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**SYNTHESIS REPORT FROM THE OECD WORKSHOP ON ALTERNATIVES ASSESSMENT AND
SUBSTITUTION OF HARMFUL CHEMICALS**

**Series on Risk Management
No. 31**

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OECD Environment, Health and Safety Publications

Series on Risk Management

No. 31

**SYNTHESIS REPORT FROM THE OECD WORKSHOP ON ALTERNATIVES ASSESSMENT
AND SUBSTITUTION OF HARMFUL CHEMICALS**

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among **FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
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The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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or contact:

**OECD Environment Directorate,
Environment, Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16
France**

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

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SYNTHESIS REPORT FROM THE OECD WORKSHOP ON ALTERNATIVES ASSESSMENT AND SUBSTITUTION OF HARMFUL CHEMICALS

Introduction

The OECD Ad Hoc Group on Substitution of Harmful Chemicals organised an expert workshop on Substitution and Alternatives Assessment in Paris on 11-12 May 2015. The expert workshop was organised as a brainstorming meeting to discuss where gaps remain in terms of possible missing tools, guidance and research to support stakeholders engaged in alternatives assessment and substitution of harmful chemicals. The conclusions of this expert workshop will help support the development of future activities of the OECD Ad Hoc Group.

The expert workshop was composed of a number of sessions aiming to:

- Outline the latest advances in substitution and alternatives assessment by giving an overview of the regulatory/policy context in which these latest advances have taken place, and looking at challenges that may remain for creating an environment favourable to the substitution of harmful chemicals;
- Identify where gaps remain in terms of specific tools that could support substitution and alternatives assessment globally (e.g., sector/industry specific guidance, guidance on specific chemical groups, guidance for risk trade-offs assessment);
- Discuss if harmonisation in specific areas would be useful (e.g., terminology, definitions, and baseline elements of alternative assessments);
- Outline practices for alternatives assessment and the substitution of chemicals of concerns, looking, for example, at:
 - Industry incentives to substitute (e.g., voluntary initiatives, response to regulation);
 - How methods and tools available for alternatives assessment and substitution are impacting the pace through substitution of chemicals of concern;
 - The level at which substitution is integrated in business models (e.g., elements of corporate governance for risk management, risk reduction measures).

This report summarises the main conclusions from the expert workshop. It does not necessarily represent the views of the OECD or a consensus among participants. The expert workshop agenda is in the Annex 1 to this report. The list of participants is in Annex 2. Affiliations of participants are as of May 2015.

Setting the scene: the challenge of substituting chemicals of concern and the need for more guidance

Alternatives assessment and substitution are used to respond to the need of consumers and societies for greener and more sustainable products or production processes that do not contain or use harmful chemicals. Both feed into current strategies to reduce risks of chemicals on human health and the environment and into industry's approach to sustainable development. The concept of substitution is also increasingly included as part of policy and regulatory measures for the management of chemicals of concern. For example, substitution has become a central element of the European Union REACH regulation¹ through the modernisation of its chemicals legislation. In the United States, a policy approach has been taken by the U.S. Environmental Protection Agency (U.S. EPA) by promoting the use of safer chemicals through its "Safer Choice Program" (formerly the "Design for the Environment Program Safer Product Labelling Program"), and by conducting several alternatives assessments (e.g., on various flame retardants) through public/private partnerships. Alternatives assessment is a key process to drive decisions to substitute a chemical of concern.

Finding suitable alternatives to chemicals of concern is not a small challenge. Alternatives should be safer, having a lower hazard and risk potential, but still present similar performance to their counterpart and be economically viable and sustainable. Substituting chemicals also goes beyond finding a drop-in chemical alternative and can include systems, materials, or process changes. Companies, in particular small and medium-size companies (SMEs), face challenges when considering the substitution of chemicals that are central in their product or process development. This can directly affect business models and competitiveness and may require the need to invest in new capacities.

Guidance and tools to support stakeholders in their alternatives assessment and substitution efforts have been very much needed, in particular following the increasing regulatory requirement for alternatives assessment in some countries/regions (e.g., EU REACH regulation, the California Safer Consumer Products Regulation) where guidance to support the good management of regulatory requirements in companies is a key aspect for compliance. Issues that have been particularly highlighted during the workshop are the need for guidance on how and where to find information on possible alternatives, on the type of scientific information needed, and the tools available to make an informed decision on a potential alternative. Also, the need to learn from each other's experiences and from successful and unsuccessful substitution cases was very much put to the front during the meeting.

Over the past decades, several government initiatives have been supporting the development of programmes and tools to encourage alternatives assessment and the substitution of chemicals of concern. Various industry sectors are also directly engaging in developing/using alternatives assessment tools during product development and in making substitution a business "good practice." Non-governmental organisations (NGOs) are also very much involved in supporting the substitution of chemicals of concern through the development of different initiatives. Stakeholders (e.g., public institutions, governments, NGOs, industry) have also been working together to develop key principles of alternatives assessment, frameworks for alternatives assessment, as well as tools and repositories.

Public programmes to support substitution and alternatives assessment

The workshop looked at some of the recent advances in regards to different practices used by countries/regions to support substitution and alternatives assessment, in particular the integration of substitution and alternatives assessment in chemicals regulation, as well as the use of a combination of policy and economic instruments as drivers to substitute chemicals of concern.

¹ REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals, for more information see the REACH website at: <http://echa.europa.eu/regulations/reach>

Substitution and alternatives assessment in regulation

As an example of regulation that includes the analysis of alternatives to chemicals of concern, aspects of the European legislation REACH, implemented by the European Chemical Agency (ECHA), relating to substitution and analysis of alternatives, were presented at the workshop.

In Europe, the substitution of chemicals of concerns is an element of the REACH regulations. Under REACH, a list of substances that require authorisation for their use or placing on the market for a use (Annex XIV - "Authorisation List") was initiated. This authorisation process has been set up to ensure that the risks from these substances are properly controlled, and that these substances are progressively substituted by alternative substances or technologies, where these are economically and technically viable. Indeed, the authorisation process requires the company, when applying for an authorisation for the use or placing on the market of a substance listed in Annex XIV, to provide an analysis of alternatives including the following elements:

- An analysis of the substance function;
- The annual tonnage;
- The identification of possible alternatives: list of possible alternatives, description of efforts made to identify possible alternatives, research and development, data searches and consultations;
- Assessment of the suitability and availability: substances identification and properties, technical feasibility, economic feasibility, reduction of overall risk due to transition to the alternative, availability; and
- Overall conclusions on sustainability and availability of possible alternatives.

