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From: General Secretariat of the Council

To: Permanent Representatives Committee/Council

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REV 4

Subject: Draft Council conclusions on the protection of human health and the
environment through the sound management of chemicals

- Adoption

1. Under the Better Regulation Agenda, the Commission has programmed a REFIT evaluation of REACH, as well as a fitness check of all EU legislation on chemicals except REACH.
2. On a number of other initiatives and papers aimed at improving the EU acquis in terms of sound management of chemicals, such as a strategic approach to pollution of water by pharmaceutical substances, the report on the assessment of chemical mixtures or the review of the Regulation on cosmetic products with regard to substances with endocrine-disrupting properties, however, the Commission failed to deliver on time.

3. Additionally, the outcome of a number of recent international conferences, such as the 70th UNGA session which adopted the 2030 Agenda, the 2nd session of the UN Environmental Assembly of UNEP, the 69th session of the World Health Assembly and the UN Habitat III Conference, have also had an impact on the international agenda for chemicals, health and the environment.
4. Against this background, on 31 October 2016 the Presidency tabled draft Council conclusions on the “Protection of human health and the environment through the sound management of chemicals” ¹.
5. On 8 November 2016, the Working Party on the Environment (WPE) examined the draft Council conclusions, and on 17 November 2016 it discussed them again on the basis of a revised draft prepared by the Presidency ². On 5 December 2016 and following three consecutive informal silence procedures on revised texts ³, the WPE agreed on the text as set out in the Annex to this Note.
6. The Committee of Permanent Representatives is therefore invited to confirm the agreement on the draft Council conclusions as set out in the Annex to this Note and to submit them to the Council (Environment) for adoption at its meeting on 19 December 2016.

¹ Doc. 13788/16.

² Doc. 13788/1/16 REV 1.

³ Docs 13788/2/16 REV 2, 13788/3/16 REV 3 and 13788/4/16 REV 4.

Protection of human health and the environment through the sound management of chemicals

- draft Council conclusions -

EMPHASISING that preserving, protecting and improving the quality of the environment and protecting human health are key EU objectives, pursuant to the provisions of Article 191(1) TFEU;

UNDERLINING that environmental protection requirements must be integrated and a high level of human health protection must be ensured into the definition and implementation of all EU policies and activities, pursuant to the provisions of Articles 11 and 168(1) TFEU;

RECALLING the commitment made at the Johannesburg World Summit on Sustainable Development (WSSD) in 2002 and at the International Conference on Chemicals Management that adopted the Strategic Approach to International Chemical Management (SAICM) in 2006 in Dubai, as reaffirmed in the Rio+20 Outcome Document "The Future We Want" in 2012, to achieve by 2020 the sound management of chemicals throughout their life cycle and of hazardous waste in ways that lead to the minimisation of significant adverse effects on human health and the environment, and ACKNOWLEDGING that further work is needed to fulfil this commitment;

RECALLING the actions and goals laid out in the emerging policy issues and other issues of concern towards sound chemicals management identified under SAICM ¹;

¹ The six emerging policy issues and two other issues of concern identified under SAICM are: Lead in paint, Chemicals in products, Hazardous substances within the life cycle of electrical and electronic products, Nanotechnology and manufactured nanomaterials, Endocrine-disrupting chemicals, Environmentally persistent pharmaceutical pollutants, Perfluorinated chemicals and the transition to safer alternatives, and Highly hazardous pesticides.

RECALLING the 2030 Agenda for Sustainable Development (the 2030 Agenda) and its Sustainable Developments Goals (SDGs) and targets, adopted by the United Nations General Assembly (UNGA) on 25 September 2015, and EMPHASISING in particular the commitments to minimize by 2020 the adverse impacts of chemicals and all wastes on human health and the environment by achieving their environmentally sound management throughout their life cycle; substantially reduce, by 2030, the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination; and improve water quality by reducing pollution, eliminating dumping and minimise release of hazardous chemicals and material in water;

RECALLING Resolutions 1/5 and 2/7 on chemicals and waste, as adopted by the 1st and 2nd sessions of the United Nations Environment Assembly (UNEA) in Nairobi on 27 June 2014 and 27 May 2016 respectively, and EMPHASISING in particular, the vision to achieve the sound management of chemicals throughout their life cycle and of hazardous wastes in ways that lead to the prevention or minimization of significant adverse effects on human health and the environment;

RECALLING the resolution on the health sector's role in the sound management of chemicals adopted at the 69th session of the World Health Assembly (Geneva, 23-28 May 2016) and the chemicals-related provisions of the outcome document adopted at the UN Habitat III Conference (Quito, 17-20 October 2016);

AFFIRMING the importance of the Basel, Rotterdam, Stockholm and Minamata Conventions to ensure protection of humans and of the environment at the global level; UNDERLINING the need to continue promoting and reinforcing the synergies among these instruments and with SAICM; and EMPHASIZING the need to speed up the processes of ratification of the Minamata Convention at the European Union as well as at the Member States' level in order to enable the Convention to enter into force as soon as possible;

