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Is the EU chemicals strategy for sustainability a green deal?

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ABSTRACT

A fully integrated Chemicals Strategy for Sustainability (CSS) in respect of chemicals is crucial and must include:

- An objective evaluation of the present situation including impacts of 'chemicals of concern' throughout their life cycle, that incorporates sustainability issues.
- A framework that facilitates innovation of chemistry-based approaches to tackle each of the key sustainability issues.

The EU CSS only addresses adverse impacts and mainly focusses on one aspect of risk assessment, the hazard to humans from individual industrial chemicals. The proposal removes consideration of the nature and amount of exposure, which is a critical determinant of risk. It can be presumed that this is solely to simplify, and hence speed up, regulatory decisions thereby enabling more chemicals to be assessed. The linkage of this proposed approach to address any of the major sustainability issues, such as environmental pollutants is obscure. For example, the well-recognised environmental problems caused by polymers such as plastics are not considered. The proposed change in the assessment methodology lacks any scientific justification and fails to address the sustainability issues the EU and the rest of the world are facing. The authors critically discuss a comprehensive innovative evaluation methodology for the impact of chemicals.

1. Introduction

An integrated strategy for the sustainability of chemicals is required. It has to embrace other EU regulatory tools that involve chemicals. The European Commission states that chemical production, use and dispersal/disposal is one of the most polluting, energy and resource-intensive sectors and is closely integrated with other energy-intensive sectors and processes (EC, 2020a). It is noted that this judgement does not consider other environmental pollutants such as radon, UV -radiation and fuel combustion products. It is recognised that chemicals, while bringing benefits to society, may be released during their lifecycles resulting in pollution which may result in harm to humans and ecosystems. The Lancet Commission on pollution and health (2018) defines pollution rather narrowly as unwanted often dangerous material that is introduced into the Earth's environment as the result of human activity. Pollution control is about risk management of pollutants where risk can be defined as: the probability of an adverse effect on man or the environment occurring as a result of a given exposure to a chemical or mixture (Van Leeuwen and Vermeire, 2007).

It has been estimated that in 2015 nine million premature deaths can be attributed to exposure to pollutants, 16 percent of global mortality (Landrigan et al., 2018). The European Environment Agency (EAA) reports that exposure to air pollution, second hand smoke, radon, ultraviolet light, asbestos and various chemicals causes over 10 per cent of cancer cases in Europe (EEA, 2022). In the absence of reliable exposure data all such estimates can be only ball park figures. Assessing the impacts of pollutants on environmental species is undoubtedly very substantial but very challenging to estimate with confidence. Over 350,000 chemicals and mixtures of chemicals have been registered for production and use. This is up to three times as many as previously estimated

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and with substantial differences in production method and volume, use and dispersal/disposal across countries/regions (Wang et al., 2020).

Society globally is confronted by a number of major increasing challenges that are already resulting in serious adverse impacts on all ecosystems, including mankind and the millions of other species that occupy our planet. The major challenges may be summarized as: (a) climate change (IPCC, 2022), (b) loss of species diversity and ecosystem viability (Dasgupta, 2021), and (c) scarcity of many natural resources, including water and food (Koop et al., 2022). The main contributors to all three challenges are: overconsumption and overpopulation. Their impacts are causing pollution of water, air, soil and sediments, biodiversity loss, as well as climate change.

To regain a sustainable planet, responsible remedial action is needed urgently, however, there will always be political and economic reasons to delay. Moreover, these challenges cannot be addressed separately because they are interdependent. Focusing on chemicals, perhaps an acronym CRISIS (C = chemical emissions, R = resource recovery, I = interspecies balance, S = sustainable products, I = integrated actions, S=Science-based solutions) would help as a reminder of the challenges and ways forward.

1.1. A more sustainable planet: the EU perspective

The term 'sustainability' is very frequently used to depict a particular objective of the EU and its Member States. This is also the case in most other nations. Unfortunately, in common with terms like 'green' and 'recyclable', it lacks a precise, widely agreed, definition. Sustainability may be defined in various ways, however, the understanding ought to be the same, to enable and maintain restoration of global homeostasis (balance). Achieving this demands a more equitable balance of power between the many organisms which occupy the globe (Sheldrake, 2020). From a human perspective, we have to learn to live in harmony with nature rather than a determination to dominate it. Many 'solutions' that are sold as being sustainable have a finite end date where these will no longer be sustainable without full life cycle plans and their implementation. E.g. the production of batteries for many purposes such as for electric cars will exhaust many natural resources (particularly in the third world) in the not too distant future unless a clear strategy is implemented for their recycling.