In addition to the application for authorisation process, other processes of REACH can provide an incentive to substitute, such as the REACH substance evaluation and the Candidate List of Substances of Very High Concern (SVHC)². Also, the Public Activities Coordination Tool (PACT)³ and the Registry of Intentions⁴ (RoI) give early warnings of substances of potential concerns, as well as the SVHC Candidate List. EU member states and ECHA itself also carry out an analysis of alternatives, for example, for substances that are proposed to be restricted under REACH.

The REACH legislation has allowed for the development of a large number of real world cases of analysis of alternatives, which make it one of the largest sources of analysis of alternatives in the world. However, the quality of the analyses provided varies, and methods to help identify best practices for

² See more information at: <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification/candidate-list-of-substances-of-very-high-concern-for-authorisation>

³ The Public Activities Coordination Tool (PACT) lists the substances for which a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB (persistent, bioaccumulative and toxic/very persistent and very bioaccumulative) properties or endocrine disruptor properties is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013.

⁴ The notifications of intention to submit a dossier to ECHA related to the risk management processes under the REACH (SVHCs and restrictions) and CLP (Harmonised Classification and Labelling (CLH)) regulations are included in the respective Registry of Intentions.

reporting alternatives assessment are being investigated, such as a scoring system. The implementation of the REACH regulation also showed that substitution does happen. There was no application for authorisation received for about 50% of the substances listed in Annex XIV following the latest application date. Companies indicated that they had not applied because they had implemented an alternative substance. About 50% of the applications received are “bridging applications,” where companies are requesting additional time to switch to an identified alternative.

As part of the implementation of the REACH regulation, the workshop highlighted the work of the REACH and CLP⁵ Helpdesk in Luxembourg. Every European Member State established a helpdesk to provide advice to manufacturers, importers and downstream users of chemical products on the implementation of the REACH regulation. In Luxembourg, the helpdesk is run by the Luxembourg Institute for Science and Technology (LIST)⁶, on behalf of the Ministry for Sustainable Development and Infrastructure and the Ministry of the Economy. The Luxembourg helpdesk has established its own concept that fits with the specificities of the companies’ landscape in the country. Luxembourgish chemical companies are mainly SMEs and downstream users. The experience of the Luxembourg helpdesk shows that, in Luxembourg, companies are not always ready for substitution. Current challenges such as communication in the supply chain or the implementation of the CLP regulation for mixtures, seem to be priorities for companies. In general, it is particularly difficult to reach SMEs and to bring them support in their substitution efforts. Companies are asking for a targeted/tailored approach with sector-specific guidance, supported by the collection of case studies showing real life examples of substitution, if possible substitution that already occurred in SMEs. More partnerships and collaboration are also needed between SMEs, and more generally among chemical industry players. Regulations are complex and there is still a need for a more thorough understanding of the procedures.

A combination of policy and economic instruments to support substitution

In addition to regulatory measures, or as a different approach, the combination of policy and economic instruments used in some countries to support alternatives assessment and substitution were also discussed at the workshop.

In Denmark, for example, there is political momentum for the substitution of chemicals of concern. The Danish Parliament has agreed, since 2006, on three chemical action plans, and a number of tools have been developed to support substitution that are a combination of legislative instruments and the “warning” lists of substances under REACH, of information and guidance, and of financial support, partnerships, economic instruments (e.g., taxes), ecolabels, and voluntary agreements set up with different sectors. In the case of fluorinated gases (F-gases), for example, Denmark established in 2001 a taxation system, and in 2002 restrictions on their uses; also, specific support was put in place for the development of alternative technologies. Investments were also made in raising awareness, and information sharing with the development of a knowledge centre. This resulted in a significant reduction in the uses of F-gases. More generally, Denmark invests in technological development and innovation, in particular for the substitution of substances of political/regulatory interest (e.g., preservatives in cosmetics, tattoo inks, phthalates, endocrine disruptors, flame retardants, fluorinated substances, and substances that may prevent recycling). The advanced development of alternative technologies can be a market place advantage for Danish companies.

⁵ The Regulation for Classification, Labelling and Packaging (CLP) is a European Union regulation that aligns the European Union system of classification, labelling and packaging chemical substances and mixtures to the Globally Harmonised System (GHS).

⁶ See the LIST website at <http://www.list.lu/>, and the REACH Luxembourg website at <http://www.reach.lu/>.

In the United States, a policy approach has been developed where the use of safer chemicals are promoted under the “Safer Choice Program” (formerly the “Design for the Environment (DfE) Safer Product Labelling Program”) of the U.S. Environmental Protection Agency (EPA). The goal of this programme is protecting consumers, workers and the environment through the availability of safer products and safer chemical ingredients. The programme is housed in the Office of Pollution Prevention and Toxics (OPPT), which addresses the risks of new and existing chemicals. The overall DfE Program has two areas of focus - the Safer Choice product labelling programme, and the Alternatives Assessment Program.

The U.S. EPA Alternatives Assessment Program⁷ is focused on providing support for and promoting the practice of alternatives assessment, at the national and international levels (for example, the U.S. EPA, together with ECHA, chair the OECD Ad Hoc Group on the Substitution of Harmful Chemicals).

In particular, the U.S. EPA Alternatives Assessment Program aims to:

- Build the community of practice for advancing the science and practice of alternatives assessment;
- Promote the selection of safer, more sustainable alternatives when combined with other information, such as performance and cost;
- Identify and assess potential alternatives for chemicals that the EPA has designated for action; and
- Provide information on functional class, intrinsic hazard, exposure properties, and environmental fate for chemical alternatives.

