EU Institutions - News

17-24 January 2019

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EUROPEAN PARLIAMENT

Endocrine disruptors

- **Summary of the meeting of the Committee on the Environment, Public Health and Food Safety**

Source: European Parliament

22 January 2019

- Exchange of views with the Commission on endocrine disruptors

Mrs JUELICHER, Director from DG SANTE of the EU Commission presented to the Members of the Committee on the Environment, Public Health and Food Safety of the European Parliament, the work of the EU Commission on endocrine disruptors.

She recalled that there is a well-accepted WHO definition of endocrine disruptors: chemicals that have 3 cumulative characteristics:

1- A hormonal function

2- An adverse effect

3- A causality between the two previous points

She then explained that on 7 November 2018, the Commission has adopted a Communication, confirming its commitment to protecting citizens and the environment from hazardous chemicals. The Communication addresses three areas:

- The science of endocrine disruptors
- EU policy and regulation of endocrine disruptors so far
- Taking forward the EU's policy on endocrine disruptors

On **science**, Mrs Juelicher noted that knowledge gaps still exist and that work should help fully understanding combined exposure, if “safe threshold” could be established and developing and validating tests methods.

On the **EU policy so far**, she noted that restrictions and bans have been adopted and that specific provisions on endocrine disruptors are present in specific legislations on REACH, water, pesticides and biocides. She also underlined that over 50 projects on endocrine disruptors have been funded by EU research programmes. The EU Commission is now developing a horizontal approach and updating update of data requirements for the identification of endocrine disruptors across EU legislation.

Regarding the **next steps for EU policy**, Mrs Juelicher reiterated that the EU Commission is committed to follow the precautionary approach. The main objectives of the future work are to:

- minimise overall exposure to endocrine disruptors,
- accelerate the development of a thorough research basis,
- promote an active dialogue allowing all stakeholders to be heard and to work together.

Mrs Juelicher reiterated that there are different approaches in different policies, and it is therefore key to adopt a horizontal approach for all policies.

The Commission will launch a Fitness Check to assess whether relevant EU legislation on endocrine disruptors delivers its overall objective to protect human health and the environment by minimising exposure to these substances. It is the first time that the EU Commission is taking a cross cutting look at endocrine disruptors. The first step of this fitness check will be the publication in the coming weeks of a Roadmap.

Also, in its future framework programme for research and innovation, Horizon Europe, the Commission will continue to ensure the necessary support to research on protecting citizens and environment from exposure to harmful chemicals, including endocrine disruptors, building on the work under the current framework programme, Horizon 2020.

The Commission will also organise a Forum on endocrine disruptors on an annual basis (the first on in 2019). The Forum will allow scientists and public and private stakeholders with expertise on endocrine disruptors to come together to exchange information and best practices, identify challenges and build synergies, in order to inform the Commission's reflections.

Debate with Members of the EU Parliament (MEP):

During the debate, MEPS underlined that the strategy proposed by the EU Commission in November 2018 was not enough, that more was expected under the term ‘Strategy’ than what the EU Commission proposed. MEPs asked for concrete measures and a timeline. According to them, the EU Commission is taking too long, starting now a process of fitness check when a strategy on “A non-toxic environment” was requested by the co legislators by end of 2018.

Also, there are many doubts regarding the relevance of the Forum that the EU Commission wants to organise.

- **Exchange of views between the European Parliament’ Committee on Environment with Ms Grațiela Leocadia Gavrilescu, Romanian Vice Prime Minister, Minister of the Environment**

Source: European Parliament

On 21 January 2019 Ms Graţiela Leocadia Gavrilesc, Romanian Vice Prime Minister, set out the priorities and objectives of the Romania presidency regarding climate change and environmental protection during an exchange of views with the European Parliament's Committee on Environment.

