ENVI

European Parliament

Committee on Environment, Public Health and Food Safety

CHAIR'S WELCOME

The next ENVI meeting will take place on 26-27 November, in Brussels.

One of the main goals of the EU health policy is that European patients benefit of safe and high-quality healthcare, including across national borders within the EU, and that they are reimbursed for such healthcare. An important achievement in that regard was the adoption of the Cross-Border Healthcare Directive. That law sets out the conditions under which patients may travel to another EU country to receive medical care and reimbursement. We will discuss the ENVI Committee's draft report which looks into the implementation of the Cross-Border Healthcare Directive. The rapporteur notes reasons for the low patient mobility such as the late implementation of the law by some Member States and low citizens' awareness about their rights to reimbursement. Inter alia, the draft report calls on the Commission and the Member States to work together to drastically simplify reimbursement procedures for patients receiving cross-border care, as well as to invest in the development of accessible and visible national contact points that can provide user-friendly information for patients and health professionals.

In the upcoming meeting we will also exchange views with a representative of the Intergovernmental Panel on Climate Change (IPCC) on findings of the IPCC Special report "Global warming 1.5 C". As part of the decision to adopt the Paris Agreement, the world's governments invited the IPCC to prepare a special report on the impacts of global warming of 1.5 °C. Finalised in October this year, the report will contribute to the international conversation ("Talanoa Dialogue") in which countries check progress and seek to increase global ambition to meet the goals of the Paris Agreement. The report indicates amongst others, that human activities are estimated to have caused approximately 1.0°C of global warming above pre-industrial levels, and that climate-related risks for natural and human systems are higher for global warming of 1.5°C than at present, but lower than at 2°C. It also confirms that limiting global warming to 1.5°C compared to 2°C is projected to lower the impacts on terrestrial, freshwater, and coastal ecosystems. Scientists' assessment proves once more the need for even greater action ahead of the UN Climate summit (COP24) taking place in Katowice, Poland next month, where countries will assess progress towards our global climate goals.

On Tuesday, Members are set to vote on several files related to food safety and public health. In response to the European Citizens Initiative on glyphosate, and specifically to the concerns voiced regarding the studies used in the evaluation of pesticides, the Commission proposed a legislative act aiming to strengthen transparency in the risk assessment process and provide additional guarantees as regards the independence of the studies used by EFSA in risk assessments. The ENVI Rapporteur proposes amongst others, that stringent transparency rules apply for EFSA, in line with those of other EU Agencies.

In similar vein, on Tuesday Members will also vote on an Objection to the increase in the maximum residue limits of acetamiprid, one of the five neonicotinoid insecticides currently approved as active substances in the EU. Neonicotinoids are used to control harmful insects; unlike contact pesticides, which remain on the surface of the treated leaves, neonicotinoids such as acetamiprid, are taken up by the plant and transported throughout the plant (leaves, flowers, roots and stems, as well as pollen and nectar). Acetamiprid is used on a number of plants, pears, peaches as well as on table olives, or olives for oil production. In the draft Objection, the co-rapporteurs express concerns about the increase of the residue limits of acetamiprid. They consider that the use of neonicotinoids represents a risk to wild bees and honeybees, and stress that acetamiprid has negative effects both on human health, resulting from its endocrine disruption effect or neurodevelopment impact, and on the environment.

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 - 26 November 2018

MEETING ITEMS

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

Votes

- Transparency and sustainability of the EU risk assessment in the food chain
- Supplementary protection certificate for medicinal products
- Establishing the Neighbourhood, Development and International Cooperation Instrument
- Accession of the European Union to the Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications
- Action of the Union following its accession to the Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications
- A Europe that protects: Clean air for all
- Natura 2000 violations
- Objection pursuant to Rule 106: maximum residue levels for acetamiprid in certain products

Considerations

- Implementation of the cross-border Healthcare Directive
- CAP Amending Regulation

Exchange of views

- with a representative of Intergovernmental Panel on Climate Change (IPCC) on findings of the IPCC Special report "Global warming 1.5 C"
- with the Commission on the Implementing Regulation regarding the extension of the approval periods of several active substances, including chlorpyrifos
- The European Youth Event (EYE) - "Ideas check" with young people