Tools and practices to support substitution and alternatives assessment

As it was largely highlighted during the workshop, alternatives assessment practices and substitution of chemicals of concern do happen (see Box 1). Increasingly, practitioners are asking for support on how to conduct these processes in an efficient manner. Different stakeholders (e.g., NGOs, the private sector, academia, public authorities) - often joining forces - have engaged in supporting alternatives assessment and substitution through the development of a number of tools aimed to guide interested parties in their substitution efforts (see Box 2). The OECD report, “Current Landscape of Alternatives Assessment Practice: A Meta-Review,”⁸ looks at the frameworks and tools developed by a number of groups, with a first attempt at detailing the specificities of each. Frameworks for alternatives assessment are the arrangement of analyses and decisions that can be used to assess alternatives. Tools for alternatives assessment and substitution are approaches for evaluating a chemical, material, process, product, and/or technology for the purpose of attribute analysis within an alternatives assessment.

⁷ For more information on the U.S. EPA DfE Alternatives Assessment Program, see <http://www2.epa.gov/saferchoice/design-environment-alternatives-assessments>.

⁸ OECD (2013), Current Landscape of Alternatives Assessment Practice: a Meta-Review, OECD, Paris, OECD Environment, Health and Safety Division, Monograph 24, see [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO\(2013\)24&docLanguage=En](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2013)24&docLanguage=En).

Box 1. The Industry of fluorotechnologies: phasing out long-chain PFASs

Per- and polyfluoroalkyl substances (PFASs) have been in use since the 1950s as ingredients or intermediates of surfactants and surface protectors for assorted industrial and consumer applications. Some of the unique physicochemical properties of PFASs that popularised their widespread use are also associated with environmental and human health concerns. For example, within the past decade, several long-chain perfluoroalkyl acids have been recognised as persistent, bioaccumulative, and toxic. Many have been detected globally in the environment, biota, food items, and in humans.

Driven by concerns about the potential adverse impacts of certain PFASs on the environment and human health, various risk reduction actions have been implemented to reduce the environmental and human exposure to, in particular, long-chain PFASs. A combination of voluntary corporate goals by some of the main companies acting in fluorotechnologies and of policy support (i.e., the U.S. EPA launched a Stewardship Programme in 2006 to eliminate long-chain PFASs from facility emissions and product content) to reduce human and environmental exposure to these chemicals has resulted in a solid public/private partnership. Work is now ongoing toward eliminating long chain PFASs from facility emissions to all media and product content by the end of 2015. A lot of efforts have been put in the past ten years in looking for suitable alternatives to long chain PFASs as a result of this partnership, with the development of shorter chain alternatives, as well as research into non-fluorinated and non-chemicals options.

Among the tools that have been developed, discussions at the workshop highlighted that each tool may better correspond to particular purposes. It is important for the community of practice to be aware of the differences and similarities between the tools in order to choose the tool that will be best suited to one's needs. At the workshop, the OECD Substitution and Alternatives Assessment Toolbox (SAAT)⁹, released in January 2015, was also discussed. The OECD SAAToolbox increases efficient access to tools and practical guidance on how to conduct an alternatives assessment. A special functionality in the toolbox – the Tool Selector – aims to help identify, through the use of a number of filters, tools of greatest relevance to specific substitution or alternatives assessment goals.

Participants at the workshop raised the importance of using available tools to inform alternatives choices, taking a “full picture” approach for product evaluation: from ingredient disclosure, hazard analysis, exposure assessment, and life-cycle consideration. Workshop participants highlighted, in particular, the importance of taking into account the life-cycle implications of substituting a chemical. The workshop also presented some of the next generation tools that are being developed for supporting exposure assessment, such as the High-throughput Exposure Assessment Tool (HEAT Model) of the Dow chemical company that aims to estimate “near field” human exposure for batches of chemicals and multiple use scenarios and exposure pathways.

Even though the frameworks and tools that have been developed provide support for conducting alternatives assessment and substitution, the workshop pointed out a number of remaining gaps regarding their efficient use:

- The workshop emphasised that the most complex step in conducting an alternatives assessment is to gather the appropriate data to feed into the tools. There seems to be a gap in sources of relevant, reliable hazard and exposure data. In addition, not all data are available to conduct a complete alternatives assessment and substitution, and guidance would be needed on how to fill-in and make decisions in light of these data gaps;

⁹ The toolbox is accessible at <http://www.oecdsaatoolbox.org/>.

- There is a need for more clarity in the description of each of the attributes in the tools and frameworks; there was particular mention made of the need to define what economic feasibility means;
- There is still a lack of guidance on how to identify and evaluate potential risk trade-offs at the end of an alternatives assessment. The workshop highlighted the necessity of using case studies of alternatives assessment and substitution to look at different risk decision analyses that have already been conducted, and to learn from those. Being transparent about the decisions that are made throughout the alternatives assessment and substitution is critical for practitioners to learn from each other's successes and challenges; and
- SMEs are facing particular difficulties (financial and technical) when faced with the increasing number of attributes that are covered in frameworks and tools for alternatives assessment and substitution. The identification of a small set of key attributes would greatly facilitate the engagement of those companies in substituting chemicals of concern.

To support stakeholders in tackling these challenges, the international community is getting together to bring more clarity to the use of these frameworks and tools, and more generally to conducting alternatives assessment and substitution. Among these international initiatives, the OECD Ad Hoc Group on Substitution of Harmful Chemicals has been set up with the goal of furthering tools and approaches to support decision making for the substitution of chemicals of concern. Its members include a broad range of stakeholders (government agencies, industry, trade associations, NGOs, and others) across OECD member countries. Also, a series of international symposia are being organised by the Lowell Center for Sustainable Production, a leading academic group in the area of alternatives assessment. The most recent symposium was organised in March 2015 on *Alternatives Assessment: Advancing Science and Practice*¹⁰, with the aim to identify the gaps in knowledge and methods, and advance and support the growing community of practice for alternatives assessment.

