AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Chemicals Strategy for Sustainability: towards targeted improvements based on better regulation

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2019, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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Executive Summary

1. **The American Chamber of Commerce to the EU (AmCham EU) supports the Chemicals Strategy for Sustainability's (CSS) ambition to strengthen the existing framework for EU chemicals policy** and adapt it to help achieve sustainability and competitiveness ambitions.
2. **The CSS rightly recognises that 'the EU already has one of the most comprehensive and protective regulatory frameworks for chemicals, supported by the most advanced knowledge base globally.'** Building on this achievement, we encourage the European Commission to pursue improvements that are targeted and incremental, avoiding the severe uncertainty that would stem from an unjustified overhaul of EU chemicals legislation.
3. **We welcome the European Commission's commitment that 'new legislative initiatives announced in this strategy will be underpinned by the Commission's better regulation tools'** and that 'legal proposals, including a revision of the Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (REACH) in the most targeted way possible, limited to achieving the objectives of this strategy, will be made on the basis of public consultations and subject to comprehensive impact assessments.'
4. **Principles of risk assessment and science-based decision-making should remain at the core of EU chemicals legislation moving forward.** We caution against moving further towards hazard-based regulatory instruments where non-approval/non-registration and risk management measures would automatically be triggered by hazard assessment and classification.
5. Existing REACH processes, including Restriction and Authorization, already create opportunities to address the criticality of a use, its importance for society, as well as the availability of alternatives which could ensure identical performance within the scope of an application while being economically viable. **It is important that such existing processes are not undermined through the introduction of a vague, horizontal definition of essential use.**
6. AmCham EU recognises the Commission's efforts to promote 'Safe and Sustainable by Design' solutions in the context of the Chemicals Strategy for Sustainability, including the development of specific criteria addressing chemicals. **The definition of 'safe and sustainable by design' criteria requires thoughtful consideration to ensure they are based on sound science and full lifecycle assessment, while continuing to enable innovative technologies that provide significant benefits to society.**
7. **Regulatory predictability** is a key success factor for REACH. We would note that several of the proposals introduced in the CSS have the potential to drastically alter the rules of REACH and other chemicals legislation, both in terms of which substances are understood to be 'of concern' and in terms of how risk management processes are subsequently pursued for these substances.
8. **AmCham EU strongly supports the Commission's ambition to make assessment processes simpler and more transparent**, in order to reduce the burden on all stakeholders and make decision-making more consistent and predictable. Streamlining the assessment and management of substances also strengthens regulatory predictability, which is essential to investment. The CSS offers a unique opportunity for regulators to improve consistency between the actions of different authorities, without pre-empting sectoral risk assessment.
9. When discussing potential changes to REACH and Classification, Labelling and Packaging (CLP) Regulation in the context of the CSS, EU decision-makers should, where possible, take into account **consistency with international regulatory instruments**. We particularly encourage the EU to make use of international bodies, institutions and conventions such as the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and work against deviations between EU legislation and international rules.

Introduction: AmCham EU supports targeted improvements to EU chemicals legislation based on better regulation

AmCham EU supports the Chemicals Strategy for Sustainability's (CSS) ambition to improve the existing framework for EU chemicals policy and adapt it to help achieve sustainability and competitiveness ambitions. The strategy's implementation must harness the role of chemicals in the goal to achieve climate neutrality and the circular economy, support economic recovery and integrate the different aspects of chemical management, including safety, circularity, resource efficiency, environmental footprint, science and innovation. The CSS rightly recognises that 'the EU already has one of the most comprehensive and protective regulatory frameworks for chemicals, supported by the most advanced knowledge base globally.' Building on this achievement, we encourage the European Commission to pursue improvements that are targeted and incremental, avoiding the lack of regulatory predictability and severe investment uncertainty that would stem from an unjustified overhaul of EU chemicals legislation. With over 50 new proposals included in the CSS, we ask the Commission to further reflect moving forward on how changes to legislation can be made in a streamlined, inclusive and focused approach, ensuring coherence to avoid double regulation, overlaps and the risk of 'outsourcing' Green Deal technology solutions to other parts of the world.