In the publication of the 'Green Deal' (EC, 2019) the EU sets out a number of important milestones and constraints for a 'greener' (circular) economy. A major feature is the high emphasis given to human health and well-being. There is, however, no assessment of the threats to the health of EU citizens from chemicals in the Green Deal other than concern about pollution and no attention is given to risk benefit aspects (Van Leeuwen and Vermeire, 2007). Moreover, the environmental and human health impacts of the 'Strategy' in other parts of the world is not addressed at all.

1.2. Sustainability and the contribution of chemicals

Our planet comprises many chemicals, these are predominantly of natural origin. To date over 50 million chemicals have been identified and this number is increasing by several thousand each year (Science Daily, 2008). Life on this planet could not exist without most of them. It should be noted that many naturally produced chemicals still await identification and characterization. Risk assessments have focussed on a few hundred man-made chemicals. To put this in perspective: over 140,000 of these have been produced since 1950 and over 5000 of these have been estimated to have almost universal human and environmental exposure (Landrigan et al., 2018). Because chemicals are involved in all aspects of life on earth it is vital to give major attention to their role in devising and implementing an optimal action plan for viable and sustainable alternatives to current activities in order to achieve global sustainability. Any action plan should comprise three elements:

- A clearly specified, attainable objective(s) that addresses all the challenges of concern (the objective(s)).
- The rationale for pursuing this objective(s) including both the benefits and detriments in comparison with alternatives (the justification).
- An appropriate, practical step wise pathway, to achieve the objective (the road map/transition pathway).

To date the EU attention has been largely on 'the objectives' that often only address the consequences without considering the real causes of the issues at stake. In the EU's Green Deal, the principal objective with regard to chemicals appears to be the attainment of zero pollution. The goal of "zero pollution" is unrealistic and unscientific. Furthermore, 'pollution' is not defined and is certainly not confined to chemicals alone. It is presumed that use of the term 'pollution' refers to air, water, sediment and soil pollution and includes zero solid waste dispersal, including plastics and other synthetic materials and not any naturally derived chemicals. Destruction of chemicals which facilitate global warming is also a neglected problem. It is a very appropriate objective, because the previous well established practice of 'dilute and disperse' to avoid any significant environmental or human health impact of waste has failed completely. Addressing pollution would help to ameliorate all three challenges although zero pollution is inevitably an unachievable objective. In terms of climate change to date it is unfortunate that the only pollutants specifically considered both by the EU and many other nations are carbon dioxide and methane because of their carbon footprint which is only one aspect of the impact of pollutants, as well as freons, that are not only responsible for ozone degradation, but also for global warming.

Pollutants do not recognize national boundaries (Van Leeuwen and Vermeire, 2007), action on the objective of zero pollution, therefore, demands an effective global cooperation. This requires minimization of the generation of pollutants (including solid wastes) throughout the life cycle (sourcing of raw materials, manufacture, uses and end of use fates). The chemical industry is just one of many pollutant producers and users of chemicals that must adopt new measures, if progress towards zero pollution is to be achieved. However because it is best placed technically, it should serve as a role model for other organisations with comparable challenges. It needs to be recognised, though, that industry in general along with academic and government organisations in the relevant sciences, has a number of other interrelated key roles to play in solving the EU and global pollution problems. In particular:

a. To enable methodologies for environmental quality monitoring and regulatory compliance.
b. To develop, with other relevant disciplines, practical methods for the reuse and/or recycling of wastes (subsequently to be applied to the many thousands of waste dumps in Europe). This must also take account of emissions during recycling as well as diffuse emissions for nonreusable or recyclable pollutants final sinks are needed that can be safely maintained.
c. To devise, with other relevant disciplines, and enable the development of other economically feasible sustainable technologies e.g., wastewater treatment, carbon trapping, energy storage, ecosystem restoration
d. To collaborate with the appropriate regulatory bodies and others in the identification and implementation of methodologies for future assessment of chemicals e.g., 'sustainable by design' products. This requires dialogue rather than confrontation.
e. To aid in the adoption of a global strategy for action to enable a more sustainable planet.

The goal of this paper is two-fold. In this paper the authors identify serious flaws in the EU Chemicals Strategy for Sustainability (CSS; Section 2) and provide an outline for a more relevant and practical strategy (building blocks for a better EU CSS; Section 3). In Section 4 additional requirements for the methodology framework are presented.