Box 2. Examples of tools to support alternatives assessment and substitution

Examples of tools aiming to guide sustainable choices of chemicals presented at the workshop:

Guide on Sustainable Chemicals: *The German Environment Protection Agency (Umwelt Bundesamt – UBA) developed a decision tool for substance manufacturers, formulators and end users of chemicals to help them make sustainable choices on chemicals. The guide describes criteria which can be used for a first assessment of the sustainability of substances and mixtures. The criteria for the selection of sustainable chemicals should enable companies to systematically implement sustainable chemistry in their daily practice. Generally, substance-specific criteria which only depend on the properties of a substance, and use-specific criteria which mainly depend on the type of its use, are distinguished. Eight criteria for alternatives assessment and substitution have been included in the guide:*

1. *Criterion 1 – list of substances of concern: there is an automatic comparison with selected lists of substances of concern;*
2. *Criterion 2 – Physical, chemical hazards;*
3. *Criterion 3: Human health hazards;*
4. *Criterion 4: Environmental hazards (assessment of PBT/vPvB properties, aquatic toxicity);*
5. *Criterion 5: Mobility (water solubility, vapor pressure, half-life time, assessment of mobility in water, air,*

¹⁰

For more information on the Symposium, see <http://www.saferalternatives.org/>

workplace, and long-range transport);

6. *Criterion 6: Greenhouse gas emissions;*
7. *Criterion 7: Consumption of raw materials (availability of raw materials, renewability, energy consumption, water consumption,); and*
8. *Criterion 8: Social Corporate Responsibility.*

An electronic version of the guide is in development. For more information, see <http://www.umweltbundesamt.de/en/publikationen/guide-on-sustainable-chemicals>.

The SIN List and SINmilarity tool: *The SIN (Substitute It Now!) List was developed by the non-for profit organisation ChemSec, The tool aims to accelerate the transition to safer chemicals, and eliminate the use of hazardous ones. The chemicals on the SIN List have been identified by ChemSec as Substances of Very High Concern based on the criteria established by the EU chemicals regulation REACH. In addition, since 2008, the SIN List has been highlighting chemicals of high concern that are likely to be subject to future EU regulation. The List is divided into 31 chemical groups, based on structure and toxic properties.*

The SIN List is associated with the SINmilarity tool, which aims to determine if substances not on the SIN List are structurally similar to SIN substances, because structurally similar substances might have similar hazardous properties. This online tool makes it possible to search among 80,000 chemicals, and compare them to the chemicals on the SIN List. For more information of the SIN tools, see <http://sinlist.chemsec.org/>.

SubSport, the portal for substitution: *SUBSPORT is a platform for information exchange on alternative substances and technologies, as well as tools and guidance for substance evaluation and substitution management. The SUBSPORT web portal aims to support companies in fulfilling substitution requirements within EU legislation, as well as being a resource for other stakeholders such as authorities, environmental and consumer organisations, and scientific institutions. The portal includes:*

- *a structured presentation of legal information on substitution throughout the European Union and, in part, on an international and national level;*
- *a database of restricted and priority substances that are legally or voluntarily restricted or subjects of public debates, a compilation of prevalent criteria for the identification of hazardous substances, and a description of existing substitution tools to compare and assess alternative substances and technologies;*
- *a database comprising case stories from companies and the literature, with general information on alternatives to the use of hazardous substances and detailed alternatives assessment reports for 10 substances or substance groups of high concern, with each including up to five essential applications;*
- *substitution training programmes (alternatives identification and assessment training); and*
- *interactive elements for discussion, networking, and exchange of information and experience, as well as for portal updates.*

For more information, see <http://www.subsport.eu/>.

Main drivers and challenges to substitution

The workshop highlighted a number of drivers that support alternatives assessment and substitution. Two of the main drivers that were mentioned are:

- The response to regulatory requirements and more generally the integration of substitution of chemicals of concern as part of the political agenda. The development of public programmes for

green and sustainable chemistry can also be drivers for research of alternatives and drivers for innovation;

- Market drivers that include: opportunities for companies to generate new patents, the reputation of the company through the engagement in sustainability goals, new market opportunities to respond to green customers' demands (e.g., alternatives producers created as spin off from an academic patent), and creation of a competitive advantage.

Other important drivers include a combination of the newly created knowledge on the health, environmental and safety concerns of particular chemicals, and the technical progress that has been made that can support stopping the use/need of a hazardous chemical. Economic instruments can also be strong incentives to substitution, in particular, taxes. The issue of availability of resources necessary to produce certain chemicals can lead to an increase in production costs and as such be an incentive to substitute these chemicals by others, the production of which will not rely on these resources.

The workshop emphasised as a particular driver the integration of substitution into the corporate strategy of certain companies, in which case there are internal drivers being created for the substitution of substances of concern. Workshop participants expressed interest in collecting case studies of such companies to gather best practices on the internal requirements set up to trigger substitution. In general, workshop participants highlighted the importance of knowing more about the drivers of substitution for companies across sectors (e.g., the drivers that trigger a more proactive or more reactive response).

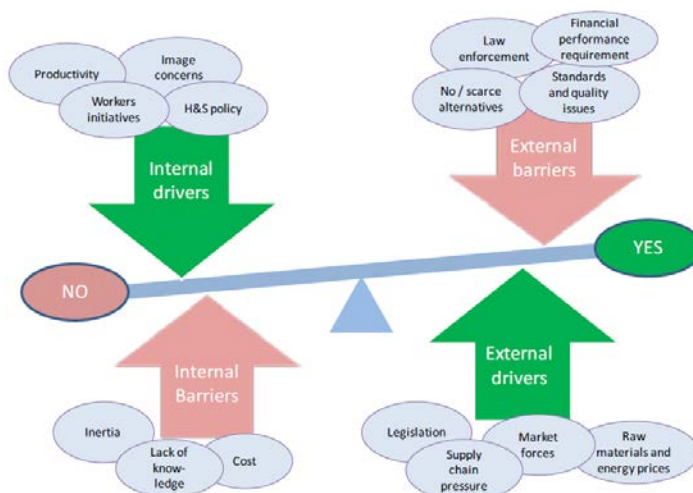
In terms of barriers and challenges to substitution, the following elements were mentioned during the workshop:

- Significant amount of expertise and experience exist from substitution cases, with real life examples of successful (e.g., cost savings, economic and social benefits) and unsuccessful substitution. This knowledge needs to be collected and shared;
- There is a lack of guidance on how to conduct a “successful” alternatives assessment, with a need for specific training and education;
- Guidance for conducting alternatives assessment is not necessarily targeted to the specificities of different industry sectors. The development of industry-specific guidance would be very valuable; also, determining which sectors are at higher risk in the event of an unsuccessful substitution (e.g., the aircraft industry) and which are at lesser risk, as well as providing guidance for the consumer market versus the specialised market. This would require a reflexion with each sector on their specificities, and how they affect the way attributes are, or should be, considered;
- A company's policy can be a barrier: if the corporate strategy of a company does not support substitution, there can be a lack of engagement at the corporate level to find alternatives to hazardous chemicals. There can also be a resistance to change, a reluctance to experiment with the unknown, and fears for regrettable substitution;
- There are technical, administrative and financial constraints associated with conducting alternatives assessment and substituting chemicals, in particular for SMEs (e.g., the direct costs associated with substitution vs. the potential long-term benefits of substitution, the complexity of research and development processes);

