on NAMs?

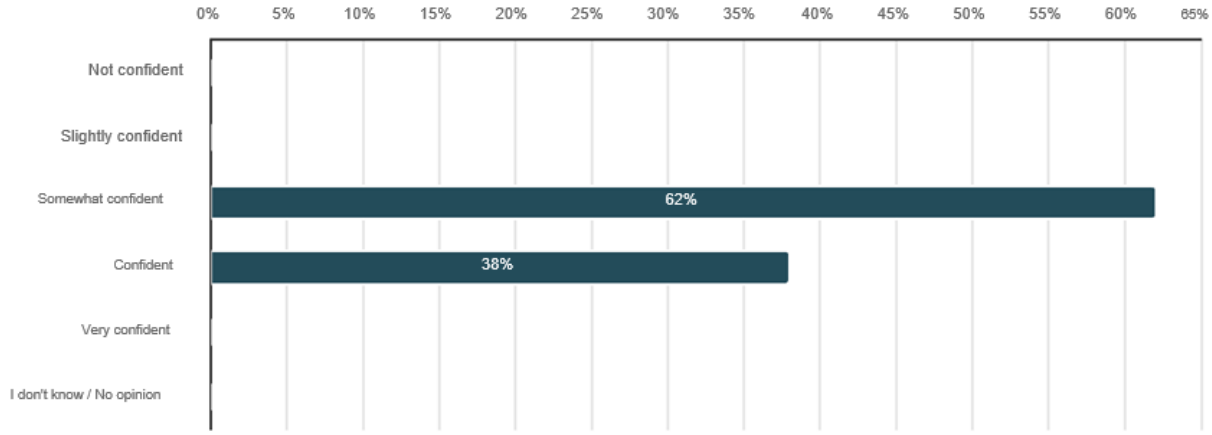
Number of respondents: 24



	n	Percent
No	0	0,0%
Yes	14	58,3%
I don't know / No opinion	10	41,7%

5a. How confident are you with NAM-based methods and defined approaches for skin sensitisation assessments after the training?

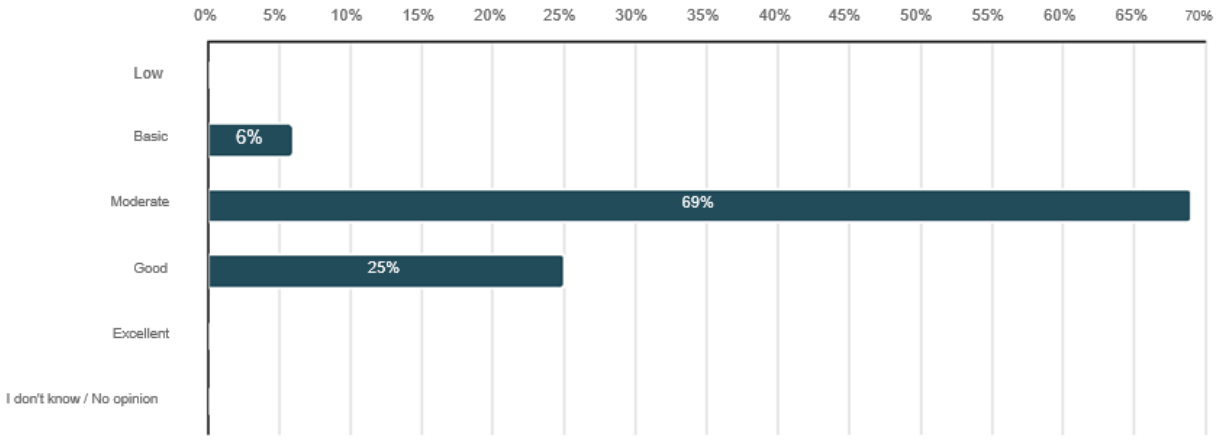
Number of respondents: 16



	n	Percent
Not confident	0	0,0%
Slightly confident	0	0,0%
Somewhat confident	10	62,5%
Confident	6	37,5%
Very confident	0	0,0%
I don't know / No opinion	0	0,0%

5b. Please rate your knowledge on predicting human skin sensitisation potential using NAM data after the training:

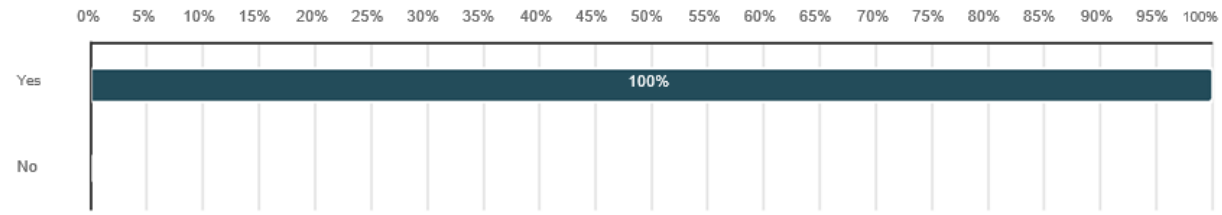
Number of respondents: 16



	n	Percent
Low	0	0,0%
Basic	1	6,2%
Moderate	11	68,8%
Good	4	25,0%
Excellent	0	0,0%
I don't know / No opinion	0	0,0%

5c. Did you find use of real NAM data from experiments during the training useful?