Here below the main points of interest for EUSA:

The Presidency will organise a political debate on **endocrine disruptors**; this topic worries scientists and the public at large. Given the data, ambitious measures need to be taken, taking into consideration the regulation tools to minimise the exposures to these chemicals.
Reusing waste water is an alternative solution to alleviate the pressure on water resources but this needs to be done safely and cost-effectively. In May 2018 the Commission presented a proposal for regulation setting minimum requirements for water reuse for irrigation. The Romania presidency intends to advance negotiations on this file within the Council. The aim is to envisaged a political debate in the Environment Council of March and reach a general approach in the June Environment Council.

Debate with Members of the EU Parliament (MEP):

MEP Françoise Grossetête (France, ALDE) argued that robust criteria to pinpoint **endocrine disruptors, biocide and pesticide**, have been put in place but now there is the need for criteria to identify these substances in a cross-cutting way. The Commission has presented a strategy that still lacks specific measures and it is not so easy to reduce citizens exposure to this noxious substance. She asked whether the presidency is planning to do more in this field.

The Romanian Vice Prime Minister, Graţiela Leocadia Gavrilesc did not reply to the question.

Chemicals

- **Commissioner Vella answers a written question by MEP Guillaume Balas (S&D) on "Consumer protection: breach of the rules on chemical substances"**

Source: European Parliament

Parliamentary written questions are questions addressed by Members of the European Parliament (MEPs) to other European Union Institutions and bodies, with request for a written answer. They are a direct form of parliamentary scrutiny of other EU institutions and bodies.

Question:

Since 2007, the regulation concerning the REACH has stipulated that manufacturers who intend to use chemical substances in their products must first provide information about any hazards associated with the substances and prove that they are safe to use. However, according to a report on the implementation of the REACH Regulation published last week by the German Federal Institute for Risk Assessment (BfR), the information provided by manufacturers is insufficient, missing or non-compliant for 32% of substances placed on the market. These deficiencies are all the more significant when it comes to the risk of ecotoxicological, mutagenic and reprotoxic effects, yet the chemical substances in question can be found in consumer goods, such as furniture, clothing or food packaging, meaning that there is a significant risk to members of the public who come into contact with them.

How does the Commission explain the lack of rigour in evaluating the data?

Does the Commission believe that the European Chemicals Agency has sufficient staff and financial resources to carry out its tasks?

To protect consumers' health, does the Commission intend to remove from the market those consumer products whose chemical substances have not been sufficiently evaluated, until it can be proven that they are safe to use?

Answer:

In the past 10 years, the EU has significantly reduced citizens' exposure to harmful chemicals, such as chromium (VI) compounds, nickel and lead in consumer products and identified 181 chemicals to be phased out. By the registration deadline in May 2018, about 21000 substances in 90000 dossiers were registered at the European Chemicals Agency (ECHA).

1. ECHA carries out compliance checks of registration dossiers that focus on substances which may pose the largest risks for health or environment. When a dossier is assessed as non-compliant, ECHA requests the missing information. ECHA exceeded the legal target of checking at least 5% of dossiers of the high volume substances. The REACH[1] review recognised that the efficiency of the evaluation processes needs to increase and requests to develop remedies, such as revising compliance check targets and procedures.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1.

2. As a follow-up to the REACH review, ECHA's future resource needs are currently being assessed. If necessary, adjustments will be considered.

3. Where REACH is directly relevant to the safety of consumer products, it requires that manufacturers and downstream users take appropriate risk-management measures based on the data in registration dossiers. Non-compliance with information requirement(s) hampers this and the issue is addressed through compliance checks and enforcement by a combined effort of ECHA, Commission and Member States. REACH does not provide for the possibility of removing substances from the market because of potentially non-compliant dossiers that still need to be evaluated.

Products such as food packaging are subject to specific legislation that set out information requirements independent from REACH; therefore, non-compliant REACH dossiers do not affect safety of those products.