- In the case of countries/regions using regulations, the complexity of regulatory systems can be a challenge, with a need for more guidance to support companies in implementing regulations. Participants at the workshop highlighted that for regulations to better integrate the substitution concept, there was a need for more clarity on how to conduct a “successful” substitution process. In particular, there is a need for:
 - Better knowledge of alternative substances and techniques, including their technical performance and indirect costs, the direct costs of substitution, and the risks of alternatives; and
 - Better knowledge of the alternative substances that are currently in use, for example by documenting and communicating the use of alternative substances in "real life" cases;
- There was a perceived need to reinforce dialogue and partnerships with stakeholders (SMEs, large companies, academics, downstream users, public authorities), in particular to tackle the complexity of communicating along the supply chain (see Box 3). This would allow promoting efficient flow of relevant and actionable information along the supply chain.

The combined effect of some of these drivers and barriers are illustrated in Figure 1, below.

Figure 1: The impact of drivers and barriers to substitution



Source: OECD Expert Workshop on Substitution and Alternatives Assessment, Paris, 11-12 May 2015, Presentation by Tatiana Santos, European Environmental Bureau. Extracted from the report: European Commission (2012), "Minimising chemical risk to workers' health and safety through substitution", Directorate-General for Employment, Social Affairs and Inclusion, see <http://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=7320&type=2&furtherPubs=yes>

Box 3. Substitution in the textile sector: the challenge of a long and complex supply chain

A presentation at the workshop included the challenges for the downstream textile industry in substitution. Textile brands are directly impacted by chemicals regulation, policy programmes, and NGOs campaigns to restrain the use of chemicals of concern and to stimulate sustainable chemistry and innovation.

There is complex chemistry used in clothing: about 10 to 20 basic chemicals are used (acids, bases, salts), 30 to 50 auxiliaries and specialty finishes, and more than 100 dyes and pigments, throughout the product trail. The supply chain in the textile sector is long and complex, with many steps and players involved: chemical suppliers; manufacturers and formulators of dyes, finishing agents and auxiliaries; dyehouses, finishers, washers; garment

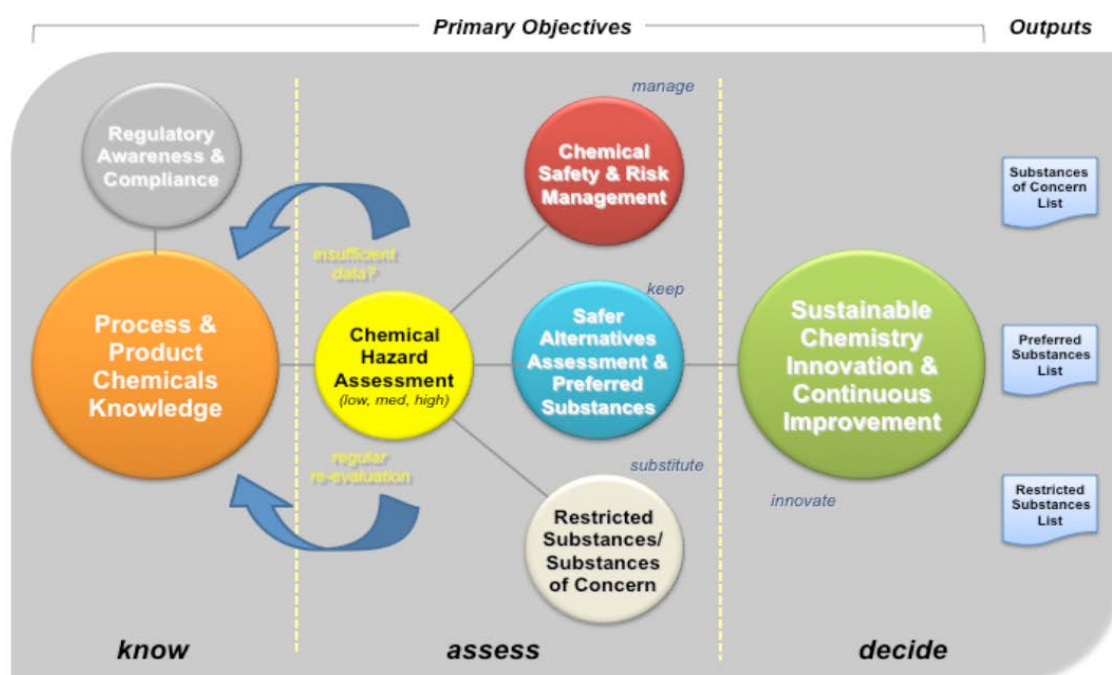
makers; vendors, agents, brokers, licensors; brands; and retailers. Success in substituting chemicals of concern requires a strong collaboration of players all along the supply chain. One of the main challenges raised is that often the substitution of a chemical of concern implies that all of the processes must change. There may not be a true “drop-in” alternative chemical, and this can lead to unforeseen impacts on downstream processes. Other challenges specific to the sector include:

- The management of tradeoffs within the substitution process, with sometimes difficult choices to make vis-à-vis energy and water consumption in the production process;
- Substitution can impact final product quality and performance; and
- The regulatory environment at a global level.

A number of issues were also highlighted that would support successful substitution in the textile sector, such as:

- Sharing information on chemicals used in formulations from suppliers – in a confidential business to business approach;
- Building capacity in the supply chain, with the creation of partnerships to facilitate knowledge generation and sharing (e.g., the Outdoor Industry Association, and the industry group Zero Discharge of Hazardous Chemicals); and
- The adoption and alignment of the supply chain system around each alternative.

Figure 2: Know, Assess, Decide



Source: OECD Expert Workshop on Substitution and Alternatives Assessment, Paris, 11-12 May 2015, Presentation by Scott Echols, Outdoor Industry Association.