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VOTES

Transparency and sustainability of the EU risk assessment in the food chain

Vote on draft report (see *meeting documents*)

On 11 April 2018, the European Commission published a proposal for a regulation on the transparency and sustainability of the EU risk assessment in the food chain, amending the General Food Law Regulation ((EC) No 178/2002) as well as eight legislative acts dealing with specific sectors in the food chain: GMOs (cultivation and for Food/Feed uses), feed additives, smoke flavourings, food contact materials, food additives, food enzymes and flavourings, plant protection products and novel foods.

The ENVI rapporteur proposes 63 amendments which aim in particular to align EFSA rules on transparency with those of other agencies, ensure that the stringent requirements for transparency also apply in the areas of risk management and risk communication, extend audit obligations to laboratories in third countries commissioned by European companies to carry out studies, and ensure that there are two representatives of industry and NGOs on EFSA's management board.

A total of 539 amendments were tabled in ENVI (including the 63 amendments in the draft report), 112 amendments in JURI Committee, and 8 amendments in PECH Committee. A total of 22 compromise amendments have been drafted.

Rapporteur: Sommer (EPP)
Shadows: Poc (S&D), Gericke (ECR), Federley (ALDE), Hazekamp (GUE/NGL), Häusling (Greens/EFA), Pedicini (EFDD)

Supplementary protection certificate (SPC) for medicinal products

Vote on draft opinion (see *meeting documents*)

This legislative initiative proposes a limited exception, by means of a 'manufacturing waiver', to the rights that may be exercised by the holder of an SPC under Regulation (EC) No 469/2009. The proposal aims to remedy certain unintended consequences resulting from the SPC regime on EU-based manufacturers of generics and biosimilars, in view of the changes that the pharmaceutical industry has undergone during the last three decades. In particular, the prices of new medicines have increased during the past decades to the point of sometimes being unaffordable for many European citizens, limiting their "right to benefit from medical treatment", as stated in the Charter of Fundamental Rights of the EU.

The rapporteur shares Commission's views and supports the idea to restore the level playing field between EU-based generic and biosimilar manufacturers and non EU-based ones, boosting the competitiveness of EU-based generic and biosimilar manufacturers especially in respect to the export to those countries where no supplementary protection certificate is in place, as well as facilitating Day-1 entry within the Union. The rapporteur not only supports a manufacturing waiver for export, but also supports introducing a stockpiling waiver, giving generic and/or biosimilar manufacturers more incentives to manufacture within the Union and not in third countries.

Members tabled 214 amendments further to the 18 amendments by the rapporteur. 23 compromise amendments have been proposed replacing more than 150 amendments.

Rapporteur: Wölken (S&D)
Shadows: Fjellner (EPP), Krupa (ECR), Meissner (ALDE), Konečná (GUE)

Objection pursuant to Rule 106: maximum residue levels for acetamiprid in certain products

Consideration of motion for resolution (see *meeting documents*)

For acetamiprid, maximum residue levels (MRLs) were set in Regulation (EC) No 396/2005. In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance acetamiprid on table olives and olives for oil production, an application was submitted for modification of the existing MRLs. EFSA concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicant were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. The objectors state that neonicotinoids, including acetamiprid, are "systemic" insecticides, which means that they are sprayed onto plants, which then absorb the chemicals and distribute them throughout the plant, in the tissue, pollen, and nectar.

Objectors recall that on 28 February 2018 EFSA published risk assessment updates for three neonicotinoids – clothianidin, imidacloprid and thiamethoxam – that confirm that most uses of neonicotinoid pesticides represent a risk to wild bees and honeybees, while acetamiprid is one of the five neonicotinoids banned by France, in addition to thiacloprid, and alongside the three neonicotinoids banned in the Union.

Co-rapporteurs: Goddyn, Balas, Ries, Rivasi, Omarjee

CONSIDERATIONS

Implementation of the cross-border Healthcare Directive

Consideration of draft report (see *meeting documents*)

The report intends to analyse the current shortcomings in the implementation of the Cross-Border Healthcare Directive and to make recommendations for the improvement of the directive.

