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#### **OUTCOME OF PROCEEDINGS**

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From: General Secretariat of the Council  
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To: Delegations

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Subject: Towards a Sustainable Chemicals Policy Strategy of the Union  
- Council conclusions

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Delegations will find in the [Annex](#) the Council conclusions on the abovementioned Sustainable Chemicals Policy Strategy of the Union, adopted by the Council at its 3705th meeting held on 26 June 2019.

**Towards a Sustainable Chemicals Policy Strategy of the Union**

**- Council conclusions -**

THE COUNCIL OF THE EUROPEAN UNION,

RECALLING:

The Decision of the European Parliament and of the Council on a General Union Environment Action Programme to 2020 "Living well, within the limits of our planet" (7th EAP)<sup>1</sup> for a resource-efficient, green and competitive low-carbon economy and TAKING NOTE of the report on the evaluation of the programme<sup>2</sup>;

The precautionary principle, the principles of preventive action and of rectification of pollution at source and the polluter-pays principle;

The UNGA Resolution of 25 September 2015 on "Transforming our world: the 2030 Agenda for Sustainable Development" and the Sustainable Development Goals (SDGs) directly relevant for the EU chemicals policy which include the protection of human health and the environment, moving towards sustainable production and consumption, promoting sustainable technologies and ensuring the sustainable management of resources;

The United Nations Environment Assembly (UNEA) resolutions 1/5 on chemicals and waste, 3/4 on environment and health, specifically the section on chemicals, 2/7 and 4/8 on sound management of chemicals and waste; the UNEA Ministerial Declaration at its fourth session, entitled "Innovative solutions for environmental challenges and sustainable consumption and production";

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<sup>1</sup> OJ L 354 of 28 December 2013, p. 171.

<sup>2</sup> Doc. 9416/19 - COM(2019) 233 final + ADD 1 and 2

The Global Chemicals Outlook II mandated by UNEA which finds that the global goal to minimise adverse impacts of chemicals and waste will not be achieved by 2020 and that more ambitious worldwide action by all stakeholders is urgently required;

The Strategic Approach to International Chemicals Management (SAICM) with actions and goals laid out in the emerging policy issues and other issues of concern and the intersessional process for a sound management of chemicals and waste beyond 2020;

The Commission's Communications "The combination effects of chemicals - Chemical mixtures"<sup>3</sup>, "On the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation"<sup>4</sup>, "Commission General Report on the operation of REACH and review of certain elements"<sup>5</sup>, "Towards a comprehensive European Union Framework on endocrine disruptors"<sup>6</sup>, "European Union Strategic Approach to Pharmaceuticals in the Environment"<sup>7</sup> and "Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses"<sup>8</sup>;

The resolutions of the European Parliament of 13 September 2018 on "Implementation of the circular economy package: options to address the interface between chemical, product and waste legislation"<sup>9</sup> and of 18 April 2019 on "Towards a comprehensive European framework on endocrine disruptors"<sup>10</sup>;

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<sup>3</sup> Doc. 10923/12 - COM(2012) 252 final  
<sup>4</sup> Doc. 5479/18 - COM(2018) 32 final + ADD 1  
<sup>5</sup> Doc. 6916/18 - COM(2018) 116 final + ADD 1 - 7  
<sup>6</sup> Doc. 14204/18 - COM(2018) 734 final  
<sup>7</sup> Doc. 7680/19 - COM(2019) 128 final  
<sup>8</sup> Doc. 10705/19 + ADD 1 - ADD 3  
<sup>9</sup> 2018/2589(RSP)  
<sup>10</sup> 2019/2683 (RSP)

The Council conclusions on

- Closing the loop - An EU action plan for the Circular Economy;
- Protection of the human health and the environment through the sound management of chemicals;
- Eco-innovation: enabling the transition towards a circular economy;
- Delivering on the EU action plan on circular economy;
- Towards an ever more sustainable Union by 2030;
- Convention on Biological Diversity (CBD) of 2018;

UNDERLINING the decision in the 7<sup>th</sup> EAP to develop by 2018 a Union strategy for a non-toxic environment, emphasized by the Council in its conclusions of 19 December 2016 in which the Commission was also invited to update its 1999 Strategy on endocrine disruptors, and NOTING with concern that the Commission has not delivered on this commitment;

NOTING further that as regards to the chemicals related actions, the Commission has not fully delivered on the commitments in the 7<sup>th</sup> EAP, notably with regard to endocrine disruptors, nanomaterials, combination effects of chemicals and risks related to the use of and exposure to hazardous substances and chemicals in products;

