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COMMISSION RECOMMENDATION

of 8.12.2022

establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

(1) The European Green Deal[1] sets out four interlinked policy goals for the transition to a sustainable economy and society: climate neutrality, biodiversity protection, circular economy and a zero pollution ambition for a toxic-free environment.

(2) The EU sustainable finance strategy[2] aims to support the financing of the transition to a sustainable economy.

(3) The Taxonomy Regulation[3] sets out four conditions that an economic activity has to fulfil in order to qualify as environmentally sustainable. It also sets out six environmental objectives, including the transition to a circular economy and pollution prevention and control.

(4) In the Chemicals Strategy for Sustainability – Towards a Toxic-Free Environment[4] (the "Chemicals Strategy"), the Commission announced that it would develop 'safe and sustainable by design' criteria' for chemicals and materials. The Commission will also incentivise Member States, industry and other stakeholders to prioritise innovation for substituting, as far as possible, substances of concern[5] across sectors, as for example textiles, food contact materials, information and communications technologies, construction materials, low-carbon mobility, batteries or renewable energy sources.

(5) The European Parliament has adopted a resolution[6] on the Chemicals Strategy, stressing the need to develop 'safe and sustainable by design' criteria to help prevent and control pollution, improve the tracing of hazardous chemicals in products, and promote their substitution by safer and more sustainable alternatives. The Council conclusions on the Chemicals Strategy[7] of 15 March 2021 also call on the Commission to promptly develop, in cooperation with the Member States and in consultation with stakeholders, harmonised, clear and precise definitions and, where

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1 COM(2019)640 final

2 COM/2021/390 final

3 EU/2020/852

4 COM(2020)667 final

5 As defined in the Chemicals Strategy for Sustainability (COM(2020)667 final).

6 European Parliament resolution of 10 July 2020 on the Chemicals Strategy for Sustainability (2020/2531(RSP)), https://www.europarl.europa.eu/doceo/document/TA-9-2020-0201_EN.pdf

7 Council conclusions 6941/21 of 15 March 2021, Sustainable Chemicals Strategy of the Union: Time to Deliver, https://www.consilium.europa.eu/media/48827/st06941-en21.pdf

adequate, criteria or principles for the concepts that are crucial for the effective implementation of the Chemicals Strategy, such as 'safe and sustainable by design' chemicals.

(6) The Circular Economy Action Plan[8] states that the Commission will support the substitution and elimination of hazardous substances through research and innovation.

(7) The EU Action Plan Towards Zero Pollution for Air, Water and Soil[9] and the Proposal for a Regulation on establishing a framework for setting ecodesign requirements for sustainable products[10], emphasise the commitment to ensure that chemicals and materials are as safe and sustainable as possible by design and during their life cycle, so that material cycles are non-toxic.

(8) A first sector-specific reference to safety and sustainability by design can be found in the EU Strategy for Sustainable and Circular Textiles[11]. The strategy highlights the importance of developing 'safe and sustainable by design' criteria for chemicals and materials to support industry to substitute or, if not possible, minimise substances of concern in textile products.

(9) European citizens also see the need to act. A 2020 Eurobarometer survey[12] shows that 84% of Europeans are worried about the impact on their health of chemicals present in everyday products, and 90% are worried about chemicals' impact on the environment.

(10) Several hundred substances have already been identified as substances of very high concern under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006[13], and many more could fall under the definition of substances of concern in the Proposal for a Regulation on establishing a framework for setting ecodesign requirements for sustainable products[14].

(11) The transition to chemicals and materials that are 'safe and sustainable by design' requires a common understanding of safety and sustainability aspects to be successful[15]. It is therefore necessary to develop a European assessment framework for 'safe and sustainable by design' chemicals and materials, that can assist in the definition of safety and sustainability criteria, to guarantee coherence between actors, sectors and value chains.

(12) The envisaged framework should make it possible to comprehensively assess the safety and sustainability of chemicals and materials throughout their life cycle and support the design, development, production and use of chemicals and materials that provide a desirable function or service while being safe and sustainable. The application of the framework will make possible the definition of 'safe and sustainable by design' criteria which should help set high standards for the safety and sustainability of chemicals and materials.