2. Observations on the EU chemicals strategy for sustainability

2.1. No clear need

Many separate pieces of EU legislation cover chemicals. The assessment of these need to be harmonized, through an appropriate methodology. With the introduction of the REACH legislation (Van Leeuwen et al., 2007), specific to large scale production chemicals, steps were taken to improve the implementation of the risk assessment of new and existing chemicals in the EU (Van Leeuwen et al., 1996; Vermeire et al., 1997). Whereas competent authorities collected all data and assessed approximately 10 high production volume chemicals per year, the REACH legislation reversed the burden of proof to industry (Van Leeuwen et al., 2007) leading to a substantial acceleration of the risk assessment and risk management process, i.e., in more than 100,000 registrations of more than 22,000 chemicals to date (ECHA, 2022). Effects of chemicals on human health and the environment can in principle be addressed by the continuation of the REACH risk management process and by proper implementation and enforcement of other existing EU legislation. However, to achieve this a new scientifically valid strategy for prioritization and risk assessment, is essential.

In the Blueprint to Safeguard Europe's Water Resources (EC, 2012) it was concluded that the legislative toolbox for achieving sustainable water resources existed, and only required consequent and consistent implementation. Some tools may require some maintenance, but evidently no new tools were deemed necessary. Furthermore, for substance and emission controls, similar regulatory frameworks are in place and the obvious reason for the current failure in achieving the desired results comes from inconsistent implementation and enforcement by the EU Member States.

There is need to update existing legislation, to improve methodologies, to expand the scope of the assessments, but the analysis should start with an inventory of existing legislation that focuses on the problems we currently face. This is not clearly addressed in the CSS. In fact, Barile et al. (2021) conclude that due to the existing system of chemicals regulation in the EU, the current level of protection of its population as a whole, including sensitive sub-populations, against chemical risk is among the highest in the world.

2.2. No clear objectives

Responsibility for evaluating the safe use of chemicals in the EU is spread through a number of its Agencies and scientific advisory committees that do not collaborate seamlessly, if they collaborate at all. Any new strategy, to be viable, must be compatible with the facilitation of all their different remits. The European Commission adopted its CSS on 14 October 2020. Its relation to the EU's Green Deal, in particular the zero pollution aim, is not realistic, and scientifically impossible. Its principal overall objective is stated as a 'toxic free environment'. This objective cannot of course be meant literally, since many toxins are of natural origin and are essential in the structure and functioning of ecosystems.

Taken at face value, the stated 'toxic free' environment would imply a completely dead environment. All chemicals are toxic, when the exposure to these is sufficiently high and/or of long duration. Regarding man-made chemicals, the objective of the CSS would enhance the Green Deal zero pollution objective by including additional unsustainable sources of environmental and human exposure to chemicals. Unfortunately, the CSS provides minimal indication of how the EU Strategy for Chemicals will, in practice, address the major sustainability issues. It ignores the Green Deal zero pollution objective concentrating instead on assessment of the impacts of 'chemicals' on human health only.

2.3. Lack of definitions

A further concern with the CSS is that there are no definitions of key terms such as 'chemicals'. Does it include polymers such as plastics which are widely recognised as a major environmental concern (Lebreton et al., 2018; Schwarz et al., 2019; Cordier and Uehara, 2019; Persson et al., 2022)? Furthermore, does it include nanomaterials for both the polymer itself (and the various chemicals that can leach from them or be adsorbed onto them)? It is vital that terms such as 'sustainable', 'green', 'environmentally friendly', 'chemicals of concern', 'essential chemicals', 'sustainable by design', 'carbon neutral', etc. have a precise application and extend to the entire life cycle. Unless the use of such terms is restricted to a specific widely accepted definition, extensive misuse of these terms and resultant confusion cannot be prevented. The consequence is that 'words mean what I choose them to mean' (Alice in Wonderland; Carroll, 1865) a recipe for Bedlam.

It also requires the development of methodology to identify and characterize a 'sustainable chemical'. A sustainable chemical may be defined as a substance that will not cause unacceptable environmental or human health impacts when produced, used, dispersed or disposed of responsibly.

2.4. Lack of priority setting criteria for the selection of chemicals

The criteria for prioritization are not mentioned but presumably, based on current practice, they will be from chemicals manufactured in the EU, based on quantity manufactured. Why this should be a priority for global or EU sustainability, or indeed for improved public health of EU citizens, is not indicated. The starting point could be the procedure described by Hansen et al. (1999), but if the EU is serious about sustainability of chemicals, additional objective criteria should be developed for both selecting the 'chemicals of concern' with regard to sustainability and the rationale for their prioritization. This must include both existing chemical pollutants as well as chemicals likely to achieve significant environmental levels.