AmCham EU brings a unique perspective on EU chemicals legislation. Since its inception, our members have been active stakeholders in the Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (REACH). We represent the entire chemicals value chain, from upstream chemicals producers to downstream users, as well as specialised consultancies and law firms. With 96% of manufactured goods relying on chemicals, Europe's chemical industry is at the heart of almost all value chains and provides the key to solutions that will deliver the Green Deal, from solar panels to batteries, wind turbines and hydrogen to building insulation, EU-made pharmaceuticals and more powerful electronics, to name just a few. We aim to be a constructive partner and share our experience and industry insights with policy-makers, both at the European and national level, in order to support effective and proportionate chemicals legislation capable of meeting the objectives of protecting human health and the environment and improving EU competitiveness and the innovation capability of the EU chemical industry. We welcome the CSS initiative to set up a high-level stakeholder roundtable, considering that private-public dialogue will be critical given the overall ambition set in the strategy. Industry needs to be able to contribute fully and effectively to the implementation of the CSS moving forward.

We welcome the Commission's commitment that 'new legislative initiatives announced in this strategy will be underpinned by the Commission's better regulation tools' and that 'legal proposals, including a revision of the REACH Regulation in the most targeted way possible, limited to achieving the objectives of this Strategy, will be made on the basis of public consultations and subject to comprehensive impact assessments.' It is critical that the re-opening of REACH and Classification, Labelling and Packaging (CLP) Regulation is surgical, building on what has been successfully achieved to date and not re-inventing the foundations. This is also necessary to manage uncertainty and attract future investments into Europe. New concepts such as essential uses, mixture assessment factors, grouping for regulatory action and generic risk management need to be thoroughly assessed before being enshrined in legislation. They should not hamper innovation, regulatory predictability or inadvertently prevent other Green Deal objectives from being achieved.

We refer, in this context, to the findings of the latest Commission REACH review (2018)[1] and to the Fitness Check on Chemicals Legislation (2019)[2], which concluded that REACH requirements 'are well tuned to achieving the

[1]'Communication from the Commission to the European Parliament, The Council and the European Economic and Social Committee. Commission General Report on the operation of REACH and review of certain elements, Conclusions and Actions', *European Commission*, 5 March 2018, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN

[2]'Report from the Commission to the European Parliament, The Council and the European Economic and Social Committee and the Committee of the Regions. Findings of the Fitness Check of the most relevant chemicals legislations (excluding REACH) and identified challenges, gaps and

needs and objectives pursued,' that 'there is currently no need to change its enacting terms' and that 'overall, the EU framework of chemicals legislation is fit for purpose and delivers a high level of protection of people and the environment in balance with the needs of an efficiently functioning internal market and of a competitive and innovative chemicals industry.' The plans outlined in the CSS to enhance enforcement policies will be critical to address imports (including via online sales), which account for the vast majority of non-compliance issues under EU chemicals legislation.

1. EU chemicals legislation should remain grounded in science and risk assessment

Generic risk management

While we consider REACH to be fit for purpose, we acknowledge that further improvements can be made by, for instance, clarifying deadlines, streamlining processes, improving enforcement and preventing regulatory overlap with sector-specific legislation.

Principles of risk assessment and science-based decision-making should remain at the core of EU chemicals legislation moving forward. AmCham EU notes the Commission's proposals in the CSS to extend the use of so-called 'generic risk management,' but we would caution against moving further towards hazard-based regulatory instruments where risk management measures would automatically be triggered by hazard assessment and classification. Decisions on regulatory risk management should take into account exposure in specific uses and applications in order for a one size fits all approach not to undermine the use of critical substances that may be hazardous but can be used safely.

We maintain that science and robust evidence should be the basis of regulatory assessments. For instance, new REACH restrictions should foresee a rigorous assessment pointing to 'unacceptable risks' before banning substances from the internal market. This is especially important for professional users, where there is no evidence to suggest that the fundamental REACH risk assessment framework is inadequate.

Scientifically reasonable standards should be applied to read-across and grouping for registration purposes for restriction/authorization purposes as well as for research and analytical purposes. Read-across justification for grouping should be substantiated with the same stringency, whether it is used by industry or by authorities. The European Chemicals Agency (ECHA) already has guidance for evaluating the scientific suitability and acceptability of a registrant's read across justification (RAFF). The same elements and standards of scientific robustness upheld by the RAFF should also be used in the context of regulatory initiatives, including that the identity of all substances in the group be specified and well defined and that comprehensive documentation be provided for the elements forming the basis of the read across.