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8 COM(2020)98 final

9 COM(2021)400 final

10 COM(2022)142 final

11 COM(2022)141 final

12 Eurobarometer survey (2020) Attitudes of Europeans towards the Environment – March 2020, https://europa.eu/eurobarometer/surveys/detail/2257

13 https://echa.europa.eu/candidate-list-table

14 COM(2022)142 final

15 European Commission 2021, Mapping study for the development of Sustainable by Design criteria, https://op.europa.eu/en/publication-detail/-/publication/f679c200-a314-11eb-9585-01aa75ed71a1/language-en

(13) The review of safety and sustainability dimensions, aspects, methods, indicators and tools[16], that is the root of the Annex to this Recommendation, although referring to a number of additional socioeconomic sustainability aspects, focuses mainly on chemical safety and environmental sustainability. Assessments of socio-economic aspects, beyond those considered already, may be necessary in order to provide additional information and enable more informed decisions, in particular when promoting substitution. Such considerations can be taken into account in the application of the framework, whenever relevant.

(14) The aim of the envisaged 'safe and sustainable by design' framework is to be at the forefront of research and innovation, and to promote use of the latest scientific knowledge to meet the highest levels of ambition for safety and sustainability in innovation.

(15) The framework should aim to become a global reference for innovation in pursuit of the green industrial transition; for substituting as much as possible the production and use of substances of concern; for promoting the use of sustainable resources and feedstock for the production of chemicals and materials; for minimising the impact of the production and use of chemicals and materials, throughout their life cycle, on the climate, on the environment, and on human health; and for driving industry's and public authorities' R&I investments in the right direction.

(16) This Recommendation proposes a European 'safe and sustainable by design' framework as a point of reference for Member States, industry, academia, research and technology organisations (RTOs) and bodies providing benchmarks for safe and sustainable chemicals and materials.

(17) This Recommendation sets a testing period for the framework with a voluntary reporting mechanism for Member States and stakeholders during this testing period. A revision process of the framework will be launched at the latest by the end of the testing period. Based on feedback collected during the testing period, the Commission will consider including in the assessment additional safety and environmental aspects, as well as economic and social sustainability aspects as an additional facet when relevant.

(18) As stressed in the Chemicals Strategy, greater public and private investments in providing safe and sustainable chemicals, and a greater capacity to innovate on the part of the chemicals industry, will be vital for developing new solutions and supporting both the green and digital transitions. The vision for 2030 that lies behind this Recommendation should therefore ensure that future European, national and international initiatives for safe and sustainable chemicals and materials are grounded in the proposed framework. The Commission will promote this Recommendation in international fora.

(19) To provide incentives for testing the framework and, in particular, address substances of concern , the Commission will support the testing period. This will be done in particular through actions in the Horizon Europe framework programme for the development of 'safe and sustainable by design' chemicals and materials, and the

[16] Caldeira, C., et al. Safe and Sustainable by Design chemicals and materials. Review of safety and sustainability dimensions, aspects, methods, indicators, and tools, EUR 30991 EN, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-47560-6 (online), doi:10.2760/879069 (online), JRC127109. 2022

development and improvement of testing methods and assessment tools to expand the assessment possibilities the framework has to offer.

(20) The Commission has also developed a Strategic Research and Innovation Plan for safe and sustainable chemicals and materials[17], identifying key research and innovation areas in the life cycle (design, production, use and disposal/recycling/remediation) of chemicals and materials to facilitate and support at European and national level the industrial transition towards safe and sustainable chemicals and materials.

(21) The Commission, aware of the data needed to implement the envisaged framework, will continue promoting findable, accessible, interoperable and reusable (FAIR) data. The Commission is also developing an EU common data platform on chemicals[18] to facilitate the sharing, access and re-use to existing data used in Union legal acts related to chemicals.

(22) This Recommendation respects the principle of subsidiarity as the envisaged 'safe and sustainable by design' framework serves the needs of the European Research Area and the single market for chemicals and materials, where there is a need for common understanding at European level of safety and sustainability for chemicals and materials. It also respects the principle of proportionality as it combines the establishment of the framework with a period of testing by non-legally binding means, without detracting from any existing or future (Union) legislation on chemicals and materials.