2.5. Oversimplification of risk assessment methodology

The CSS focusses on simplification of the assessment methods, required for regulatory purposes, to protect human health for individual chemicals. The CSS offers only a very brief mention of environmental concern and life cycle analysis. It does not consider at all the problems created by the many thousands of existing waste sites and contaminated land areas within the EU. The CSS focusses only on the methodology it considers is required by EU regulators to ensure the human health protection of chemicals (principally industrial chemicals) and gives scant attention to exposure assessment and environmental concerns. The changes the CSS proposes to current widely recognised risk assessment methodology practice are:

- Replacement of risk assessment (which requires both hazard and exposure estimates) with hazard assessment. This change ignores the first principle of toxicology established over 500 years ago by Paracelsus, that it is the exposure (dose) that determines whether a chemical causes adverse effects.
- One substance one assessment. NB. The CSS identifies that currently the same chemical may be assessed a number of times by different parts of the Commission. It is noted that all the other assessors of chemicals than ECHA (e.g. EFSA, EMEA, SCCS, EEA, SCHEER) will inevitably continue to require a detailed risk assessment that includes exposure aspects.
- Reduction of data requirements, although continuing with the requirement of data using specific OECD animal tests.
- Grouping of chemicals in order that assessment of the hazard of one member is adequate to evaluate the hazard of all its members.
- Inclusion of concern on the effects of mixtures of chemicals.

Consideration of all available relevant data, a long-established principle in risk assessment (weight of evidence; WoE) is presumably deemed no longer important (see appendix 1). It can be predicted that this lack of a sound and science-based assessment in the CSS will be contested in the near future. Interestingly, a recent court case on TiO2 has endorsed the importance of weight of evidence in identifying risks to health (General Court, 2022). Serious, fully justified concerns have been raised already about the suitability of the proposed approaches (Herzler et al., 2021).

2.6. Introduction of inconsistencies

Replacement of risk assessment by hazard assessment is a very major departure from the well-established risk assessment practice (Van Leeuwen and Vermeire, 2007). In regard to one chemical one assessment: how exposure assessment can be ignored for chemicals that are designed to have effects on humans (e.g., medicines, cosmetics) or other species (e.g. biocides) is not indicated. In fact, the CSS introduces inconsistencies compared to the EU assessment methodologies for other products (e.g. plant protection products, biocides, cosmetics, and medicines; EC, 2020b; EC, 2020c). It is also unclear whether qualitative assessments of hazard alone could be relied on to evaluate the hazard from each chemical or whether a reliable evaluation of potency, which is a vital aspect of hazard assessment, is also a requisite. Moreover, when the hazard of a substance is established, this is a property that cannot be managed other than by rejection or acceptance. Whereas exposures can be managed by treatment or releases, use restrictions and/or product stewardship advice.

2.7. Mixture assessment factor(s)

No consideration is provided on how sustainability of chemicals will be addressed, including pollution aspects. However, the CSS considers the hazard posed by exposure to mixtures of chemicals by introduction of mixture assessment factor(s), but practical details of how this can be done are lacking. A number of publications have noted that, although exposure to mixtures is very common, individual chemicals are still the driver for risk assessment of mixtures such as polluted media. It is evident that all species are exposed to many thousands of natural and man-made chemicals every day. Thus although in principle this is an important factor to consider, it is an issue that can only be addressed by the development of new methodology which must begin with assessment of exposures. It is noted that this issue has been addressed many times before without strong conclusions on how it should be addressed (e.g., see EC, 2011). In fact, better and practical scientific methodologies are already available (EFSA, 2019; Van Straalen et al., 2022; Van de Meent et al., 2022; Escher et al., 2022; Tralau et al., 2021).

2.8. Unclear cost-benefit analysis

It would appear that the purpose of the CSS proposal is primarily to enable a faster track and hence a higher throughput for regulatory decision-making on human safety by simplifying the assessment process. Banning or regulating substances without the need for in-depth assessment would without doubt speed things up tremendously, but this would not be sustainable and would be a great mistake, as science matters (General Court, 2022; Guéguen and Marissen, 2022). The CSS does propose measures to reduce resource demands involved in risk assessments for decision making as summarized below. Moreover, it does not define how the proposed changes in methodology will enhance the quality, consistency, objectivity, cost effectiveness and trust in the regulatory decisions made. There remains too, the most important, yet unanswered question, of how the CSS will evaluate the sustainability of 'chemicals of concern'.