One of the successes of REACH thus far has been the effective combination of hazard, risk and socio-economic assessments. Automatic restrictions triggered through a hazard-based approach would fail to take into consideration key socio-economic factors including the availability and performance of alternatives. Restrictions purely based on hazard carry the risk of hindering investment certainty and discourage companies from achieving new material innovations.

weaknesses', *European Commission*, 25 June 2019, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530857605&uri=COM:2019:264:FIN

Essential use criteria

AmCham EU takes note of the Commission's proposal in the CSS to define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. According to the CSS, 'criteria for essential uses […] will in particular take into consideration the needs for achieving the green and digital transition.' The Commission has offered further reflections on this proposal in a paper circulated for discussion at the meeting of Competent Authorities for REACH and CLP (CARACAL) in November 2020.

We would stress that existing REACH processes, including Restriction and Authorization, already create opportunities to address the criticality of a use, its importance for society, as well as the availability of alternatives which could ensure identical performance within the scope of an application while being economically viable. It is important, in our view, that these existing processes are not undermined through the introduction of a vague, horizontal definition of essential use.

From an economic and social perspective, essentiality should not be looked at in isolation when evaluating, restricting or authorizing substances under REACH. Doing so can only lead to unjustified bans of large families of chemicals, as well as restrictions on uses that may be considered non-essential but that do not pose a direct risk or are an alternative to existing chemicals of concern where no more sustainable solution currently exists (eg chemicals used in closed systems).

We strongly encourage the Commission to take the following key elements into account as part of further action on criteria for essential uses:

1. 'Non-essentiality' is not in itself a condition to drive regulatory restrictions. AmCham EU members believe that restrictions should be considered if a risk associated with a given use has been identified.
2. Essentiality criteria should support, but not pre-empt regulatory decisions. A generic definition of 'essential uses' would not bring any additional value to existing REACH processes. Instead, industry and authorities could benefit from a harmonised set of criteria to be considered when assessing essentiality for substances that are subject to regulatory processes. These could be used as a reference in the context of the socio-economic impact analysis by the ECHA Committee for Socio-economic Analysis (SEAC) under existing REACH processes.
3. Essentiality criteria should include socio-economic impacts and the availability of alternatives delivering the required performance.
4. Essentiality criteria must allow for a holistic consideration of what is 'essential' (including, for example, technological developments or pandemic response). Among other factors this should include an assessment of substances' ability to deliver critical functionality and output to sectors of 'systemic relevance' and/or essentiality to the functioning of 'critical infrastructure' sectors for the benefit of society.
5. Essentiality also has a production asset dimension. If only essential applications are allowed, companies may not be able to respond to a medical/environmental emergency by shifting production to essentially required products (eg medical, hygiene, PPE).

Safe and sustainable by design

AmCham EU recognises the Commission's efforts to promote 'Safe and Sustainable by Design' solutions in the context of the CSS, including the development of specific criteria addressing chemicals. The definition of 'safe and sustainable by design' criteria requires thoughtful consideration to ensure they are based on sound science

and full lifecycle assessment while continuing to enable innovative technologies that provide great benefits to society. We also note the importance of ensuring appropriate financial support is granted to the development of safe and sustainable chemicals.

It is important that, when chemicals have been assessed and found to be safe in key applications, this is recognised at EU level and that future regulatory initiatives are fully consistent with the outcomes of existing assessments.

Any criteria and requirements for chemicals in products should be based on thorough impact assessments and broad stakeholder consultation. They should take into account sustainability benefits over the entire lifecycle of products, rather than focusing exclusively on the hazard profiles of certain chemicals. Product sustainability assessment should include as much as possible circularity (including durability), resource-efficiency, energy use, water and land use, as well as other societal concerns. It is also important to ensure that specific design standards are defined in certain sectors, such as pharmaceuticals.

In addition to reducing overall environmental footprint, the strategy should contribute to stepping up safe recycling and re-use of materials to keep them in a circular economy by addressing 'legacy substances,' exploring innovative digital technologies and standards to 'track and trace' these substances along the value chain (while protecting critical confidential business information and ensuring IT security) and enabling the production of high-quality recycled materials. As acknowledged by the CSS, chemical recycling has a role to play in this respect.

We stress the importance of ensuring a coordinated and consistent approach between actions undertaken under the CSS and the ongoing review being conducted by the Commission in the context of its upcoming Sustainable Products Initiative under the Circular Economy Action Plan.

2. A more coherent and predictable regulatory framework built on 'One Substance – One Assessment'

Regulatory predictability is a driver for investment

While AmCham EU acknowledges that information and knowledge evolve and that predictability can never be complete, we believe improvements are needed to key processes under EU chemicals legislation in order to enable companies to reasonably estimate the level and timeframe on which they can expect a return on their European investments.

