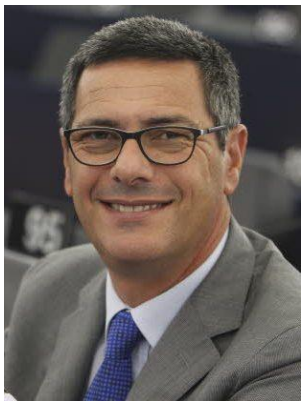
ENVI

European Parliament

Committee on Environment, Public Health and Food Safety

CHAIR'S WELCOME



The next ENVI Committee meetings will take place in Brussels on 7-8 November 2016.

We will vote on draft opinions on logistics and **multimodal transport** in the EU and **psychoactive substances.** An oral question on **paediatric medicines** will also be voted and a draft motion for a resolution on the same issue will be considered. An objection to the approval of the **active substance bentazone** will also be considered and voted.

Additionally, in a joint meeting with the AFET Committee, we will consider a draft report on a **European Union policy for Arctic**. We will also hold exchanges of views with Mr **Geert Dancet,** Executive Director of **ECHA** and Mr **Guido Rasi**, Executive Director of **EMA**.

Moreover**,** I would like to highlight that Mr **Jyrki Katainen, Commission Vice-President for Jobs, Growth, Investment and Competitiveness** will participate in an exchange of views on the **Circular Economy Plan.**

Finally, ENVI will hold discussions with the Commission on the development of the 3rd and 4th **real driving emissions** (RDE) packages.

Giovanni La Via

MEETING ITEMS

Votes:

- Logistics in the EU and multimodal transport in the new TEN-T corridors
- Information exchange, early warning system and risk assessment procedure on new psychoactive substances
- Objection: Renewing the approval of the active substance bentazone
- Oral question on Regulation on Paediatric Medicines

Considerations:

- An integrated European Union policy for the Arctic (jointly with AFET)
- Regulation on Paediatric Medicines
- Objection: Renewing the approval of the active substance bentazone

Exchange of views:

- With Mr Geert Dancet, Executive Director of ECHA
- With Mr Guido Rasi, Executive Director of EMA
- With Mr Katainen, European Commission Vice-President responsible for Jobs, Growth, Investment and Competitiveness, on the implementation of the Circular Economy Plan
- With the Commission on the 3rd and 4th real driving emissions (RDE) package
- With the Commission on Transmissible Spongiform Encephalopathies

Next meeting of the ENVI Committee

28-29 November 2016 (Brussels)
See also the *2016 meeting dates* for future meetings.

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.

Subscription

If you wish to receive the ENVI newsletter, please send an email with your contact details and the subject "newsletter" 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 contact them, write to *Poldep-Economy-Science@europarl.europa.eu*. The **EP Library** regularly prepares briefings summarising information related to topical subjects. Find the latest updates via the links *briefings* and *blog*.

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VOTES

Regulation on Paediatric Medicines

Vote on question for oral answer and consideration of draft motion for a resolution (see *meeting documents*)

The Paediatric Regulation (EC) No 1901/2006 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 aged 0 to 17 years. The Regulation has delivered on many of its goals, but several shortcomings were identified in the progress report adopted by the Commission in 2013.

The resolution calls on the Commission to deliver the foreseen report on its application, including an analysis of the estimated consequences for public health by the end of January 2017. It urges the Commission to consider changes, including through a legislative revision of the Regulation that give due consideration to mechanism-of-action-based paediatric development plans, drug prioritisation models, earlier and more feasible PIPs, and incentives that better stimulate research and more effectively serve the need of the paediatric population.

Co-rapporteurs: Grossetête (PPE), Gentile (S&D), Piecha (ECR), Ries (ALDE), Eck (GUE), Mélin (ENF)

Objection: Renewing the approval of the active substance bentazone

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

The approval of the active substance bentazone expires on 30 June 2017. The draft measure renews the approval of the substance. In accordance with Regulation (EC) No 1107/2009 and in the light of current scientific and technical knowledge, certain conditions and restrictions are included. In particular, there is a requirement in the Annex to provide further confirmatory information.

The objector opposes the draft measure on the grounds that it exceeds the implementing powers provided for in Regulation (EC) No 1107/2009. According to the objector, the Commission's draft implementing regulation fails to apply the precautionary principle and ignores the Ombudsman's proposals to improve the Commission's pesticide approval system.

Rapporteur: Poc (S&D)
Shadows: Jahr (EPP), Girling (ECR), Boylan (GUE/NGL)

CONSIDERATIONS

An integrated European Union policy for the Arctic

Consideration of draft report (Rule 55 with AFET) (see *meeting documents*)

The Commission and the High Representative adopted a joint communication to develop a more coherent framework for EU action and funding programmes for an integrated EU Arctic policy.

The co-rapporteurs welcome the joint communication as a positive step towards a more integrated EU policy. They raise issues related to geopolitics, international cooperation, security challenges and governance in the Arctic region. The EU has committed to achieving Sustainable Development Goals by 2030. Sustainable development is the only feasible way of development in the Arctic region and therefore the EU Arctic policy should reflect better the requirements of individual SDGs in the Arctic context.