Main conclusions from the expert workshop and way forward

The expert workshop identified a number of issues associated with the way alternatives assessment and substitutions are taking place today:

- A large amount of expertise and experience is being generated from past alternatives assessment and substitution cases. Efforts should be made to collect and compile this “real life” experience. This would serve as a critical source of knowledge to identify and address common challenges, as well as to identify and share good practices and success stories, and to make the business case for substitution;
- There is a recognised complexity of the alternatives assessment and substitution processes. Providing flexible guidance and best practices to help manage the complexity and uncertainties in the process would support companies, in particular SMESs, to engage into alternatives assessments and substitution processes. It was also acknowledged that the level of complexity of the assessment and the attributes addressed should fit the purpose of the assessment, and avoid "paralysis by analysis";
- There is a large variety of approaches used by countries to support substitution. It is important to learn from each other's' experiences in this area, to strengthen public policy and programmes for substitution.

With these conclusions, the workshop participants identified a number of actions that could help support the field further. These actions are outlined below.

Building on “real life” experiences and lessons learnt from past alternative assessments and substitutions

One of the main messages from the workshop is that substitution of chemicals of concern is actually happening. There is a growing base of “real life” experience that is becoming available, and can be used to illustrate:

- the challenges and uncertainties that are faced, across countries, by the stakeholders involved in alternatives assessment and substitution;
- the lessons learnt from past alternative assessments and substitutions (e.g., success stories, pitfalls, regrettable substitutions, specific examples of cost savings, and economic and social benefits);
- the way in which tools are being applied (e.g., which tools are applied in which context, how the data applied in the tools are being gathered and used), and how we can capitalise on existing tools;
- how hazard and risk trade-offs are being managed in practice;
- the role of regulation, and economic and fiscal incentives as drivers for substitution; and
- what makes the “business case” for substitution (e.g., examples of substitution as part of the corporate strategy, how can policy makers and regulators help in making the business case for substitution).

The expert workshop concluded that **there is a need for a repository of alternatives assessments that will compile case studies, and a registry of substitutions that will catalogue actual substitutions. There would then be an opportunity to analyse the lessons learnt from the experiences collected.** Building on existing knowledge will help to make informed decisions on how to overcome some of the challenges faced in alternatives assessment and substitution today. It will be of particular relevance for SMEs that have fewer resources to engage in these areas, and that could share the challenges they face and learn from, perhaps, other SMEs' experiences.

There was specific interest raised by the workshop participants in learning from company successes, and to collect case studies from companies that have created internal drivers for substitution to become an integral part of the company strategy. There was also interest in collecting information on how alternatives assessment are being conducted – how is uncertainty managed, what tools are used and in which context, how the data are being accessed, and how data gap issues are being overcome. There was also mention of the possibility of looking at cost/benefit analyses and economic feasibility studies that have been conducted in the past and further looking at ways to assess and present the long term economic benefits of substitution.

The way in which information on previous alternatives assessments and substitutions will be collected will need to acknowledge confidentiality issues in companies. Even so, the reporting should cover a wide range of topics (such as those mentioned above) so that an informed analysis can be made of lessons learnt in different sectors, and at different stages in the alternatives assessment and substitution process.

The analysis of “real world” examples might also support the business case for substitution by providing data on the economic and social benefits of making a substitution, and by helping to share and address common challenges.

The OECD SAAT Toolbox might be a good place to host/link to such a repository (e.g., as part of the currently existing case studies section). The workshop also raised the possibility to integrate information already available in existing databases and/or websites (such as SubSport).

Facilitating the engagement in and conducting of an alternatives assessment and substitution for chemicals of concerns

The expert workshop strongly emphasized the complexity of engaging in an alternatives assessment and in a substitution process more generally, in particular for SMEs. It is a difficult task and very resource intensive to look for and analyse the alternatives potentially available and suitable for a particular purpose, to gather the data necessary to feed into the existing alternatives assessment frameworks and tools, and to manage knowledge gaps and uncertainties throughout the process.

There are three elements in the substitution process that can be considered as particularly challenging:

- the choice of the attributes to be used in the alternatives assessment, according to available knowledge and resources;
- how to define when a “successful” alternatives assessment/substitution has been conducted; and
- the criteria to help manage hazard and risk trade-offs.

To simplify the process of engaging in an alternatives assessment, the expert workshop suggested:

- There might be opportunities to **develop a minimum set of attributes** that companies, and in particular SMEs, could easily manage. This minimum set of attributes should be sufficiently flexible, and consider the characteristics of specific sectors and adapt to the specific needs of companies (e.g., sectors at high risk, such as the aircraft industry), and in particular to their position in the value chain.
- The possibility to **develop a short list of questions that would help define whether the alternatives assessment was well conducted/"successful", or if weaknesses remain in some areas**. For example, questions could ask how uncertainty was minimised during the process, if life cycle implications have been taken into account in the choice made for substitution (e.g., if a chemical is substituted in a mixture, there might be problems arising with another chemical in that mixture, are there other solutions available than substituting a chemical of concern by another chemical, is it the safest alternative that has been chosen or the cheapest).
- The possibility to develop **a short set of best practices to help manage hazard and risk trade-offs**. These best practices could be based on the analysis of case studies (see section above) and on common current practices taking place in the alternatives assessment and substitution community.

On a different level, the expert workshop stressed the importance of the OECD SAAToolbox as a unique compilation of resources relevant to chemical substitution and alternatives assessments - in particular, the Tool Selector in the toolbox that provides access to practical guidance on how to conduct an alternatives assessment. Through the use of a number of filters, the tool selector can identify tools of greatest relevance for the user's specific purposes. The workshop participants pointed out the need for more awareness raising/training activities on the toolbox for stakeholders involved in the field. This might facilitate engagement in the substitution effort, allow gathering of regular feedback on the usefulness of the toolbox in the practice of alternatives assessment, and also identify opportunities for further improvements.

Learning from policy and regulatory approaches across countries to support substitution

There are differences of approaches across countries for driving substitution, for example, in terms of regulation or absence of regulation, in the use of economic and fiscal incentives, and in the establishment of partnerships between public and private stakeholders. The expert workshop highlighted, for example, the approach taken by the United States, which might be generally more market driven, with many partnerships engaged between the public and private sectors. This is different from the approach taken in Europe, which is more regulatory driven under the REACH framework.