The Rapporteur welcomes the actions taken by the Commission to assess

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whether Member States have transposed the directive correctly, including in the recent 2018 Commission report on the operation of the Cross-Border Healthcare Directive. In respect of funding, the Rapporteur expresses serious concerns about the proposed reduction in funding for the health programme. In respect of patient mobility, he notes that the reasons for low patient mobility are threefold: i) some Member States were quite late implementing the directive; ii) citizens' awareness about their general rights to reimbursement is extremely low and iii) Member States have transposed the directive in ways that could be construed as limiting cross-border healthcare, and asks the Commission to continue the structured dialogues with Member States, providing greater clarity regarding prior authorisation requirements.

The Rapporteur also addresses the reimbursement for cross-border healthcare and asks the Commission and the Member States to work together to assess, realign and drastically simplify reimbursement procedures for patients receiving cross-border care, and to install a one-stop-shop front office.

Rapporteur: Belet (EPP)
Shadows: Wölken (S&D), Krupa (ECR), Ries (ALDE), Pedicini (EFDD), Mélin (ENF)

EXCHANGE OF VIEWS

Exchange with a representative of the Intergovernmental Panel on Climate Change (IPCC) on findings of the IPCC Special report "Global warming 1.5 C"

The Intergovernmental Panel on Climate Change (IPCC) was jointly established by the United Nations Environmental Programme (UNEP) and the World Meteorological Organization (WMO) in 1988. The Panel was established to provide policymakers and other stakeholders with an objective source of information about climate change.

Under the Paris Agreement adopted in December 2015, 197 countries agreed to aim to hold the rise in global average temperature to "well below 2 °C above pre-industrial levels" and to pursue efforts to limit it to 1.5 °C. As part of the decision to adopt the Agreement, the IPCC was invited to prepare a special report in 2018 on the impacts of global warming of 1.5 °C above pre-industrial levels and related global greenhouse gas emission pathways. The report was finalised in October 2018. Its findings show, amongst others, that human activities are estimated to have caused approximately 1.0°C of global warming above pre-industrial levels; global warming is likely to reach 1.5°C between 2030 and 2052 if it continues to increase at the current rate; climate models project robust differences in regional climate characteristics between present-day and global warming of 1.5°C, and between 1.5°C and 2°C.

In this context, pathways limiting global warming to 1.5°C with no or limited overshoot would require rapid and far-reaching transitions in energy, land, urban and infrastructure (including transport and buildings), and industrial systems.

The European Youth Event (EYE) - "Ideas check" with young people

The third edition of the EYE was held in Strasbourg on 1-2 June 2018. 9,000 young European citizens between the age of 16 and 30 gathered to debate and exchange ideas with political decision makers and inspiring personalities (politicians, scientists, artists, entrepreneurs, academics and other experts). The follow-up is one of the events organised in Parliament's committees in order to have an exchange of views on ideas between young people selected by DG COMM and the Members.

As a follow-up to the event in June this year, young European citizens will present at the ENVI Committee meeting their ideas on the following topics:

1. Health - (a) **European Electronic Medical Record** and (b) **Obesity**

2. Waste - (c) **Promoting food donations and avoiding food waste** and (d) **Reducing the use of plastics**

3. Sustainability - (d) **Sustainable cities** and (e) **Green citizenship / eco lifestyle**

A discussion will follow after each topic, where MEPs will respond to the idea-givers. Except for webstreaming, a twitter wall will be active during the event, where followers will be able to react and send in questions live

NEWS FROM THE POLICY DEPARTMENT

Recent Publications

- Briefing on *China's climate policies with an emphasis on carbon trading markets*
- Study on *Guidelines for submission and evaluation of applications for the approval of active substances in pesticides*
- Briefing on the *Global Climate Action Summit*, San Francisco (12-14/09/2018)
- Workshop proceedings on the *Sustainability of Health Systems*
- Workshop proceedings on *Digitalisation and big data: implication for the health sector*