2.9. Additional observations

The assessment of the adverse health effects of chemicals consequently is the only aspect of the so-called 'Strategy' that can be discussed in any detail. Key inter-related question that needs to be addressed are:

- In which respects does it enhance the reliability of the internationally recognised risk assessment methodology practiced and further developed over many decades? Considerations include impact on environmental species, resource depletion and carbon footprint. A recent report by the Joint Research Centre (EC, 2022) also refers to environmental sustainability assessment and social and economic sustainability assessment.
- How will the CSS proposal enable a common methodology for risk assessment of chemicals to be used by all the EU agencies and many Member States scientific advisory committees?
- Does it reduce the resources required to enable trusted decisions to be made on human and environmental health issues? From a sustainability and animal welfare perspective, is additional testing only sought (which requires resources) where crucial?
- Will it facilitate progress towards a harmonized, and therefore more sustainable risk assessment methodology internationally? This is important because the EU exports chemicals to many other countries and imports many chemicals as well.

2.10. Is the CSS a green deal?

From a regulatory perspective, changing the data requirements, as outlined in the CSS, may be efficient and may allow more chemicals to be assessed using the same resources, but this is questionable (Herzler et al., 2021; General Court, 2022). The benefits to human society and Planet Earth are also very unclear. In considering the appropriateness of any substantial modifications to the current widely recognised and internationally accepted assessment process consideration must be given to:

- Integration of environmental and human health risks.
- Evaluation of the contribution to sustainability of a chemical/product.
- Reduction of the requirements for animal testing, except where there is no trusted alternative (NB. this is already EU policy, as exemplified in the Cosmetics Directive and REACH Regulation).
- Identification and use of all the relevant available data and avoidance of scientifically unjustified studies.
- Compatibility and consistency with the risk assessment methodologies for chemicals and other substances practiced both in the EU and by non-EU nations.

It follows that a complete rethink of the new 'Strategy' is clearly fundamental. It must be based on the principles of trusted risk assessment (see appendix). Moreover, the evaluation of sustainability must be an integral feature, key aspects of which must be pollution and recycling/reuse potential. It should be both an EU and worldwide priority where the consequences of both inaction (substantial delays) and action are objectively evaluated on a regular basis.

3. Building blocks to improve the EU chemicals strategy for sustainability

The CSS can be improved considerably. In this section, we focus on risk assessment of chemicals and describe seven steps (3.1–3.7 below) for improving the CSS. In section 4 we will focus on additional requirements for the methodology framework. In our view consideration should be given to the following to meet the objective of reducing unnecessary detailed assessments:

i) Objective selection criteria for 'chemicals of concern' in terms of sustainability, environmental impacts and human health risk applied to all chemicals not of natural origin.
ii) A tiered framework in which chemicals can be identified as of minimal or no concern and eliminated from further assessment at any stage in progress through the tiers.
iii) Greatly improved use of already available data on each 'chemical of concern' and previous risk assessments.
iv) Objective and transparent, scientifically justified, criteria for determining whether additional specific data is required.
v) Objective and scientific criteria to justify inclusion and exclusion of a chemical from a 'group'.
vi) Much greater encouragement for non-animal method development.
vii) Harmonization of the 'new' methodology with international practice.

3.1. Prioritization of chemicals for assessment

None of the documents produced by the EU to date provide clarification on how chemicals will be prioritised for their 'sustainability'. No proposal has yet been described on the key criteria that should facilitate the identification of a 'sustainable chemical'.

In our increasingly confrontational society, a body of independent, objective and trusted experts in a number of different disciplines and with appropriate professional experience is probably necessary for this task. It might be called 'The Academy of Sustainability Analysis'. Without such a development, vested interests will undoubtedly dominate any progress. Their first task should be to establish clear definitions of key 'green' terms and highlight their inappropriate use.

Hereafter, for the purposes of addressing the proposal of the CSS, priority chemicals are referred to as 'chemicals of concern'. High priority must be given to the identification of those chemicals which actually pose a substantial risk to man and the environment and to ensure that any proposed replacements existing chemicals meet all of the 'safe and sustainable' criteria. Furthermore, socio-economic analyses are important, but completed neglected in the present political environment resulting in hazard-based decisions to counteract any sustainability goals. It is vital that objective, robust and transparent assignment criteria are made widely accessible and enacted to justify priority selection because there are competing considerations. For example:

- New chemicals, particularly those with a novel structure or structural features resembling a known potent toxic chemical (QSAR-based; Van Leeuwen and Vermeire, 2007).
- Production and/or end of life fate results in significant waste (unwanted, non-retained materials) e.g., air, water or solid waste pollutants.
- Adverse health reports from occupational health of workers manufacturing or utilizing a particular chemical and/or environmental concerns in the area around a factory with significant chemical manufacture or use.
- Number and nature (age, gender, sensitivity) of individuals potentially exposed (e.g. if appropriate based on high annual tonnage and use pattern) with substantial identifiable data gaps of major relevance to confidence in the safety assessment.
- Environmental impact concerns. At this stage it is unclear from the CSS how ecological risk assessment will be conducted or of the importance attached to such assessments.