Regulatory predictability is a key success factor for REACH. We would note that several of the proposals introduced in the CSS have the potential to drastically alter the rules of REACH and other chemicals legislation, both in terms of which substances are understood to be 'of concern' and in terms of how risk management processes are subsequently pursued for these substances. As stated above, it is important that changes pursued by the Commission in the context of CSS are incremental in nature, based on thorough impact assessments, and take into account the findings of its most recent regulatory fitness and performance programme (REFIT) evaluations for chemicals legislation.

It is critical, in particular, that when considering changes to the current regulatory framework decision-makers take into consideration the possible impact on predictability and long-term investment certainty. An important success factor will be the ability to take into account long term investment cycles, particularly from multi-national companies (or public-private partnerships) which are strongly influenced by regulatory predictability and rely on stable, coherent systems of risk assessment and management. We believe that the current functioning of REACH provides a solid framework that companies can rely on when innovating. Unjustified and significant departures from existing rules and procedures could hamper long-term predictability and discourage

investment in a time when the development of new, more sustainable solutions is critical to the EU's recovery and long-term competitiveness on the global stage.

One Substance – One Assessment

AmCham EU strongly supports the Commission's ambition to make assessment processes simpler and more transparent in order to reduce the burden on all stakeholders and make decision-making more consistent and predictable. Streamlining the assessment and management of substances also strengthens regulatory predictability, which is essential to investment. The CSS offers a unique opportunity for regulators to improve consistency between the actions of different authorities.

Outcomes of comprehensive assessments carried out under the REACH and CLP regulations must be taken into account when considering further sectoral assessments under product legislation, such as Restriction of Hazardous Substances Directive (RoHS). Before new regulatory processes are initiated, formal mechanisms should be in place to ensure the authorities are aware of and can adequately reference previous assessments that have been performed for the same substances. Strong formal cooperation between EU agencies, Commission services and stakeholders is essential in this respect. While 'one substance – one assessment' should serve to promote coherence and coordination in the EU legislative framework for chemicals, it should not pre-empt sectoral risk assessment, for example under Food Contact Material (FCM) legislation.

AmCham EU is strongly supportive of a more structured use of the Regulatory Management Options Analysis (RMOA) tool as a means to ensure upfront coordination on the most appropriate measures to address concerns for specific substances. We call on the European Commission and ECHA to make guidance publicly available explaining the benefits of RMOAs, when these should be used and how they should be structured.

Promoting a level playing field internationally

AmCham EU strongly supports international alignment on chemicals legislation to strengthen mutual market access and ensure a level playing field between different regulatory environments across the globe. Regulatory divergence creates obstacles to economic growth and prevents actors from reaping the full benefits of global trade.

When discussing potential changes to REACH and CLP in the context of the CSS EU decision-makers should, where possible, take into account consistency with international regulatory instruments. We particularly encourage the EU to make use of international bodies, institutions and conventions such as the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and work against deviations between EU legislation and international rules. Strong international alignment ensures that companies can continue to operate globally, decreasing the cost of unnecessary regulatory burden that could be invested in more fruitful activities.

3. New and emerging concerns

Science-based horizontal identification of endocrine disruptors

AmCham EU supports the Commission's objective to establish a horizontal, legally binding mechanism to identify endocrine disruptors (EDs) based on the World Health Organization (WHO) definition. We welcome the

Commission's commitment that such a mechanism should build on criteria already developed for pesticides and biocides as we believe this will promote consistency in assessments conducted across EU legislation.

We note that in the action plan accompanying the CSS, the Commission suggests that horizontal ED identification could be achieved through new hazard classes under the CLP regulation. We urge the Commission to take into account that CLP is primarily designed to classify adverse effects, whereas endocrine disruption – as defined by the WHO – consists of an endocrine mode of action that is causally linked to an adverse effect. Additional actions could be introduced under CLP without creating new hazard classes, such as supplementary EU hazard statements (EUH) or an 'ED flag' under existing hazard classes to highlight an endocrine mode of action.

Horizontal ED identification would be best achieved through Substances of Very High Concern (SVHC) listing under the REACH regulation, including by formally introducing ED criteria under REACH, as is also proposed in the CSS. In this respect we note that the Fitness Check on endocrine disruptors, which was released together with the CSS, found that while a majority of respondents from all stakeholder groups think that the absence of harmonised criteria poses a problem to a coherent approach for the identification of EDs, almost half of all stakeholders interviewed did not support introducing an ED hazard class in CLP[3]. We ask the Commission not to limit policy options in its upcoming impact assessment to the CLP regulation only.