Policy and regulatory interventions can play an important role in driving all stages of the substitution process, and can target different parts of the supply chain (e.g., incentives affecting downstream users that will directly impact chemical suppliers). Instruments used can include:

- Direct regulation or standards;
- Economic instruments: providing fiscal incentives or access to finance to enterprises to support elements of the substitution process. For example, government funding for specific areas of research, taxes, subsidies;
- Information and co-ordination: creating or supporting networks and partnerships to provide information to stakeholders (including consumers);

- Knowledge development: through R&D investment and investment in skills and education needed in the labour force;
- Stimulating the market: creating demand that drives new product development in the early market (e.g., by public procurement policies or purchase subsidies);
- Business environment: broader factors, such as providing supportive frameworks for intellectual property management, safety regulation, and guidance on alternatives assessment and substitution; and
- Engaging in public-private partnerships: for example, for supporting data and knowledge sharing.

The workshop suggested that a **cross-country analysis could be performed, looking at the different approaches taken by authorities to support substitution**, and to a larger extent to support responsible innovation in the chemical sector. This would help describe the policies in place, their impact and effectiveness, and the context in which they have been developed.

ANNEX 1: FINAL DRAFT AGENDA - OECD EXPERT WORKSHOP ON SUBSTITUTION AND ALTERNATIVES ASSESSMENT

11 – 12 May 2015, OECD Headquarters, 2 rue André Pascal, 75016, Paris

Monday 11 May 2015

09.00-09.15 Welcome and Introduction by the Workshop Chairs and the OECD Secretariat

Kathy Hart, US EPA and **Thierry Nicot**, ECHA: *Co - Chairs of the OECD Ad Hoc Group*

Eeva Leinala, Principal Administrator, OECD

09.15 – 10.45 Session I - Roundtable on Country/Region Perspectives on Substitution and Alternatives Assessment

This session aims to outline latest advances in substitution and alternatives assessment. It will give a short overview of the regulatory/policy context in which these latest advances have taken place and if any specific challenges remain in terms of creating an environment favorable to substitution of harmful chemicals. It will particularly emphasize if any additional tools/frameworks could help support policies for substitution and alternatives assessment.

Session Chair: Kathy Hart, US EPA

Substitution and alternative assessment under REACH and the authorisation process

Denis Mottet, Risk Management Implementation Unit, European Chemical Agency

Sustainable chemistry - Perspective from Germany

Christopher Blum, International Chemicals Management, Federal Environment Agency, Germany

A perspective from Denmark

Sidsel Dyekjær, Senior Advisor, Chemicals Division, Danish EPA, Denmark

Regulatory driven innovation and substitution - constraints and perspectives

Ruth Moeller, European Registered Toxicologist, Luxembourg Institute of Science and Technology (LIST), REACH&CLP Helpdesk, Luxembourg

Question and answer session

10.45 – 11.15 Coffee Break

11.15 – 13.00 Session II - Gap Analysis (*First Part*)

This session will aim to identify where gaps remain in terms of specific tools that could support substitution and alternatives assessment globally and if harmonisation in specific areas would be useful

(e.g. terminology, definitions, and baseline elements of alternative assessments). Also if some further research analysis on policy drivers for substitution and alternatives assessment could help authorities further support the field.

Session Chair: Kathy Hart, US EPA

The session will start with a presentation of the conclusions from the Symposium on Alternatives Assessment, organised by the Lowell Center in March 2015, focusing on tools that are being developed and needs that were identified.

Molly Jacobs, Senior Research Associate, Lowell Center for Sustainable Production, University of Massachusetts Lowell, United States

It will be followed by a presentation providing an NGO perspective on gaps for tools and guidance for supporting alternatives assessment and substitution.

Tatiana Santos, Senior Policy Officer, European Environmental Bureau

Discussion with the workshop participants (11.50 – 13.00)

The session will continue with a discussion among the workshop participants to identify where gaps remain in terms of specific tools that could support substitution and alternatives assessment globally and if harmonisation in specific areas would be useful.

Lunch Break 13.00 – 14.30

14.30 – 16.00 Session III - Developing the field of Substitution and Alternatives Assessments – Tools and Partnerships

This session will outline practices for alternatives assessment and the substitution of chemical of concerns, looking, for example, at:

- Industry incentives to substitute (e.g. voluntary initiatives, response to regulation);
- Challenges in substitution and missing tools and guidance;
- How methods and tools available for alternatives assessment and substitution are impacting the pace through substitution of chemicals of concern.
- The level at which substitution is integrated in business models (e.g. elements of corporate governance for risk management, risk reduction measures).

The session will focus either on success stories, challenges, partnering, and identification of tool needs.

Session Chair: Thierry Nicot, ECHA

Informing alternative choices—the feasibility of a hazard and exposure comparative analysis using existing tools

Pamela Spencer, Scientific Director of Toxicology and Environmental Research & Consulting, Dow Chemical Company, United States

Challenges for the downstream textile industry in substitution

Scott Echols, Independent Consultant, Member of the steering committee for the Outdoor Industry Association Chemicals Management Working Group (OIA CMWG)

Voluntary Industry Initiatives to Develop Alternatives to Long-chain Perfluorinated Compounds
Ronald Bock, EMEA Product Stewardship Manager, Chemours International Operations

Question and answer session

16.00 – 16.30 Coffee Break

16.30 – 18.00 Session IV - Gap Analysis (Second Part)

This session aims to identify possible missing tools and guidance in substitution and alternatives assessment (e.g. the need for sector/industry specific guidance, guidance on specific chemical groups, guidance for risk trade-offs assessment). It will also discuss if further analysis could be done on partnership models to support substitution. **Tuesday**

Session Chair: Thierry Nicot, ECHA

This session will start with a presentation from ChemSec on experience in developing tools and guidance with different stakeholders involved in substitution (academia, business, regulators, and civil society) and on where challenges remains in terms of tools or policies that the OECD could play a role in.

Anna Lennquist, Toxicologist, ChemSec, Sweden

Discussion with the workshop participants (16.50 – 18.00)

The session will continue with a discussion with the workshop participants to identify possible missing tools and guidance in substitution and alternatives assessment.