Access the information:

http://www.europarl.europa.eu/doceo/document/E-8-2018-005256_EN.html

EUROPEAN CHEMICAL AGENCY (ECHA)

Workers' exposure

- **ECHA to provide recommendations for occupational exposure limits**

Source: ECHA

The European Commission and ECHA have signed an agreement for the Agency to provide recommendations on a regular basis for occupational exposure limits (OELs) that protect workers exposed to hazardous chemicals. The agreement requires ECHA to assess four to five OELs per year from 2020 onwards.

Access the information:
https://echa.europa.eu/-/echa-to-provide-recommendations-for-occupational-exposure-limits

Classification, Labelling and Packaging (CLP) Regulation

- **Consultation on harmonised classification and labelling**

Source: ECHA

ECHA is looking for comments on the harmonised classification and labelling proposals for:

- cypermethrin (ISO); α-cyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; cypermethrin cis/trans +/- 40/60 (EC 257-842-9; CAS 52315-07-8), which has existing harmonised classification and labelling in Annex VI to CLP. Comments are invited on acute toxicity, specific target organ toxicity - repeat exposure and environmental hazard classes; additional information.
- acetamiprid (ISO); (1E)-N-[(6-chloropyridin-3-yl)methyl]-N'-cyano-N-methylethanimidamide; (E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine (EC -; CAS 135410-20-7; 160430-64-8), which has existing harmonised classification and labelling in Annex VI to CLP. Comments are invited on acute toxicity, carcinogenicity, reproductive toxicity and hazardous to the aquatic environment hazard classes.
- thiamethoxam (ISO); 3-(2-chloro-thiazol-5- ylmethyl)-5-methyl[1,3,5]oxadiazi nan-4-ylidene-N-nitroamine (EC 428-650-4; CAS 153719-23-4), which has existing harmonised classification and labelling in Annex VI to CLP. Comments are invited on flammable solids, acute toxicity, reproductive toxicity and hazards to the aquatic environment hazard classes.
- tetrafluoroethylene (EC 204-126-9; CAS 116-14-3). The substance has no existing harmonised classification and labelling in Annex VI to CLP. Comments are invited on the carcinogenicity hazard class.
- (3aS,5S,6R,7aR,7bS,9aS,10R,12aS,12bS)-10-[(2S,3R,4R,5R)-3,4-dihydroxy-5,6-dimethylheptan-2-yl]-5,6-dihydroxy-7a,9a-dimethylhexadecahydro-3H-benzo[c]indeno[5,4-e]oxepin-3-one; 24-epibrassinolide (EC -; CAS 78821-43-9). The substance has no existing harmonised classification and labelling in Annex VI to CLP. Comments are invited on selected physical hazards, on selected human health hazards including acute toxicity, skin corrosion/irritation, serious eye damage, skin sensitisation, specific target organ toxicity - repeat and single exposure, germ cell mutagenicity, carcinogenicity and reproductive toxicity, as well as on hazards to the aquatic environment. For more information, consult the draft assessment report currently under public consultation on EFSA's website.
- carbendazim (ISO); methyl benzimidazol-2-ylcarbamate (EC 234-232-0; CAS 10605-21-7), which has existing harmonised classification and labelling in Annex VI to CLP. Comments are invited on selected physical hazards, skin sensitisation, and hazards to the aquatic environment.

The deadline for comments is 22 March 2019.

Access the information:
https://echa.europa.eu/harmonised-classification-and-labelling-consultation

- **Targeted consultation on harmonised classification and labelling of 10 copper-containing substances**

Source: ECHA

The Committee for Risk Assessment (RAC) has been requested to develop and adopt an opinion on the M-factors for long-term aquatic hazard for 10 copper-containing substances listed in Regulation (EU) 2016/1179.

The targeted public consultation invites comments on the proposed M-factors for long-term aquatic hazard which will be forwarded to the European Commission for inclusion in the existing regulation.

The deadline for comments is 4 February 2019.

Access the information:
https://echa.europa.eu/harmonised-classification-and-labelling-targeted-consultations