ENVI

European Parliament

Committee on Environment, Public Health and Food Safety

CHAIR'S WELCOME

Welcome back! The first ENVI meeting of 2018 will take place on the 11th of January, in Brussels.

In 2017 ENVI members have continued their work to ensure that the EU plays its role to the full in the fight against climate change, in turning the objectives of the Paris Agreement into reality and in delivering the highest environmental, health and food safety standard for all EU citizens. In December we have reached preliminary agreements with Council on key pieces of legislation: on mandatory plans for Member States to compensate for forest losses (land use, land-use change and forestry regulation), on the whole waste package and on the effort sharing regulation. In 2018 we will strive to finalise pending legislation and the new proposals tabled by the Commission such as on Clean Mobility or on the Civil Protection Mechanism. We will also continue to monitor the implications of the Brexit negotiations so as to minimise the disruption for EU citizens in ENVI's areas of competence.

On 23 November the Commission proposed changes to the 2013 Decision on a Union Civil Protection Mechanism which aim to provide a stronger collective response at European level in case of natural disaster and improve prevention and preparedness capacities. The suggested changes would, among others, create genuine EU civil protection assets (rescEU), a shared pool of emergency response resources (the European Civil Protection Pool), EU financing to better equip national civil protection bodies and further the coordination and sharing of national prevention and preparedness strategies. Christos Stylianides, Commissioner for Humanitarian Aid and Crisis Management will appear before the ENVI Committee at our meeting on 11 January to present the proposal.

On the same day we will also consider the draft opinion on the revision of the 'Comitology' regulation. When adopting EU legislation, EP and Council may empower the Commission to adopt non-legislative acts in the form of implementing acts (Article 291 TFEU). The Commission is assisted and controlled by committees consisting of Member States' representatives which may vote to adopt or reject the implementing act. Yet, in sensitive cases – often ENVI-related - Member States tend to skirt their responsibility and avoid taking a stance through the so-called 'no-opinion' (abstention) scenario and thus put the burden back on Commission's shoulders. According to the rapporteur, the political choice of abstaining should not block the 'comitology' system.

Follow our discussions live and get involved in the debate at *http://www.europarl.europa.eu/committees/en/envi/home.html*

Adina-Ioana Vălean

Brussels - 10 January 2018

MEETING ITEMS

Votes:

- Objection pursuant to Rule 106 : The use of bisphenol A in varnishes and coatings intended to come into contact with food
- Early non-objection pursuant to Rule 106: Scheme for greenhouse gas emission allowance trading within the Community. EU Emissions Trading System (EU ETS) Directive

Results of the votes of the last ENVI meeting are available **here**.

Considerations:

- Rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers
- Objection pursuant to Rule 106 : The use of bisphenol A in varnishes and coatings intended to come into contact with food

Exchange of views:

- Exchange of views with Mr Christos Stylianides, Commissioner for Humanitarian Aid and Crisis Management, on Civil Protection Mechanism
- Exchange of views with the Commission on the Commission report on the state of paediatric medicines in the EU - 10 years of the EU Paediatric Regulation

ENVI IN PLENARY

- Governance of the Energy Union (joint ENVI/ITRE)
- International ocean governance

VOTES

Objection pursuant to Rule 106 : The use of bisphenol A in varnishes and coatings intended to come into contact with food

Consideration and vote on draft motion for a resolution (see *meeting documents*)

Bisphenol A (BPA) is used in the manufacture of certain materials and articles intended to come into contact with food. This draft measure limit the use of bisphenol A in varnishes and coatings intended to come into contact with food and amends Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials.

The objectors oppose the draft measure on the grounds that the scope of the measure is not broad enough to ensure a high level of protection

of human health and that the levels set for the migration of BPA cannot be said to be safe and they will as well be difficult to enforce. They therefore call for a ban on BPA in all plastic material and articles, as well as in varnishes and coatings, intended to come into contact with food, and ask for this ban to enter into force without delay. The objectors underlines that only a full ban will be effective and enforceable, and provide certainty for both consumers and industry.

This is a measure falling under the Regulatory Procedure with Scrutiny (RPS); EP has veto right within the deadline set by the Commission - the deadline for this act is 28 January 2018.

Co-Rapporteurs: Häusling (Greens/EFA), Balas (S&D), Ries, Pietikäinen
Shadows: Collin-Langen (EPP)

Early non-objection pursuant to Rule 106: Scheme for greenhouse gas emission allowance trading within the Community. EU Emissions Trading System (EU ETS) Directive

Vote on draft recommendation for a decision to raise no objections (see *meeting documents*)

ETS Aviation Regulation provides that in order to protect the environmental integrity of the EU emissions trading system ("EU ETS"), aircraft operators and other operators in the EU ETS shall be prohibited from using allowances that are issued by a Member State in respect of which there are obligations lapsing for aircraft operators and other operators, and to that end, it empowers the Commission to adopt the necessary safeguard measures with respect to the standardised and secured system of registries, in accordance with the regulatory procedure with scrutiny (RPS).