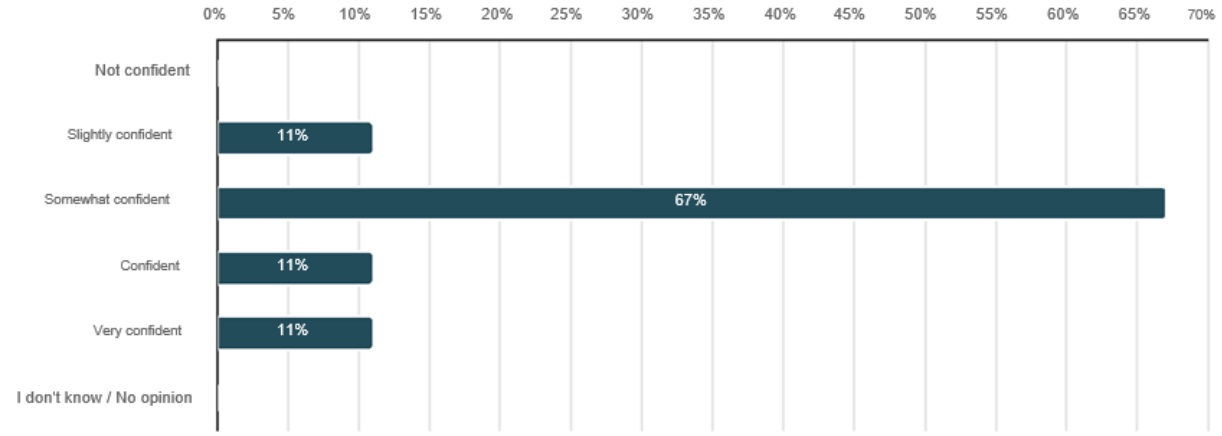
Number of respondents: 16



	n	Percent
Yes	16	100,0%
No	0	0,0%

6a. How confident are you in using (OR in evaluating?) in vitro biotransformation data for bioaccumulation assessment after the training?

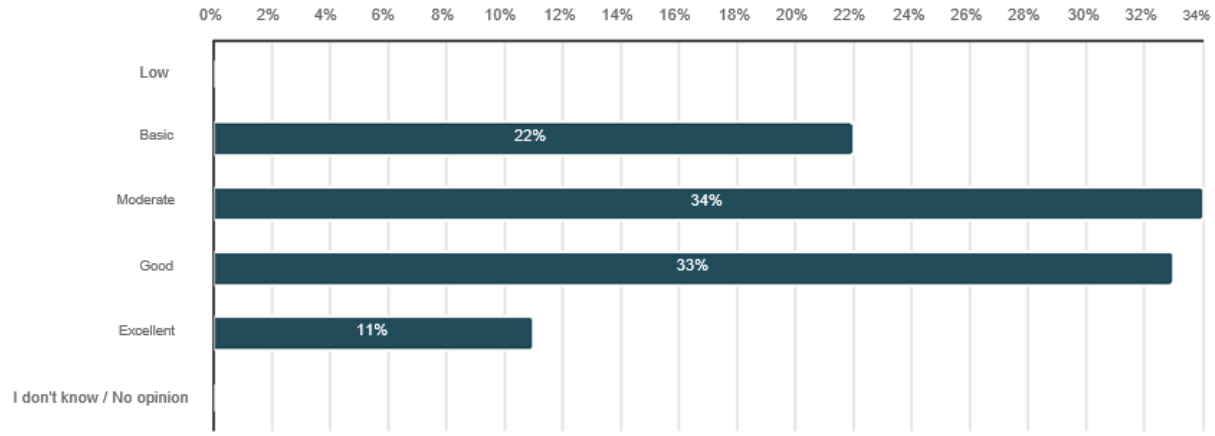
Number of respondents: 9



	n	Percent
Not confident	0	0,0%
Slightly confident	1	11,1%
Somewhat confident	6	66,7%
Confident	1	11,1%
Very confident	1	11,1%
I don't know / No opinion	0	0,0%

6b. Please rate your knowledge on bioconcentration factors (BCFs) using in vitro data as input for extrapolation models (e.g. IVIVE models) after the training:

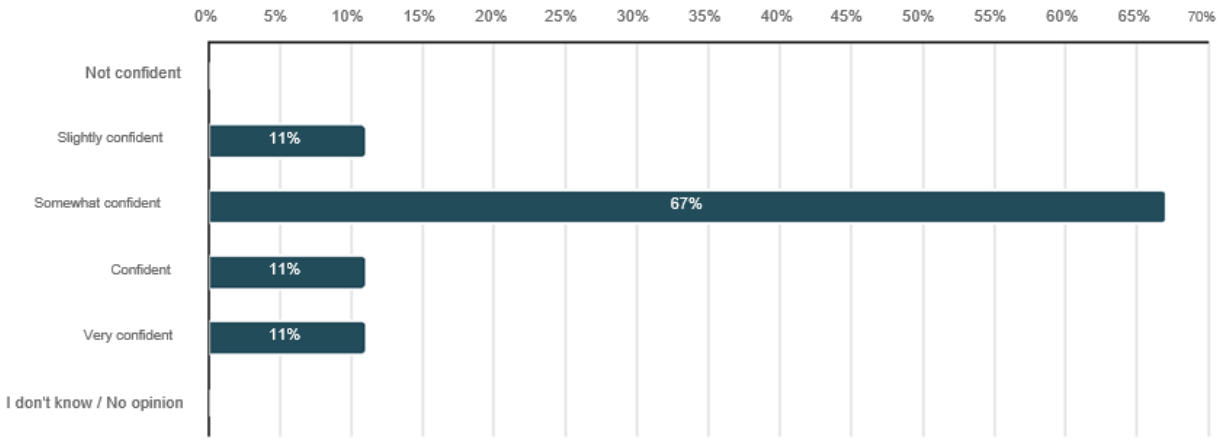
Number of respondents: 9



	n	Percent
Low	0	0,0%
Basic	2	22,2%
Moderate	3	33,4%
Good	3	33,3%
Excellent	1	11,1%
I don't know / No opinion	0	0,0%

6c. How confident are you in your ability to apply OECD TG 319 and IVIVE methodologies for regulatory applications after this training?

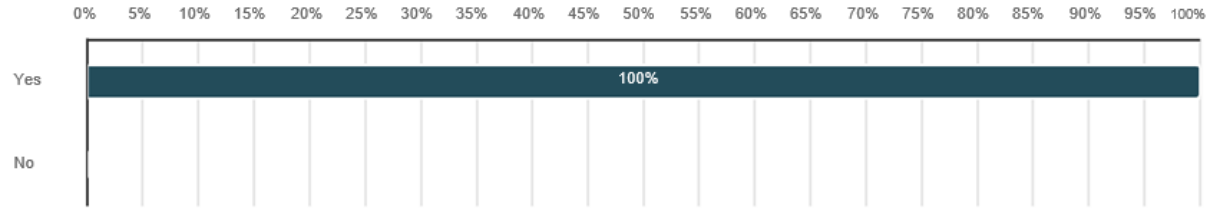
Number of respondents: 9



	n	Percent
Not confident	0	0,0%
Slightly confident	1	11,1%
Somewhat confident	6	66,7%
Confident	1	11,1%
Very confident	1	11,1%
I don't know / No opinion	0	0,0%

6d. Did you find use of real NAM data from experiments during the training useful?

Number of respondents: 9



	n	Percent
Yes	9	100,0%
No	0	0,0%

5.3 Appendix 3

Speaker biographies

Georg Streck, European Commission, DG GROW
Georg has a background in environmental chemistry, toxicology and ecotoxicology. Since more than 12 years he has been working for the European Commission in the unit responsible for the REACH Regulation, a major legislation on chemicals. In the unit, he covered or is still covering all policy developments in the area of endocrine disruptors, persistent and complex substances. He is also involved in the update of REACH information requirements. Since beginning of last year, he is responsible for the DG GROW team on animal-free methods. He prepared, together with colleagues, a Commission Communication replying to a European Citizens Initiative announcing the preparation of a roadmap towards phasing out all animal testing for chemical safety assessments.

Mounir Bouhifd, European Chemicals Agency (ECHA)
Mounir Bouhifd is a regulatory officer at the European Chemicals Agency. He is member of the Alternative Methods Team in the prioritisation Directorate. Before joining ECHA, Mounir was a faculty member at the School of Public Health of the Johns Hopkins university. HE was also working on the development and application of Alternative methods and their validation, at the European Centre of Validation of Alternative methods (ECVAM). At ECHA, Part of his tasks is on the assessment of QSAR predictions. New Approach Methodologies and alternatives to animal testing are among his areas of work.