From 18.00 Cocktail - Room Georges Marshall, Château

Tuesday 12 May 2015

09.30–11.00 Session V - Presentation of the OECD SAAToolbox and discussion on possible additions and new functionalities

Session Chair: Kathy Hart, US EPA

The session will start by a demonstration of the toolbox and of opportunities for improvement and extension.

Emily Connor, Environment and Resources Division, Abt Associates

Discussion with the workshop participants

The presentation will be followed by a discussion with the workshop participants on possible additions and new functionalities to the toolbox, e.g.:

- Addition of new Chemical Hazard Assessment tools to the tool selector;

- Addition to the regulation and restrictions section/to the case study section;
- Addition of other categories of tools to the toolbox.

11.00 - 11.20 Coffee Break

11.20- 12.30 Session VI - Discussion on proposed areas of future work of the OECD Ad Hoc Group

Session chair: Eeva Leinala, Principal Administrator, OECD

The expert workshop will end with a discussion among the participants on future projects that the Ad Hoc Group could undertake.

**ANNEX 2: PARTICIPANTS LIST - WORKSHOP ON SUBSTITUTION AND ALTERNATIVES
ASSESSMENT**

11/5/2015 - 12/5/2015

Belgium/Belgique

M. Benjamin DELCOURT

*REACH
SPF Santé Publique*

Mme Martine ROHL

*Attachée
SPF Santé Publique, Sécurité de la Chaîne alimentaire
et Environnement*

Canada

Ms. Heather PATTERSON

*Senior Evaluator, Assessment Strategies
Existing Substances Risk Assessment Bureau
Health Canada*

Denmark/Danemark

Ms. Sidsel DYEKJÆR

*Senior Advisor
Danish Environmental Protection Agency*

France

- M. Geoffrey ARGILES** *Direction de l'Evaluation des Risques (DER)
Agence nationale de sécurité sanitaire (Anses)*
- Mr. Jean-Marc BRIGNON** *Responsable de l'Unité "Economie et Décision pour
l'Environnement"
Direction des Risques Chroniques, Pôle Modélisation
Environnementale et Décision
INERIS*
- Mrs. Karine FIORE** *Evaluation des Risques - Substances Chimiques
REACH
National Agency for Food, Environmental and
Occupational Health & Safety (ANSES)*

Germany/Allemagne

- Dr. Christopher BLUM** *Section IV1.1 International Chemicals Management
Federal Environmental Agency*

Luxembourg

- Ms. Ruth MOELLER** *European Registered Toxicologist
Department ERIN - Environmental Research and
Innovation
Luxembourg Institute of Science and Technology
(LIST)*

Netherlands/Pays-Bas

- Ms. Julia VERHOEVEN** *Bureau REACH
National Institute of Public Health and the
Environment (RIVM)*

United Kingdom/Royaume-Uni

Mr. Patrice MONGELARD

*Secretary – UK Chemicals Stakeholder Forum
Head of Secretariat to Hazardous Substances Advisory
Committee
DEFRA (Department for Environment Food and Rural
Affairs*

United States/États-Unis

Ms. Kathy HART

*Design for the Environment/Safer Choice Program
US Environmental Protection Agency*

EU/UE

Mr. Urban BOIJE AF GENNÄS

*Policy Officer
DG Environment
European Commission*

Mr. Denis MOTTET

*Risk Management Implementation Unit (D.3)
ECHA (European Chemicals Agency)*

Mr. Thierry NICOT

*Risk Management Implementation Unit
European Chemicals Agency (ECHA)*

***Business and Industry Advisory Committee (BIAC)/Comité
consultatif économique et industriel (BIAC)***

Dr. Marlies BERGHEIM

*HSA – Corporate Scientific Services
Henkel AG & Co. KGaA*

Mr. Ronald BOCK

*EMEA Product Stewardship Manager
Chemours International Operations Sàrl*

Dr. Jean-Charles BOUTONNET

*Head of Toxicology-Environment Department
Toxicology-Environnement Department
ARKEMA*

Ms. Caroline BRAIBANT	<i>Senior Manager, EHS and REACH EHS Eurométaux</i>
Dr. Martijn ROOSEBOOM	<i>Toxicologist Shell International B.V.</i>
Ms. Pamela SPENCER	<i>Scientific Director of Toxicology and Environmental Research & Consulting Dow Chemical Company</i>
Dr. Wera TEUBNER	<i>Regulatory Toxicologist Produktesicherheit Schweiz BASF Schweiz AG</i>
Mrs. Kim VAN LONDEN	<i>Toxicologist Akzo Nobel N.V.</i>

***European Environmental Bureau/Bureau européen de
l'environnement***

Mrs. Dolores ROMANO	<i>European Environmental Bureau / Bureau Européen de l'Environnement</i>
Miss Tatiana SANTOS	<i>Senior Policy Officer on chemicals and nanotechnology Chemicals and nanotechnology EEB (European Environmental Bureau)</i>

***UN Environment Programme (UNEP)/Programme des Nations Unies
pour l'environnement (PNUE)***

Ms. Vera BARRANTES	<i>Consultant, Responsible Industry and Value Chain Unit Sustainable Lifestyles, Cities and Industry Branch</i>
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OECD/OCDE

Mlle. Marie-Ange BAUCHER	<i>Administrator, Chemical Accidents, Risk Management ENV/EHS</i>
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Ms. Eeva LEINALA

*Principal Administrator
ENV/EHS*

Ms. Nausicaa MASI

*Assistant
ENV/EHS*

Abt Associates, Inc.

Ms. Emily CONNOR

Contractor to U.S. EPA

CEFIC

Ms. Amaya JÀNOSI

*Manager REACH
Programme Product Stewardship*

ChemSec

Anna LENNQUIST

Toxicologist

ClientEarth

Mr. Ken HUESTEBECK

Independent consultant

Mr. Scott ECHOLS

*Independent Consultant & Member of the steering committee for the Outdoor Industry Association Chemicals Management Working Group
Member of the steering committee for the Outdoor Industry Association Chemicals Management Working Group*

Kooperationsstelle Hamburg

Ms. Isabella BANDUCH

Mr. Lothar LISSNER

University of Massachusetts Lowell

Ms. Molly JACOBS