The European Commission has transmitted to the European Parliament the draft Commission regulation amending Commission Regulation No 389/2013 establishing a Union Registry ("the draft RPS measure"), which opened the three-month scrutiny period for Parliament to object to that draft act. The Commission also submitted a request to Parliament asking that Parliament deliver an early non-objection decision on this RPS measure in order for the safeguard measures in the draft RPS measure to enter into force as a matter of urgency. According to the Commission entrance into force is urgent in order for the measures to take effect, so that allowances can be allocated for free, received in exchange for international credits or auctioned in 2018.

Rapporteur: Girling (ECR)

CONSIDERATIONS

Rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers

Consideration of draft opinion (see *meeting documents*)

On several occasions concerning the adoption of acts which are subject to the comitology procedure, the Commission has found itself in a situation where it is legally obliged to take an authorisation decision in the absence of a qualified majority of the Member States taking position (either in favour or against) in the committee. This 'no opinion' situation is in the Commission's view particularly problematic when it concerns politically sensitive matters, for instance in the field of health and safety of humans, animals or plants (GMOs and Glyphosate are often mentioned as examples). The Commission considers that there is a need to address this issue through limited and targeted changes to the current procedure. It is proposed:

• to change the voting rules for the appeal committee in order to reduce the risk of a no opinion scenario and to clarify the positions of the Member States by considering that Member States which are not present, or which abstain, are 'non-participating Member States' for the calculation of the qualified majority

• to provide for the possibility of a further referral to the appeal committee where no opinion is delivered (this will allow addressing the problematic issues again at the appropriate political level and to this end it is proposed that the Chair may decide to hold a further appeal committee meeting while indicating that the appropriate level of representation for that meeting is at ministerial level)

• to make public the votes of the Member States' representatives in order to increase clarity, and

• to enable the Commission to formally refer specific cases after a no opinion outcome in the appeal committee for a non-binding opinion to the Council, with a view to obtaining its political orientation on the implications of the no opinion outcome, including the institutional, legal, political and international implications.

In her draft opinion, the Rapporteur welcomes the Commission proposal. She also underlines that the system established by Regulation (EU) No 182/2011 has proven to work well in most cases and that the proposed changes by the Commission only concerns the few problematic cases which come before the appeal committee. An aspect that remains to improve is transparency and the Rapporteur therefore proposes a few amendments to increase it. She also proposes a few amendments to make sure that the Parliament is always informed about the acts to be adopted at the same time as the Council and about any position taken in the Council in case a matter is referred to it (as provided for in the Commission proposal). All in all the rapporteur proposes 13 amendments.

Rapporteur: Delahaye (EPP)
Shadows: Kadenbach (S&D), Girling (ECR), Ries (ALDE), Flanagan (GUE/NGL), Staes (Greens/EFA), Pedicini (EFDD)

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EXCHANGE OF VIEWS

Exchange of views with Mr Christos Stylianides, Commissioner for Humanitarian Aid and Crisis Management, on Civil Protection Mechanism

Commissioner Stylianides has been invited in order to present to the ENVI Committee's Members the Commission proposal on amending the Union Civil Protection Mechanism.

The proposal is intended to introduce some targeted changes to Council Decision No 1313/2013/EU on a Union Civil Protection Mechanism, under which the European Union supports, coordinates and supplements the action of Member States in the field of civil protection to prevent, prepare for and respond to natural and man-made disasters within and outside the Union.

The need to strengthen European Civil Protection in the light of disaster trends, including extreme weather, and against the background of internal security concerns, has been - according to the Commission - widely recognised.

The changes contained in this proposal are aimed at achieving the following objectives:

a) Strengthening the effectiveness of prevention action as part of the disaster risk management cycle, as well as reinforcing links with other key EU policies acting in the field of disaster prevention and disaster response;

b) Reinforcing the Union and Member States' collective ability to respond to disasters, and addressing recurrent and emerging capacity gaps, especially with the creation of a dedicated reserve of response capacities at Union level, with decisions on deployment taken by the Commission, which retains command and control (to be known as rescEU). rescEU will be equipped with selected emergency capacities to respond to wildfires, floods, earthquakes and health emergencies as appropriate. Following discussion with Member States, a field hospital that can rapidly be deployed inside or outside the Union as part of the European Medical Corps should also be foreseen for cases of epidemics such as Ebola and Zika. Also, Europe has been hit by numerous terrorist attacks. Making such capacities available at EU level will also help generate economies of scale and reduce costs of procuring the same capacities individually;

c) Ensuring the Union Mechanism is agile and effective in its administrative procedures in support of emergency operations.