3.2. Effective utilization of existing data

A well validated comprehensive and transparent database is a vital starting point to minimize unnecessary further data requirements and as the basis for grouping chemicals. Thus the information on the databases on the 'chemical of concern' and that of closely related chemicals should be examined along with the physicochemical properties to identify what is already known about the chemical and where there are important data gaps from a human and environmental health risk viewpoint. A database (see below) also needs to be developed to identify a generic conservative threshold of toxicological concern (TTC) for each critical hazard as identified by an expert panel. It is essential too that a parallel database of environmental TTC values is established for ecosystem impacts.

3.3. Estimates of exposure assessment

Hazard assessment alone is totally inadequate as the basis to prioritize and further assess the risk of chemicals. Risk is defined as the function of the probability of an adverse health effect due to exposure and the severity of that effect, consequential to a hazard. It therefore necessitates exposure assessment too. Some hazard classes of chemicals meet regulatory bans, such as PBTs and CMRs in the EU, but even then, exposure assessment is essential for determining the environmental pollution potential, risk-benefit analysis, the evaluation of alternatives and essential uses, and the implementation, evaluation and impact assessment of policy options, including a shift towards sustainability, safe by design strategies, and circularity. A report 'exposure science in the 21st century A vision and a strategy' by the National Research Council (2012) used the following description 'exposure science links human and ecological behaviour processes in such a way that the information generated can be used to mitigate or prevent future adverse exposures'.

Recently a group of European exposure scientists called for strengthening exposure science in order to address these issues and defined the following challenges to achieving this (Bruinen de Bruin et al., 2022):

- Availability of exposure data, information and knowledge for use across policy domains.
- Acceptance criteria for exposure data and methods across policies.
- Integration of scientific exposure assessment and modelling frameworks.
- Integration of exposure knowledge into companies' management systems.
- Regulatory adoption of innovative monitoring approaches.
- Consideration of combined exposure to multiple chemicals.
- Harmonizing the use of exposure science across all relevant policy domains.

The substantial gaps that currently exist in exposure information and exposure assessment can be bridged to some extent by applying tiered assessment as developed in various regulatory frameworks such as, e.g. in Europe under REACH and in the USEPA (Van Leeuwen and Vermeire, 2007). A first tier usually is composed of a worst-case exposure assessment for key life cycle stages of the chemical, the results of which are compared to simple and worst case hazard criteria such as the TTC (Kroes et al., 2004). An example of a much used first tier exposure assessment tool for workers is the ECETOC targeted risk assessment tool (Urbanus et al., 2020). Worst case is appropriate because unexpected sources of exposure to many chemicals might arise.

A similar measure in ecotoxicological assessment, the Threshold of Ecotoxicological Concern is under development (Barron et al., 2021). To complete this tier, characterization of the uncertainties in the assessment and the allowance needed for these should addressed. If the estimated worst-case exposures are established with confidence to be below the hazard criterion, no further assessment should be necessary. If not, at higher tiers more realistic exposure assessments should take into account metabolism and other toxicokinetic paraments, mixed and aggregated exposures, specific emission rates and mass flows as well as (bio)monitoring data. For specific categories of chemicals, it can be considered to prioritize on the basis of exposure assessment alone: for example, it was recommended that prioritization of nanomaterials for hazard assessment should be based on the likelihood of human and environmental exposure during manufacture, use and end fate (EC, 2007).

An example of a tiered risk assessment methodology is the European System for the Evaluation of Substances (EUSES), developed in the late nineties (Vermeire et al., 1997). This system has become the European reference tool for companies, authorities and researchers to prepare their environmental exposure assessments under the Biocidal Products Regulation and the REACH Regulation and was updated in 2019 (EUSES, 2019).

3.4. Hazard identification and potency assessment using New Approach Methodologies

New Approach Methodologies (NAM) based tests, including *in silico* models, for a number of hazards of concern are already developed or in an advanced development stage. The tests should first be used to identify whether the specific anticipated hazardous properties from knowledge of closely related chemicals are detected. If so, the more sophisticated methods to evaluate potency should be embarked on (e.g., use of well characterized reference chemicals as positive controls). It is vital that the endpoints selected are appropriate for the identification and characterization of risk to man. These can be compared against the estimates of worst-case exposure. Guidance on the application of WoE to integrate different forms of NAM data and with any existing animal date needs to be developed. A parallel approach needs to be developed for ecosystem protection purposes. This is also the appropriate stage for initial consideration of sustainability potential. The primary considerations should be pollution potential (including carbon footprint), resource utilization and recycling potential.