RECALLING that the EU chemicals *acquis* has been modernised over the last decade, in particular through the Regulations on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ², Classification, Labelling and Packaging of substances and mixtures (CLP) ³, Plant Protection Products ⁴ and Biocidal Products ⁵, thus providing essential knowledge on hazard properties and risks of chemicals and a broad baseline of protection, thereby contributing to the SAICM 2020 goal on sound management of chemicals;

RECALLING that in order to improve the EU *acquis* in terms of sound management of chemicals; the Commission was expected to develop by September 2015 as far as possible a strategic approach to pollution of water by pharmaceutical substances ⁶; publish by June 2015 the report on the assessment of chemical mixtures ⁷; review by January 2015 the Regulation on cosmetic products ⁸ with regard to substances with endocrine-disrupting properties; and review by June 2013 REACH as regards procedure for authorisation of substances with endocrine disrupting properties; and that the Commission is also expected to propose by September 2017 measures, where appropriate, to address the possible environmental impacts of pharmaceutical substances;

RECALLING the General Union Environment Action Programme to 2020 "Living well, within the limits of our planet" (the 7th EAP) ⁹ and UNDERLINING that the 7th EAP, and its implementation, shall be based on the precautionary principle, the principles of preventive action and of rectification of pollution at source and the polluter-pays principle ¹⁰;

² OJEU L 396, 30.12.2006, p. 1.
³ OJEU L 353, 31.12.2008, p. 1.
⁴ OJEU L 309, 24.11.2009, p. 1.
⁵ OJEU L 167, 27.6.2012, p. 1.
⁶ OJEU L 226, 24.8.2013, p. 1.
⁷ Doc. 10923/12 - COM (2012) 252 final.
⁸ OJEU L 342, 22.12.2009, p.59.
⁹ OJEU L 354, 28.12.2013, p. 171.
¹⁰ Article 2(2) of the 7th EAP.

UNDERLINING the decision in the 7th EAP to develop by 2018 a Union strategy for a non-toxic environment, building on horizontal measures that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions, building on four horizontal measures to be undertaken by 2015 to ensure: (1) the safety of manufactured nanomaterials and materials with similar properties; (2) the minimisation of exposure to endocrine disruptors; (3) appropriate regulatory approaches to address combination effects of chemicals and (4) the minimisation of exposure to chemicals in products, including, inter alia, imported products, with a view to promoting non-toxic material cycles and reducing indoor exposure to harmful substances ¹¹;

UNDERLINING the need to step up efforts to ensure that, by 2020, all relevant substances of very high concern (SVHC), including substances with endocrine-disrupting properties which give rise to an equivalent level of concern, are placed on the REACH candidate list ¹²;

RECALLING that the Commission's Better Regulation Agenda ¹³ aims at delivering economic growth and fostering innovation, competitiveness, SMEs and job creation, the functioning EU Single Market, and ensuring that EU regulation brings added value, while reaching a high level of protection of human health and the environment and respecting existing protection standards;

STRESSING the need to ensure that the EU regulatory framework be transparent, simple and cost-efficient, always ensuring a high level of protection of environment, health, employees and consumers, including the right to information in order to enable consumers to make informed choices and the protection of vulnerable groups such as children and pregnant and breastfeeding women, and supported by general awareness raising of the public on chemicals;

UNDERSCORING that a sustainable EU chemicals policy should build on innovation, respect the precautionary principle and provide for sustainable jobs and growth; and UNDERLINING the importance of coherence and consistency within the regulatory framework in order to meet these objectives;

¹¹ Paragraph 54 (iv) of the 7th EAP.

¹² Article 57(f) of the REACH Regulation.

¹³ Docs 9079/15 - COM(2015) 215 final + ADD 1 + ADD 2.

THE COUNCIL OF THE EUROPEAN UNION

1. STRESSES the importance of its active role in the intersessional process under the strategic approach for international chemical management in order to adopt an ambitious framework by 2020 to ensure the sound management of chemicals and waste beyond 2020; NOTES that the effective sound management of chemicals and waste requires innovative cooperation among all relevant sectors such as environment, health, education, labour, trade, agriculture, water, waste management and industry; and EMPHASIZES the need to develop a long-term vision on future sound management of chemicals and waste that is clearly linked to the 2030 Agenda and the Outcome document on “Strengthening the Sound Management of Chemicals and Waste in the Long Term” incorporated in resolution 1/5 of UNEA;
2. WELCOMES the inclusion, under the Better Regulation Agenda, of a fitness check of the EU chemicals *acquis* in the form of a refit evaluation of REACH ¹⁴ and a fitness check of all chemicals legislation except REACH ¹⁵, and EMPHASISES the importance of this work to ensure a high level of protection for human health and the environment, particularly for vulnerable groups, to secure a coherent and consistent approach across legislations and as a contribution to establishing the factual basis for developing the EU’s non-toxic environment strategy;
3. CALLS UPON the Commission, in its refit evaluation of REACH, to pay particular attention to the following aspects: (1) compliance, quality, sufficiency and usability of the REACH registration information; (2) effectiveness and efficiency of REACH risk management procedures; (3) procedures to remove dossier non-compliances or data gaps; and (4) the stability of financial basis for relevant European Chemical Agency (ECHA) activities post 2018;

¹⁴ http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf (this evaluation is the report mentioned in article 117.4 of REACH).