Exchange of views with the Commission on the Commission report on the state of paediatric medicines in the EU - 10 years of the EU Paediatric Regulation

The Paediatric Regulation came into force on 26 January 2007. Its objective was to improve the health of children in Europe by facilitating the development and availability of medicines for children. On 26 October 2017 the Commission adopted a report outlining the Regulation's achievements both in public health and economic terms. Figures show that the Regulation has had a positive impact on the development of paediatric medicines, on the authorisation of new medicines, on the use of rewards (limited to 55% of the completed paediatric investigation plans PIPs). However those positive results do not evenly spread among all therapeutic areas, they do concentrate in certain areas, often linked to research priorities in adults rather than children. This shows that the Regulation works best in areas where the needs of adult and paediatric patients overlap. Additional effort is needed to combine the effect of the Regulation with those of the Orphan medicines regulation to address shortcomings in treating rare diseases in children.

The Commission now intends to take a closer look at the combined effects of the Orphan and Paediatric Regulation, through a joined evaluation of those two legal instruments in order to providing results by 2019.

NEWS FROM THE POLICY DEPARTMENT

Recent Publications

- *Workshop proceedings on "Complementary and alternative therapies for patients today and tomorrow"*
- *Briefing on "Personalised Medicine – Current Status"*
- *Workshop proceedings on "An Urgent Strong Antimicrobial Action Plan"*
- *Workshop proceedings on "Autoimmune diseases – modern diseases"*

Upcoming Publications

- Workshop proceedings on "Limits and potential of the public health programme"
- Briefing on the IMO MEPC72 meeting

Upcoming Events

- Workshop on Climate Diplomacy, together with AFET (scheduled for 20 February '18, tbc)

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NEWS FROM THE AGENCIES

European Environment Agency (EEA)

Tracking the environmental performance of industry in Europe: new interactive country profiles. The 33 profiles of the member countries of the EEA (EEA-33) give an updated snapshot of sources of industrial pollution across Europe. The interactive profiles summarise the latest data available (from 2015) related to industry, and cover air and water emissions, waste generation (in this case from 2014), energy and water use. More

European Chemicals Agency (ECHA)

The IUCLID Cloud Services by ECHA now provide detailed, soon multi-lingual guidance on how to build a complete REACH registration dossier for the REACH 2018 deadline. With IUCLID Cloud, registrants can prepare their REACH registration dossier directly online without the need for local software installation. The latest release of IUCLID Cloud includes a step-by-step guide for preparing a REACH 2018 IUCLID dossier, from scratch. This tailored help will be translated into 22 EU languages in early 2018. More

European Food Safety Authority (EFSA)

EFSA has finalized a protocol for sodium dietary reference values (DRVs). The protocol will determine how EFSA's nutrition experts select and use evidence in their assessment. It will be applied to the sections of the scientific opinion covering: the assessment of possible relationships between sodium intake and health outcomes; and the integration of different lines of evidence for setting DRVs. The protocol was completed following a public consultation. A second public consultation will be held in 2019, when the final draft of the scientific opinion is ready. More

European Centre for Disease Prevention and Control (ECDC)

On 6 December 2017, France reported an outbreak of Salmonella Agona in infants <1 years of age linked to consumption of infant milk formula. As of 5 January 2018, the outbreak has affected 35 children in France and one in Spain and the distribution of the potentially contaminated products has been reported to 12 EU countries. A broad recall of infant products, export ban and suspension of placing on the market, have been implemented since the beginning of December 2017 in order to reduce the risk for human infections. ECDC is offering whole genome sequencing services and working with EFSA on a joint assessment of the event. More

European Medicines Agency (EMA)

Orphan medicines in the EU – An overview. EMA published a new fact sheet on rare diseases and the EU orphan designation programme. There are over 6,000 rare diseases and an estimated 30 million people in the EU suffer from one of them. Treating these patients can be very difficult, because there are only few medicines available. This represents a huge unmet medical need and a significant public health challenge. More

Next meeting of the ENVI Committee
24-25 January 2018 (Brussels); For future meetings see *2018 meeting dates*.

Watch online
Watch the Committee meeting live on the *EP web site* or on *Europarl TV*. Past meetings are available via the *EP Live multimedia library* and you can also download the extracts of speeches.

More information
Contact the ENVI Secretariat: *envi-secretariat@europarl.europa.eu* or visit the *website* of the ENVI Committee.

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About the editor:*European Parliament, Directorate General for Internal Policies of the Union, Secretariat of the Committee on the Environment, Public Health and Food Safety - Responsible administrators: Giacomo Fassina, Ioana-Alice Postu. Responsible assistants: Irena Aramina, Elise Hancotte.*