Finally, we stress that the CLP regulation is designed to implement the UN GHS in the EU. We strongly encourage the Commission to, at the very least, test the viability of introducing EDs under GHS before changes are made in the EU that could lead to significant international divergence.

The use of persistency and mobility criteria in chemicals regulation

The CSS proposes to introduce new hazard classes and criteria in the CLP Regulation to fully address environmental toxicity, persistency, mobility and bioaccumulation. It also suggests including persistent, mobile and toxic as well as very persistent and very mobile (PMT/vPvM) substances as SVHC categories under REACH.

REACH has so far regulated Persistence in the context of PBTs and vPvBs where persistence (P) must be associated with bioaccumulation (B) and toxicity (T) (or very persistent (vP) properties must be associated with very bioaccumulative (vB) properties) to justify qualification as a SVHC. The CSS proposal to extend SVHC qualification to PMT/vPvM substances would associate persistency with mobility and toxicity. We note that mobility is a process whereby a substance is transported between environmental compartments, while bioaccumulation is a process in which a chemical biomagnifies in the food chain. These are two different types of assessments, since the first informs on the potential for exposure in an environmental matrix (ie water soil) by including key information on emissions and environmental partitioning between media, while the second informs on the potential for increasing concentration in the food chain which can cause harmful concentrations in upper trophic level organisms and human beings. Due to the lack of a bioaccumulation concern, which was used as a basis for regulating PBT/vPvB substances, we recommend that substances demonstrating 'mobile' properties (which are only one aspect of the exposure assessment) be managed using existing REACH risk assessment processes. As such, inclusion of additional SVHC criteria is not warranted.

With respect to the proposal on new CLP hazard classes, it is important to highlight that PBT and PMT properties reflect environmental fate properties of a substance. The existing CLP hazard classes for chronic hazards to the aquatic environment already overlap to some extent with PBT/PMT criteria. We ask the Commission to clarify what incremental benefits additional labelling for PBT/PMT substances would bring. As with endocrine

[3] 'Targeted Stakeholder Consultation in the context of a Fitness Check of the EU legislation with regard to Endocrine Disruptors – Factual Summary Report', *European Commission, Joint Research Centre,* 21 March 2020, Available at: https://publications.jrc.ec.europa.eu/repository/bitstream/JRC120148/jrc120148pdf.pdf

disruptors, we encourage the Commission to, at the very least, test the viability of introducing PBT/PMT criteria under GHS before changes are made in the EU that could lead to significant international divergence.

Although persistence of a chemical in the environment may trigger a certain level of potential concern, persistence alone is not sufficient in our view to assess present or future risks to human health and the environment. Once a concern is identified, further risk assessment measures should be taken, such as additional testing or hazard assessment in order to characterize the risk and, if confirmed, adopt risk management measures. We highlight that persistence is an area of research where investments and scientific collaboration at global level will be crucial to provide direction; evaluating gaps within existing regulatory frameworks.

More broadly, it is important to note that persistent substances are often durable, which contributes to high performance applications of high societal value necessary to modern life (eg medical devices and medicines, aerospace and automotive applications, renewable energy, EEE and semiconductor applications, construction materials, refrigeration systems and others). This durability of products directly contributes to the circular economy by expanding the lifecycle of products. An overly narrow regulatory focus on persistence only will undermine innovation to produce materials that support sustainability goals. We would note that the Commission has committed to promote durability, including in the context of the Sustainable Products Initiative.

Actions on Per- and polyfluoroalkyl substances (PFAS)

The CSS proposes several actions that are specific to Per- and polyfluoroalkyl substances (PFAS). PFAS substances are a large and diverse group of chemical compounds consisting of approximately 4,700 individual chemistries. Sufficient efforts should be made to ensure that PFAS substances of proven risk are grouped separately. Grouping of substances for regulatory purposes should not lead to considering safer substances in the same family as those that are different from a structure, physico-chemical and risk perspective.

It is important to distinguish among 4,700 highly diverse substances. It is possible to scientifically define distinct classes based on physico-chemical properties. Broadly, we would encourage EU regulators to differentiate between long- and short-chain PFAS and between polymers and non-polymers. Restrictions of particular substances should be justified by appropriate evidence of an acceptable risk occurring at the EU level.