ACKNOWLEDGING the importance to continuously deepen the knowledge about the hazards of chemicals and (eco)toxicological effects and to adequately address the uncertainties regarding the exposure to chemicals, RECALLING the significance of environmental monitoring and human biomonitoring for recording the combined exposure of the environment and humans to chemicals and the unique role of these instruments to identify hitherto unknown exposure to substances problematic for human health and the environment and to control the efficacy of rules and regulations aiming to reduce such exposure; UNDERLINING the urgent need for a sustainably funded structure for applied research in this area. This should embrace inter alia a continuation of existing initiatives in the areas of human biomonitoring, the development and adaptation of test methods in toxicology and the scientific basis for risk assessment and risk management of chemicals;

ACKNOWLEDGING that an evaluation of the impact on the environment, climate or health of other chemical substances, such as pesticides, is carried out in the framework of dedicated processes, such as Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, which is currently subject to a REFIT evaluation, and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides;

HIGHLIGHTING that regulatory cooperation in the chemical sector should safeguard EU standards and principles and the right to regulate, especially as regards human health and the environment, and that free trade agreements should promote the highest possible international standards, particularly those related to health and environment;

1. STRESSES the importance of the process under the Strategic Approach to International Chemicals Management (SAICM) to develop a new enabling framework for the sound management of chemicals and waste beyond 2020, also with a view to helping to meet the Sustainable Development Goals; HIGHLIGHTS the importance of synergies between all existing international and regional conventions on chemicals and waste; URGES the Commission and the Member States to continue to actively contribute to this process, inter alia by preparing clear common positions for the intersessional meetings in order to achieve a crosscutting and holistic long-term approach to sound management of chemicals and waste at the international level, to be considered by all relevant organisations and stakeholders in implementation of the 2030 Agenda, including at the fifth meeting of the International Conference on Chemicals Management (ICCM 5); this provides an opportunity for the EU to contribute to this process in line with its political objectives and rules and on the other hand can be used to draw benefits for an effective sound chemicals and waste management;

2. UNDERLINES the need to improve and mainstream the chemical risk assessment and management of chemicals across EU legislation in order to avoid unnecessary burden and to increase the coherence and effectiveness of the EU chemicals-related legislation to achieve a high level of protection for human health and the environment, especially with respect to the precautionary principle and to the effective protection of workers; SUPPORTS the development and implementation of an early warning system at EU level for identifying new, emerging chemical risks that allows to undertake appropriate actions to protect human health and environment and to implement measures to prevent or control issues of concern;
3. HIGHLIGHTS the importance of reviewing and revising, as appropriate, existing testing requirements to ensure that health objectives of particular relevance for children and other vulnerable groups are adequately, consistently and coherently addressed (e.g. neurotoxicity, impacts on the development of the immune system, endocrine disruption, toxicokinetics etc.) across EU chemicals legislation; HIGHLIGHTS the need to develop a relevant mechanism coordinating the protection of vulnerable groups such as children and pregnant and breastfeeding women, including by introducing consistent risk management requirements into relevant pieces of EU legislation regarding substances of concern, including neurotoxins and endocrine disruptors;
4. UNDERLINES the need of strengthening the science policy interface on chemicals and waste issues, including at international level; HIGHLIGHTS the importance of sustainable research and innovation funding towards improving the scientific understanding of the impacts of hazardous chemicals on the environment, health, biodiversity and eco-system resilience, as well as promoting research on improving methods for the identification of hazards related to chemicals;

5. ACKNOWLEDGES the research programme on human biomonitoring HBM4EU at the interface of science and European chemicals policy, as well as the IPChem initiative (Information Platform for Chemicals Monitoring) and ENCOURAGES a similar research programme on environmental monitoring as well as the improved sharing and use of local, regional, national and EU-level monitoring data both between countries but also between policy areas (e.g. water, chemicals, air, biomonitoring, health, etc.) and relevant institutions; WELCOMES the progress achieved so far in combining and further developing European human biomonitoring activities; REQUESTS the Commission to ensure that these activities can be continued under the new Horizon Europe programme; INVITES Member States and the Commission to stimulate the development of appropriate infrastructure to fully enable that data is Findable, Accessible, Interoperable and Reusable (FAIR) in order to stimulate its reuse and prevent unnecessary duplication;
6. ENCOURAGES promoting approaches, such as green and sustainable chemistry and non-chemical alternatives and embedding key elements of these concepts in the EU chemicals policy through regulatory measures, which reinforce especially the effort to find alternatives for substances of concern, and non-regulatory measures in order to facilitate the development of safe and sustainable chemical and non-chemical solutions, including, among others, promoting the non-toxic circular economy; in this context, INVITES Member States and the Commission to stimulate technical research and the development of appropriate methodologies, service-based business models and other safe by design approaches throughout the entire value chain in the innovation process; UNDERLINES the need to support in particular the efforts of SMEs towards substitution of substances of concern by promoting R&D, investments in sustainable chemicals and technological innovation through EU programmes, including Horizon Europe; STRESSES the right to information in order to enable consumers to make informed choices, as well as the producers, retailers and recyclers in order to move towards non-toxic circular material cycles and to ensure that the use of secondary materials is sustainable;