Upcoming Publications

- Study on international climate negotiations in view of COP24 in Katowice
- Workshop proceedings on Cardiovascular diseases and lifestyle

Upcoming Workshops

- On robots in healthcare: a solution or a problem?" (19/02/2019 15-17h)

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NEWS FROM THE AGENCIES

European Environment Agency (EEA)

Why should we care about floodplains? Rivers are much wider than the channels we associate them with. The areas next to rivers, which are only covered by water during floods, are also part of the river system. Known as floodplains, in their natural condition they are an important ecological part of this system: they filter and store water, secure both natural flood protection and the healthy functioning of river ecosystems, and help sustain the high biological diversity present there More

European Chemicals Agency (ECHA)

ECHA's website allows now to track what is happening to a specific chemical substance and save queries from the Search for Chemicals by creating an account and logging into ECHA's main website. By following your substance, you will receive a weekly alert whenever your substance is included or updated in one or more specific regulatory processes (e.g. Candidate List of substances of very high concern, restrictions, etc.). This account will also give access to additional features on ECHA's other websites. More.

European Centre for Disease Prevention and Control (ECDC)

Anni Virolainen-Julkunen was elected Chair of ECDC's Management Board at the Board's meeting on 13-14 November 2018, for a two-year term. Zofija Mazej Kukovič, Management Board member representing the European Parliament, was elected Deputy Chair of ECDC's at the same occasion. Dr Virolainen-Julkunen, MD, PhD, Specialist in Clinical Microbiology, is employed by the Ministry of Social Affairs and Health in Finland and serves there as Ministerial Counsellor. She has been ECDC's Management Board member from Finland since 2011, and has served as Deputy Chair since November 2016. Ms Mazej Kukovič is member of the ECDC Management Board since 2016, and has previously served as Minister of Health of Slovenia and as Member of the European Parliament.

European Food Safety Authority (EFSA)

European Antibiotic Awareness Day took place on 18 November. Fighting antimicrobial resistance is a priority for EFSA. The latest data confirms that across the European Union the number of patients infected by resistant bacteria is increasing and that resistance is a major threat to public health. Prudent use of antibiotics can help stop resistant bacteria from developing and keep antibiotics effective for future generations.

EFSA's scientists are working with the European Centre for Disease Prevention and Control (ECDC) on the latest annual report on resistance levels in bacteria found in humans, food and animals. In 2019, EFSA will also publish a review of current monitoring methods of AMR in animals and food and recommend improvements. EFSA's Panel on Biological Hazards will start work on evaluating the role of the environment in the emergence and spread of AMR through the food chain. More.

European Medicines Agency (EMA)

EMA, the Heads of Medicines Agencies and the Commission are organising a workshop on 28 November 2018 in London to discuss with various stakeholders common key principles to pave the way for implementing electronic product information (ePI) in the EU. The product information of a medicine in the EU includes the package leaflet for patients and the summary of product characteristics (SmPC) for healthcare professionals. The workshop offers a platform to discuss opportunities, needs and concerns identified by different stakeholder groups; ongoing initiatives in the EU; and how ePI fits into other EU and global initiatives. The outcome of the workshop will serve as a basis to draft key principles for the use of ePI in the EU, which will be released for a six-month public consultation in January 2019.

The workshop will be live streamed on EMA's website.

Next meeting of the ENVI Committee : 6 December 2018 (Brussels);
Future meetings: *2018 meeting dates*; *2019 meeting dates.*

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

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

Subscription: Please send an email to *envi-secretariat@europarl.europa.eu*.
To sign up for ENVI committee press releases or for media enquiries, please write to *envi-press@europarl.europa.eu*

Further information sources: The **EP Policy Departments** *publish* studies, notes, information notes and workshop proceedings; To request a hard copy of any publication please contact *Poldep-Economy-Science@europarl.europa.eu*. The European Parliamentary Research Service (EPRS) provides research publications in the area of environment, public health and food safety. You can find all the latest publications on the European Parliament website's *Think Tank* pages.

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: Elise Hancotte, Anna Pawlik, Isabelle Rihani*