For more information on our work around PFAS, please see the papers below:

- On the principle of persistence: A narrow regulatory focus on persistence-only is not justifiable and can undermine innovation to produce materials that support societal sustainability goals (July 2020);
- On essential use criteria: REACH Restriction: Essential use criteria in the context of socio-economic impact analysis when unacceptable risk is demonstrated (July 2020);
- On the grouping of PFAS: Regulation by distinct PFAS classes is scientifically superior to classification by a broad PFAS group

4. Export restriction or prohibition

AmCham EU supports the Commission's objective to play a leading role globally by championing and promoting high standards. We also support the intent to meet international commitments by ensuring that banned chemicals are not produced in the EU. However it is important that a clear distinction is drawn between internationally banned, restricted or prohibited chemistry (eg listed in certain annexes in the Stockholm Convention) versus chemicals that are unapproved, unregistered etc in the EU but which have essential,

approved uses elsewhere in the world; or in the case of dual-use chemicals which may have both approved and non-approved uses within and outside, the EU.

We recommend that the Commission carefully considers any restrictions on export of EU non-approved chemicals, limiting export restriction to internationally banned chemicals only. Furthermore, it is necessary to ensure adherence to the Rotterdam Convention and the principle of prior informed consent that is already applied in EU law. This provides safeguards to ensure that Governments from recipient nations expressly accept the exported chemicals.

A good example would be biocidal substances such as insecticides or rodenticides that are not currently EU approved but that are sometimes required in other regions. To control plagues of locusts in Africa and the Middle East, the UN Food and Agriculture Organisation (FAO) Pesticide Referee Group advises on the use of substances in certain circumstances. The FAO advice on precautionary steps in the use of substances against the desert locust 'starts with the selection of the pesticide, its formulation quality control and the control technique.'[4] High quality formulations with specific characteristics are more suited to ultra-low volume applications needed to control the locusts, whilst minimising risks to people and environment.[5] As European law ensures that chemical production in the EU has high environmental and human safety, with very high quality and safely packaged products, it is important that these chemicals can continue to be produced for export even if there is no need for the same chemicals in the EU due to the difference in insect populations requiring control. Displacing production to other countries potentially puts current and future EU jobs at risk and would have the unintended consequence of displacing investment in R&D as well as the development of new chemicals specifically for the European market.

6. Combination effects of chemical mixtures

The CSS proposes several actions to tackle combination effects of chemical mixtures. In particular, it proposes to introduce a unilateral Mixture Assessment Factor (MAF) in REACH chemical safety assessments. However, combined exposure is a complex matter and cannot be addressed via this 'simple' solution. An appropriate and pragmatic approach is required which would be both proportionate (balancing a scientifically demonstrated risk associated with a specific group of substances with quantified socio-economic impact) and flexible (not a one-size-fits-all assessment factor). Therefore, it is important to gather sufficient evidence and scientifically identify real-life cases to target in a legislative approach. As an example, while a single fixed MAF applied to all substances has the allure of simplicity, it could not be considered a proportionate approach should the same value be used for the vast range of chemistries on the market. To illustrate this point, the manufacture of 1t of a substance which is an inorganic gas will have a different exposure potential to a 100t liquid substance which is a readily biodegradable natural product extract as well as to that of the production of >1000t of organic solid used only in industrial settings to make articles.

While the CSS states that there is an infinite number of potential combinations of chemicals, the reality is that emissions and use patterns within a given timeframe and spatial scale determine the potential for combined exposure. There is growing evidence from field studies and model predictions indicating that for a given type of effect, a large part of the combined effects from multiple chemicals in the environment is caused by a relatively small fraction of the chemicals involved. REACH has collected a vast amount of exposure information such as environmental releases which should be used to the fullest extent with modern data analysis techniques to

[4] 'Fighting the locusts…safely: Pesticides in desert locust control: Balancing risks against benefits', *Food and Agriculture Organization of the United Nations,* 24 June 2005, Available at: http://www.fao.org/ag/locusts/common/ecg/812_en_FightingDLsafelyE.pdf

[5] G. Matthews, 'The Pesticide Referee Group of FAO and its contribution to locust control. *Journal of Orthoptera Research,* 14, 2005, p. 203-206, Available at: https://www.researchgate.net/publication/250070565_The_Pesticide_Referee_Group_of_FAO_and_its_contribution_to_locust_control

identify potential temporal and spatial co-exposures, grouped by relevant chemistries, that can be validated with real-world environmental monitoring data sets.

The challenge of addressing the issue of combination effects of unintentional mixtures is to find a reasonable and robust approach allowing to 'handle the unknown' without uncertainty leading to disproportionate action. This will not be achieved via the introduction of a single MAF value which does not take into account real life situations.