7. CALLS UPON the Commission to present options to introduce requirements in the relevant pieces of EU chemicals legislation to ensure that the combination effects of chemicals (cocktail effects) and the combined exposure of humans and the environment from all relevant sources are properly and consistently addressed in the risk assessment and risk management processes;
8. STRESSES the need to ensure the effective and efficient work of the European Chemicals Agency (ECHA) by establishing sustainable financing and resourcing for the Agency; UNDERLINES the importance of reinforcing transparency and scientific cooperation with EU and non-EU institutions, as well as other decentralised agencies, to ensure coherence and benefits from synergies and involving ECHA in other legislative areas;
9. INVITES the Commission to assess the possibility to have a mechanism whereby the European agencies should be able to independently undertake, exceptionally and for a very limited number of cases, studies that are complementary to those provided by the industry, notably in controversial cases or when serious doubts emerge, without jeopardising the precautionary and polluter pays principle, in order to strengthen the robustness of the system without compromising the principle of industrial responsibility;
10. REITERATES the Council Conclusions from December 2016 as regards the 7th EAP provisions on developing a clearly defined Union strategy for a non-toxic environment by 2018; therefore, URGES the Commission to develop, without further delay, a Union strategy for a non-toxic environment in close collaboration with the Member States and the Union institutions, in line with all relevant 7th EAP provisions, the broader SDGs and the global objective on the sound management of chemicals and waste and linked to current EU policies to protect the environment, in particular the Circular Economy, and the EU policies on growth, jobs and competitiveness, that proposes clear medium to long term objectives for a comprehensive long-term sustainable EU chemicals policy;



11. STRESSES that the Union strategy for a non-toxic environment should inter alia aim at preventing or minimising the exposure to all substances of concern, especially to substances of very high concern (SVHC), that are put on the market or are released into the environment, in order to prevent or substantially reduce human health and the environment impacts from hazardous chemicals; this strategy should embed the principles of green and sustainable chemistry in EU policy, including cross-sectoral policy approaches, and take into account, inter alia, the REACH Review Report, the chemicals, products and waste interface and its follow-up consultation and the Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH);
12. CALLS upon the Commission to include in its proposal for an 8th EAP, to be adopted early 2020 at the latest, commitments to implement the follow-up measures to the Union strategy for a non-toxic environment and to address forward looking chemical related challenges;
13. REQUESTS the Commission to explore the merits of harmonising definitions, data requirements and test methods, across substances legislation to improve its consistency, efficiency and transparency;
14. UNDERLINES the increasing health and environmental concerns posed by highly persistent chemicals; NOTES in specific the growing evidence for adverse effects caused by exposure to highly fluorinated compounds (PFAS), the evidence for wide spread occurrence of PFAS in water, soil, articles and waste and the threat this may cause to our drinking water supplies; CALLS on the Commission to develop an action plan to eliminate all non-essential uses of PFAS;

## Pharmaceuticals

15. WELCOMES the Commission's Communication on the EU Strategic Approach to Pharmaceuticals in the Environment which identifies six action areas concerning all stages of the pharmaceutical life cycle, where improvements can be made; UNDERLINES the growing evidence that specific pharmaceuticals and their residues found in the soil and water pose a risk to the environment and to human and animal health;
16. STRESSES the importance to accelerate concrete and ambitious actions to reduce the risk from pharmaceuticals and their residues to the environment, while acknowledging that further research is required in order to better understand the extent of the emerging human health and environmental impact of pharmaceutical and their residues; CALLS UPON the Commission to assess and define the most effective measures, including legislative measures, to mitigate the effects of pharmaceuticals in the environment and to combat the development of antimicrobial resistance and to reinforce the link with the health sector in this regard;

## REACH

17. WELCOMES the Commission report on the review of REACH and CALLS for a swift implementation of the action points identified therein;