Sofia Batista Leite, European Food Safety Authority (EFSA)
Dr. Batista Leite is a biochemist with a PhD in in vitro Biotechnology (IBET, Portugal). During her academic research years, she explored new approaches for culturing liver cells for use in toxicology and biomedical research. She has worked at the European Commission Joint Research Centre to promote the use of non-animal methods in regulatory and biomedical areas. Her major expertise is in complex in vitro systems including microphysiological systems and organ-on-chip. Having (in vitro) methods and models in mind, her worked explored strategies to increase scientific trust using good reporting, cross-disciplinarity and knowledge sharing approaches.
Since February 2023 she is a scientific officer in the European Food Safety agency (EFSA) where she works in pesticides risk assessment and is part of the core group of the EFSA Knowledge Innovation Community on NAMs.

Erika Witasp Henriksson, Swedish Chemicals Agency (KemI)
Erika works as a senior regulatory toxicologist. Her current role principally involves applying and developing the existing chemicals legislation (Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation ((EC) No 1907/2006) and Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008)) with focus on restricting hazards and risks of industrial chemicals. She has extensive experience of hazard identification according to the classification criteria in the CLP Regulation that encompasses reviewing information generated from non-animal test methods as well as predicting toxicological properties of substances by ‘read-across’ approach. She is currently a member of the Informal Working Group of the UN Sub-Committee of Experts on the Globally Harmonised System (GHS) on use of non-animal testing methods for the classification of health hazards.

Anne Gourmelon, OECD
Anne Gourmelon is principal administrator at the OECD in the Environment Directorate. She has a long standing experience of test method validation and Test Guidelines development, and a good understanding of differences in chemicals regulations across countries. Anne is an engineer by education, with a Master's degree in environmental sciences from the University of Wageningen. She enjoys working collaboratively and embraces innovation and change management in her work. Her dedication to advancing chemical safety and regulatory science is evident through her extensive research and active participation in international initiatives.

Qasim Choudry, Scientific Committee on Consumer Safety (SCCS)
Prof. Chaudhry is currently a visiting Professor at University of Chester (UK). He has academic background in chemistry (BSc (Hon); MSc) and biochemical toxicology (PhD), with longstanding expertise in the health and environmental safety of chemicals and nanomaterials. His past scientific career at the UK's Food and Environment Research Agency has encompassed safety assessment of chemicals and nanomaterials; computational toxicology; natural products from plants; bioremediation of environmental pollutants; modes of toxic action of pesticides; mechanisms of pesticide resistance; and development of immunodiagnostics. As an Independent Expert, Prof. Chaudhry provides his scientific advice on the safety of cosmetic and personal-care products to the European Commission's Scientific Committee on Consumer Safety (SCCS) based in Luxembourg; on food/feed safety to the European Food Safety Authority (EFSA) based in Italy; and the UK's Food Standards Agency based in London. Prof. Chaudhry is a Fellow of the Royal Society of Chemistry (FRSC), and author/ co-author of over 75 scientific publications that include research papers, book and book chapters, reviews, as well as numerous scientific Opinions, Memoranda, and Guidance documents published by the European Scientific Committees.

Elisabet Berggren, European Commission, DG JRC
Elisabet Berggren is Deputy Head of Unit of the Systems Toxicology Unit, at the Joint Research Centre (JRC), European Commission. Currently she is contributing to the setţing up of the Commission roadmap towards phasing out of animal testing in chemicals safety assessment, as a response to the European Citizens' initiative "Save Cruelty Free Cosmetics - Commit to a Europe without animal testing". In this context also the initiative the EPAA Designathon based on a future vision of chemicals safety assessment - Chemicals 2.0, is very relevant. Elisabet is contributing to the United Nations Globally Harmonised System for Classification and Labelling of Chemicals. She started to work for the European Commission in 1996 at the European Chemicals Bureau. When its responsibilities were handed over to ECHA, she changed to her current unit, which is also hosting the European Union Reference Laboratory for Alternatives to Animal Testing (ECVAM) as established under the Directive 2010/63/EU on the protection of animals used for scientific purposes.

Katie Paul Friedman, U.S. Environmental Protection Agency (US EPA)
Dr. Katie Paul Friedman is a Computational Toxicologist and Branch Chief for the Computational Toxicology and Bioinformatics Branch in the Center for Computational Toxicology and Exposure in the Office of Research and Development at the US EPA. Her research focuses on application of new approach methods to chemical safety assessment, with additional interests in variability in traditional toxicity information, endocrine bioactivity, and in vitro kinetics. She is a leader for the ToxCast program. She is active in multi-stakeholder projects to develop alternatives and their acceptance, including through technical leadership at Federal Advisory Committee reviews and in the consortium Accelerating the Pace of Chemical Risk Assessment. Her laboratory background includes development of high-throughput screening assays and combined use of in vitro and in vivo approaches. Dr. Paul Friedman received a Ph.D. in Toxicology from the University of North Carolina at Chapel Hill and has authored > 60 peer-reviewed publications and mentored > 18 early career trainees.