¹⁵ http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_grow_050_refit_chemicals_outside_reach_en.pdf.

4. CALLS UPON the Commission, in its refit evaluation of REACH and in the parallel fitness check evaluation of all chemical legislation except REACH, to pay particular attention to:
- the coherence between REACH and Occupational Safety and Health legislation, including the methodologies for establishing protective limit concentrations at the workplace, and risk management measures;
 - the fitness of the chemical legislative framework to (1) ensure the safety of manufactured nanomaterials, the minimisation of exposure to endocrine disruptors, appropriate regulatory approaches to address combination effects of chemicals and the minimisation of exposure to chemicals in products, e.g. textiles, including, imported products; (2) encourage innovation and substitution including non-chemical alternatives and to promote sustainable chemistry; and (3) ensure the public's right to information to enable consumers to make informed choices;
 - the identification of possibilities to facilitate implementation, including reduction of compliance costs, in particular for SMEs, while ensuring high level of protection of human health and the environment;
5. WELCOMES the development of a strategic approach to chemicals as part of the Circular Economy package ¹⁶ including analysing and proposing options on the interface between chemicals, products and waste legislation, including on how to reduce the presence and improve the tracking of chemicals of concern in products throughout their life cycle, and NOTES that this work should feed into the non-toxic environment strategy;
6. INVITES the Commission, when developing the strategic approach to chemicals as part of the Circular Economy package, to take into account the 7th EAP and 2030 Agenda provisions to support development of non-toxic material cycles to minimise the adverse effect of all wastes on human health and the environment, as well as the Council Conclusions ¹⁷ on the EU action plan for the circular economy, in particular its paragraphs 11 and 17;

¹⁶ Docs 14972/15 - COM(2015) 614 final + ADD 1.

¹⁷ Doc. 10518/16.

7. NOTES the Commission Communication accompanying its proposal for scientific criteria to identify Endocrine Disruptors ¹⁸; CALLS UPON the Commission to comply with the relevant 7th EAP provisions ¹⁹ when further developing those criteria in order to better protect humans and the environment from endocrine disruptors; and INVITES the Commission to subsequently update as appropriate the 1999 EU endocrine disruptors strategy ²⁰;
8. WELCOMES the launch of the European Human Bio-monitoring Initiative and of the Information Platform for Chemical Monitoring ²¹ as good first steps towards developing a comprehensive chemical exposure knowledge base in line with the 7th EAP ²²;
9. NOTES that given the decline in the number of SVHC dossiers, achieving the objective to list all relevant SVHC in the REACH candidate list by 2020 is at risk, and INVITES the Commission and Member States to take appropriate measures to safeguard the timely realisation of this objective;
10. NOTES with concern that the four horizontal measures ²³ to be undertaken by 2015 in line with the 7th EAP have not been undertaken, and that the Commission is late with the implementation of several legal obligations aimed at improving the protection of human health and the environment;
11. REQUESTS the Commission to report by 30 June 2017 on the progress made in undertaking the four horizontal measures agreed in the 7th EAP and other provisions that have not yet been implemented, and CALLS ON the Commission to accelerate their implementation, in order to enable the relevant conclusions to feed into the future non-toxic environment strategy;

¹⁸ Docs 10442/16 - COM(2016) 350 + ADD 1 to ADD 17.

¹⁹ Paragraphs 50, in particular its 3rd subparagraph, and 54 of the 7th EAP.

²⁰ Doc. 5257/00 - COM(1999) 706 final.

²¹ <https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html> and doc. 9705/16 - SWD(2016) 188 final.

²² Paragraph 73 (iv) of the 7th EAP.

²³ Paragraph 54(iv) of the 7th EAP.

12. CONSIDERS that a clearly defined non-toxic environment strategy must be developed by 2018, complementing the chemicals *acquis* by setting out the EU's chemicals policy for the decade beyond 2020 and therefore constituting, alongside the effective implementation of the EU's chemicals management *acquis*, the EU's main chemicals management contribution to achieving the SDGs by 2030 and implementing the 2050 vision of the 7th EAP;
13. INVITES the Commission to develop a non-toxic environment strategy in close collaboration with the Member States and the Union institutions by 2018, in line with all relevant 7th EAP provisions and the better regulation agenda, taking into account the progress made on the four horizontal measures, the gaps, inconsistencies and inefficiencies identified in the refit evaluation of REACH and in the fitness check of all EU chemicals legislation except REACH, and considering further measures, including non-regulatory measures such as assessing a function on EU-level to support substitution and the development of sustainable chemical and non-chemical substitutes, for a general reduction of chemicals exposure from different sources, in order to provide a high level of protection to the environment and human health.