3.5. Animal tests

Specific animal test should only be embarked on if the above data is seriously inadequate to identify and characterize the real risks to human health or the environment from the various uses of each chemical of concern. Vertebrate testing for ecosystem safety evaluation purposes should also only be adopted if substantially inadequate data is accessible. It must be recognised that animal testing requires substantive use of resources (an important aspect of sustainability).

3.6. Final appraisal

All the data should be subject to a robust WoE. This is the basic requirement and should be performed along sound scientific criteria (General Court, 2022). A critical issue in decision making, that is not really addressed in the CSS, is the nature and extent of uncertainty in any assessment. What extent of uncertainty is acceptable for regulatory purposes? This is touched on in Partnership for the Assessment of Risk from Chemicals (PARC) but ignored in the other documents. If the Commission is focused on minimal data, as the basis for decisions, uncertainties will inevitably increase, and it is vital that attached to each decision is a realistic identification of the uncertainties in the assessment. The use of safety (default) factors cannot be used to address this. Such uncertainties must be made transparent. This should involve uncertainties in the integration of the human and environmental data (e.g., see Wilks et al., 2015) to establish overall risk conclusions.

3.7. Consideration of other factors

This should include adaptation potential, interaction with other stressors, including other chemicals and potential benefits from the use of the chemical. This analysis should also embody both risk to the environment and human health (integrated risk assessment), sustainability benefits and viable alternatives as well as the socioeconomic consequences of the decision proposed. In the past too many major decisions have been made without the longer-term consequences of the decision being considered.

4. Additional requirements for the methodology framework

4.1. Pollution and life cycle analysis

It is crucial to recognize that if a primary purpose of the Green Deal in regard to chemicals is to minimize pollution, then a life cycle analysis of each chemical to identify the pollutants generated and their subsequent fate is essential. This must include evaluation of end-of-life fate including safe disposal of unwanted chemicals. Whether minimization of pollution and waste has a higher priority than risk assessment of the use of a chemical is a challenging issue. From a global sustainability perspective, it should be. Of course, pollutants such as carbon dioxide, methane and freons are already identified as a priority for reduction. Specific chemicals have also been banned because they affect particular environmental targets or in the case of freons the ozone layer. However, pollution inevitably involves multiple chemicals. Emission of chemicals to air and/or water is common during sourcing (e.g., mining), manufacture, distribution, use and end of life fate. It may also occur during use. Priorities for pollutant reduction will need to be determined. Strategies for assessing environmental and human health impact are likely to be important in identifying the priorities. Chemical analysis (monitoring) will play a crucial part in identifying and quantifying the chemicals of particular concern and in ensuring compliance (Brack et al., 2019). Chemical based methods may also be needed to minimize the level of pollutants. Missing from the Strategy is a requirement to clean up chemical waste and other solid waste sites. To this end very effective collaboration between the domains of chemistry and microbiology will be essential. Criteria are needed for final secure and safe 'sinks' to contain recoverable pollutants where there is no environmentally safe means of destruction and a practical programme implemented.

4.2. Environmental monitoring

Current information to facilitate prioritization of chemicals for their environmental impacts is much weaker than for humans. Moreover, because exposure of ecosystems is typically to complex mixtures of chemicals of frequently varying composition, investigation of effects on selected sentinel species in an ecosystem are likely to be particularly informative. Selection of species to monitor effluents e.g., from manufacturing and waste disposal sites should bear in mind the appropriateness of the species, in addition to other factors such as ethical aspects and species sustainability. Innovative methods to achieve this are available (e.g. Hughes et al., 2021). Effective human and environmental (bio)monitoring is also important to ensure compliance with the regulations (Zare Jeddi et al., 2021). In terms of end-of-life fate off gas generation is often not recognised as an important air pollutant source. Monitoring of waste facilities to identify pollutants of importance is needed.

4.3. Harmonization of approaches and actions

Harmonization of strategies for sustainability is crucial for success. Currently it is not evident how a fully integrated action plan will be arrived at or implemented. Attempts at harmonization of risk assessment across the various parts of the EC is not new. A substantive report (EC, 2001) has been accepted by the various Scientific Committees that constituted the EC Scientific Steering Committees. However, with the establishment of separate agencies in the EU for chemicals, medicines, foods etc. this was abandoned. The transition document talks about better integration of the chemical industry with the digital world. Surprisingly and at least equally important, but not mentioned, is integration with biologically orientated research and development activities in the EU.