HAS ADOPTED THIS RECOMMENDATION:

1. PURPOSE AND SCOPE

1.1. This Recommendation proposes that a European framework for 'safe and sustainable by design' chemicals and materials be established for R&I activities. The details of the testing period and the framework, based on technical reports from the Commission's Joint Research Centre[19,20], are set out in the Annex to this Recommendation.

1.2. The envisaged framework consists of methods for assessing the safety and sustainability aspects of a chemical or material. The results obtained from applying the framework will make it possible to define 'safe and sustainable by design' criteria, including scoring systems and thresholds developed based on the results obtained. The process of criteria definition will be launched in parallel with the revision of the framework. The purpose of this Recommendation is to launch the testing of the assessment framework and get feedback to be able to improve relevance, reliability and operability.

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17 European Commission, Strategic Research and Innovation Plan for Safe and Sustainable Chemicals and Materials, Publications Office of the European Union, 2022, ISBN 978-92-76-49115-6, doi 10.2777/876851

18 COM(2020)667 final

19 Caldeira C., Farcal L., Moretti,C., et al. Safe and Sustainable by Design chemicals and materials. Review of safety and sustainability dimensions, aspects, methods, indicators, and tools, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-47560-6, doi:10.2760/879069

20 Caldeira C., Farcal L., Garmendia, I., et al., Safe and sustainable by design chemicals and materials: Framework for the definition of safe and sustainable by design criteria for chemicals and materials, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-53264-4, doi: 10.2760/487955

1.3. This Recommendation is addressed to Member States, industry, including small and medium-sized enterprises (SMEs), academia and research and technology organisations (RTOs) that contribute to or work on the development of chemicals and materials. It invites them to use the framework in their R&I programmes and activities related to chemicals or materials. They are also encouraged to refer to the framework in relevant policy or strategy documents.

1.4. Member States, industry, academia and RTOs should also ensure that the methods, models and data produced and used when applying the framework tally with the findable, accessible, interoperable and reusable (FAIR) guiding principles.

2. USES BY MEMBER STATES

Member States are encouraged to:

2.1. Promote the framework in their national R&I programmes, thereby supporting the testing period with applications and use cases.

2.2. Increase the availability of high-quality FAIR data for assessing safety and sustainability by incorporating this aspect into their national R&I programmes and into related policies when relevant.

2.3. Support the improvement of assessment methods, models and tools, and make new ones available, to integrate into the framework in order to improve the assessment of safety and sustainability.

2.4. Support the development of educational curricula to ensure that the skills required to implement the framework are taught.

3. USES BY INDUSTRY, ACADEMIA and RTOs:

Industry (including SMEs), academia and RTOs are encouraged to:

3.1. Use the framework in their R&I processes for developing chemicals or materials, thereby supporting the testing period.

3.2. Make available high-quality FAIR data for assessing safety and sustainability, without flouting intellectual property rights and, if relevant, security considerations.

3.3. Support the development and making available of new assessment methods, models and tools that can be integrated into the framework to improve the assessment of safety and sustainability.

3.4. Support the development of professional training and educational curricula to ensure the teaching of the skills required to implement the framework.

4. REPORTING ON THE IMPLEMENTATION OF THE RECOMMENDATION:

4.1. Member States, industry, academia and RTOs are encouraged to report to the Commission on the implementation of this Recommendation during the testing period.

4.2. To facilitate their reporting, the Commission will make a reporting template available. The information transmitted should include the following.

- How Member States, industry, universities and RTOs use the framework in their R&I programmes, activities and elsewhere.
- Initiatives and use cases for testing the framework.

- Initiatives for the development of new methods, models and tools for assessing safety and sustainability and how their outcomes can be accessed and used.
- Initiatives for the development of ‘safe and sustainable by design’ chemicals and materials.
- Assessment reports presenting the results obtained from testing the framework.
- Problems and bottlenecks identified with the use of the framework
- Information on the establishment of scoring systems and thresholds that can support setting of ‘safe and sustainable by design’ criteria in a revised framework.

Done at Brussels, 8.12.2022

For the Commission
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Member of the Commission

CERTIFIED COPY
For the Secretary-General

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EUROPEAN COMMISSION