18. REITERATES the importance of concrete actions by the Commission to ensure the compliance and improve the quality of REACH registration dossiers, as this data is the basis on which all necessary measures will be taken to protect human health and the environment; TAKES NOTE of ECHA's Integrated Regulatory Strategy and CALLS UPON the Commission to monitor its timely implementation; EMPHASISES that all relevant registration dossiers, e.g. those that have been identified in this process as of priority for data generation, should be checked by ECHA for their compliance with the REACH standard data requirements by 2028; UNDERLINES the need for an effective mechanism for the updating of registration dossiers including, for instance, update queries by ECHA where registrations have not been updated for a long time, as well as a measure for accelerating and streamlining the REACH evaluation procedures; CALLS upon the Commission and ECHA, in close cooperation with all stakeholders, to develop by December 2019 an action plan on dossier compliance;
19. CALLS UPON the Commission to improve the REACH authorisation and restriction procedures by enhancing the analysis of alternatives to substitute SVHC and, in particular, to ensure that alternative substances or technologies that are generally available for industry in the EU are quickly phased in, and to avoid regrettable substitution through substances that may create unacceptable risks, and by strengthening the collection and sharing of available information between industry and ECHA; CALLS UPON the Commission and ECHA to refuse authorisation where the information available is not sufficient; and also CALLS UPON the Commission to initiate a general discussion regarding the socioeconomic analysis, the identification and assessment of alternatives, including non-chemical alternatives, the acceptable level of risk compatible with the high level of protection across all regulatory processes, the criticality of uses and the appropriate choice of risk management measures in order to fully exploit authorisation and restriction as means to achieve the phasing out of substances of concern; to facilitate the effective enforcement of the REACH and Occupational Safety and Health (OSH) legislation, STRESSES the need for special attention to ensure coherence with regard to the interface between both legislations;

20. RECALLS that by 2020, all relevant SVHC, including substances with endocrine-disrupting properties of equivalent concern, should be placed on the REACH candidate list and EMPHASISES that also beyond 2020 efforts will be needed to detect possible further SVHC and to continue to ensure full compliance of registration dossiers;
21. REQUESTS the Commission to address the risk and regulatory management of substances of concern in recovered materials under REACH aiming at non-toxic material cycles and the better alignment of chemicals, products and waste policy in order to stimulate a market for high-quality secondary raw materials which uses are safe for human health and environment;
22. UNDERLINES that additional efforts will be necessary to create a proper level playing field for imported articles and articles manufactured in the EU to ensure a high level of protection of human health and the environment, by restricting the use of SVHC in imported articles where such use is not authorised in the EU, and to avoid competitive disadvantages between EU and non-EU companies; CALLS for strengthening the enforcement of REACH by competent authorities and REQUESTS the Commission to study options to facilitate the work of customs authorities, in particular on the TARIC code for substances, mixtures and articles; STRESSES the importance of combatting the illegal trade and trafficking of harmful substances and waste also at global level;
23. INVITES the Commission to consider the simplification of the extended Safety Data Sheets in particular by setting minimum requirements for exposure scenarios and INVITES ECHA to develop methodologies of exposure scenarios for mixtures;
24. REQUESTS the Commission to regularly update Member States and stakeholders on the actions undertaken and the progress achieved on the implementation of the measures set out in the Communication on the REACH review by March 2020;

## **Nanomaterials**

25. STRESSES the need to gather information on uses and exposure regarding nanomaterials and to update and improve risk assessment and validated test methods in this respect; URGES the Commission to finalise the review of the Recommendation on the definition of nanomaterials, revise it as necessary and ensure that nanomaterials are consistently identified and addressed in all legislation by a legally binding definition;
26. NOTES that ECHA in 2017 launched the EU-Observatory on Nanomaterials (EUON) with a mandate until 2020; REQUESTS the Commission to extend ECHA's mandate to collect and make available research data on the characterization, the hazard and potential exposure of nanoforms of substances that were so far not registered under REACH because their yearly tonnage is below the threshold of 1 tonne/year and to regularly ask ECHA to evaluate the performance and the impact of EUON;

## **Endocrine disruptors**

27. URGES the Commission to ensure a high level of protection of human health and the environment by minimising exposure to endocrine disruptors, as endorsed by the 7th EAP, and by stimulating substitution by safer chemicals, as far as technically and practically possible, and to provide, without undue delay, an action plan with clear and concrete measures and an ambitious timeline for doing so;

28. WELCOMES the Commission's initiative to update the data requirements in all relevant legislations in order to improve and accelerate the identification of endocrine disruptors, and URGES the Commission to make this a high priority and with high ambition to allow the identification of substances with endocrine disrupting properties; INVITES the Commission to increase the knowledge base regarding the mechanisms through which endocrine disruption occurs by the development and introduction of Adverse Outcome Pathways (AOP) that support biological plausibility of endocrine disruption; WELCOMES in this respect the establishment of the Endocrine Active Substances Information System (EASIS);
29. URGES the Commission to develop a horizontal approach for the hazard-based identification and risk management of endocrine disruptors taking into account the uncertainties as regards identifying hazards and assessment of risks for chemicals with endocrine disrupting properties; and UNDERLINING the urgent need for special attention regarding cocktail effects and combined exposures of humans and the environment from all relevant sources.