In addition, achieving timely global sustainability requires global action. In political terms there will always be a case to delay the necessary action. A strategy for the EU has to be compatible with that of other major nations, because the EU risk assessment methodology is deeply rooted in the international risk assessment community, being at the forefront of progressing risk assessment methodology and practical implementation at the international level, e.g. under the umbrella of the Organization for Economic Co-Operation and Development and the World Health Organization (Herzler et al., 2021).

In respect of chemicals the EU imports many chemicals and exports others. Common criteria on the safety and sustainability of exported and imported chemicals needs to be in place and acted on to first slow and finally to begin to reverse the current deterioration of our environment. Recent experience of the lack of international cooperation on the covid pandemic and the lukewarm commitments at the recent Glasgow and Bonn climate change conferences are indicators of how challenging international coordinated action is likely to be.

However, harmonization of terminology and methodology and sharing of the findings from such harmonized methodology utilization is potentially achievable based on the experience and follow-up of the 2001 report (EC, 2001). It is important too, from a purely EU perspective, because the EU both relies on chemicals produced from outside its borders for various purpose and also exports chemicals to many other countries. Moreover, pollutants do not respect national boundaries.

5. Conclusions

Our society is confronted by a number of major increasing challenges which are already resulting in serious adverse impacts on both mankind and the millions of other species that occupy our planet. These challenges may be summarized as:

- Pollution of water, air and soil.
- Climate change.
- Loss of species diversity and ecosystem viability.
- Scarcity of many natural resources and,
- Overconsumption and overpopulation by humans.

These should not be considered separately because they are interdependent, nor can remedial action wait until our knowledge base is expanded. The EU Green Deal is an important landmark document in identifying these challenges. One important aspect which needs to be addressed is the potential contribution of various industries to the solutions e.g., the chemical industry and how to promote this. The Chemical Strategy for Sustainability is not an appropriate title for an EU publication that does not contain a strategy for sustainability of chemicals. Instead, it focusses on speeding up the regulation of chemicals. It does not provide any rationale on why the prosed changes in chemical safety assessment should be a priority in attaining EU/global sustainability of chemicals. Nor how greater regulation of chemicals will benefit the health of EU citizens. It is notable that the CSS gives only very limited attention to methodology for the assessment of the impacts of chemicals on the environment and as such it may be questioned if it delivers to the Green Deal. It is unclear too whether the priority should be to better assess the risk from chemicals in the EU as major progress has been made under the REACH legislation. The methodology changes proposed in the CSS, represent a serious, scientifically unsupportable simplification of the methodology framework for risk assessment of chemicals used currently by other EU Agencies and by many other countries, including the OECD member states. Further serious deficiencies, from a sustainability viewpoint, are the lack of any proposal as to how to tackle chemical waste (including plastics) and the cursory attention given to the need to promote the use of chemical innovation to rectify the progressive loss of global sustainability, where chemical-based innovation has an important part to play and is urgently needed. An outline alternative assessment methodology is proposed based on a tiered scientifically justified structure for the future evaluation of chemicals.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Helmut Greim and Kees van Leeuwen both report a relationship as Member of the Scientific Committee of the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC).

Data availability

No data was used for the research described in the article.

Appendix 1. Current EU risk assessment methodology used by EU independent Scientific Advisory Committees

When the EU was founded, hazard/risk assessment of chemicals became the responsibility of a number of DG's and since the early part of this century several agencies. ECHA is responsible for industrial chemicals and aspects of pesticides plus worker safety from chemicals, EFSA is responsible for food constituents and aspects of pesticides and antibiotics, EMEA is responsible for human and veterinary drugs and medical devices EEA for environmental data gathering and the SCCS (DG Sante) is responsible for cosmetics. To date, adverse effects of chemicals on the environment have been considered very secondary to adverse effects on humans by each agency. The risk assessment advice for every agency except ECHA is provided by a committee of independent, well recognised experts. Their primary task is to identify exposure levels of each chemical that in use will not cause adverse health effects. These levels are then embodied in regulations and guidelines. The methodology required to assess chemicals currently is designed to assess the safety in use of individual chemicals. The acronym *trusted* is useful as a reminder of what is required for health risk assessment of a chemical.

- **T** = Threshold for the adverse effect(s) clearly identified
- **R** = Reference points and read across (chemicals/situations) clearly defined and justified
- **U**=Utilization of **all** the relevant information including previous risk assessments
- **S**=Science based, taking fully into account current scientific understanding and avoidance of bias
- **T** = Transparent weighting of the data for both relevance and quality (including reasons for any data discounted)
- **E** = Exposure estimates and extrapolations justified
- **D** = Deficiencies/uncertainties in the assessment clearly stated along with how they are addressed and the rational for this specified.

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