The report calls on the Commission and the Member States to take a stronger role in the effective implementation of international conventions. It also states that a way to establish more stringent safeguards for the vulnerable environment as well as for fundamental rights of indigenous people, is through an Arctic specific Environmental Impact Assessment preceding the projects executed in the Arctic region.

Rapporteurs: Paet (AFET/ALDE), Pietikäinen (ENVI/EPP)
Shadows: Gahler (EPP), Schaldenmose (S&D), Jaakonsaari (S&D), Dohrmann (ECR), Fotyga (ECR), Jäätteenmäki (ALDE), Kyllönen (GUE/NGL), Valero (Greens/EFA), Škrlec (Greens/EFA), Castaldo (EFDD), Affronte (EFDD)

EXCHANGE OF VIEWS

Exchange of views with Mr Geert Dancet, Executive Director of ECHA

The annual exchange of views is part of the regular dialogue between the Executive Director of the European Chemicals Agency (ECHA) and the European Parliament. The visit of Mr Dancet gives Members an opportunity to discuss the Agency's Work Programme and in particular its strategic objectives until 2018 which include: maximising the availability of high quality information to enable the safe manufacture and use of chemicals; working with national authorities and stakeholders to identify and address chemicals of concern; tackling current and new legislative tasks efficiently and effectively, while adapting to resource constraints.

As regards the specific legislation under the responsibility of ECHA, the Executive Director will report on progress on the implementation of the Biocides and REACH regulations within the present and future work programmes.

Exchange of views with Mr Guido Rasi, Executive Director of EMA

The annual exchange of views is part of the regular dialogue of the Executive Director of the European Medicines Agency (EMA) with the European Parliament. The visit of Mr Rasi gives Members an opportunity to discuss the Agency's Work Programme 2016 and how it fits into the multiannual work programme of the Agency to 2020.

The multiannual work programme is structured around four themes: human health; animal health and human health in relation to veterinary medicines; the operation of the network and contributions to the global regulatory environment. The 2016 work programme covers all agency activities related to human and veterinary medicines evaluation activities, and more specifically addresses timely access to promising medicines, public health priorities such as antimicrobial resistance, stakeholder requirements for transparency, and key legislation changes including developing implementation for the clinical trials regulation or future changes in veterinary medicines.

Exchange of views with Mr Katainen, European Commission Vice-President responsible for Jobs, Growth, Investment and Competitiveness

Vice-President Katainen is invited to the ENVI Committee to present the progress achieved in **the implementation of the Circular Economy Action Plan** since the first exchange of views on this topic, which took place on 16 March 2016.

The Circular Economy Action Plan makes part of the Circular Economy Package, published on 2 December 2015. The Plan establishes a specific programme of actions to "close the loop"; the measures cover the whole product lifecycle from production and consumption to waste management and the market for secondary raw materials. Specific actions will be taken on plastics, food waste, critical raw materials, and biomass and bio-based products.

The 3rd and 4th real driving emissions (RDE) package

Exchange of views with the Commission

Regulation (EC) 715/2007 requires the Commission to monitor the procedures, tests and requirements for type-approval of light-duty vehicles as well as the test cycles used to measure emissions. These shall be adapted so as to adequately reflect the emissions generated by real driving on the road. This is done with the development of the real driving emissions (RDE) test procedure. The use of portable emission measurement systems (PEMS) and not-to-exceed (NTE) regulatory concepts has been followed.

The 1st RDE package, adopted by the Technical Committee on Motor Vehicles (TCMV) in May 2015, sets out the RDE procedure with PEMS. The 2nd RDE package, adopted in October 2015, sets out the not-to-exceed limits for NOx emissions and tolerated divergences for PEMS test results ("conformity factor"). The 3rd RDE package will contain quantitative requirements for particle number and provisions for cold starts, and the 4th RDE package will contain in-service-conformity requirements.

Additionally, the Commission will present progress on the development of guidelines on defeat devices, which use was brought to light by the Volkswagen scandal last year.

Transmissible Spongiform Encephalopathies

Exchange of views with the Commission

TSEs (Transmissible Spongiform Encephalopathies) are a family of diseases occurring in humans and animals and are characterised by a degeneration of brain tissue. The family includes Creutzfeldt Jakob Disease (CJD) in humans, and Bovine Spongiform Encephalo-pathy (BSE) in cattle.

Regulation (EC) No 999/2001 forms the legal basis for almost all legislative actions on TSEs. It casts all adopted BSE measures into a single, comprehensive framework, consolidating and updating them in line with scientific evidence and international standards. It applies both to live animals susceptible to TSEs and the animal products derived from them. The purpose of the TSE legislation is to protect the health of consumers and animals and to eradicate TSEs. In addition, all live animals presented for slaughter must undergo a veterinary inspection to ensure that suspected cases do not enter the food and feed chain.

Each Member State has to carry out an annual monitoring programme for TSEs based on active and passive surveillance. Since 2001, Member States have published their reports on the monitoring and testing. The Commission published two TSE Roadmaps, in 2005 and 2010, assessing the need for possible future amendments to BSE measures and reviewing existing measures to adjust them to the current situation in the EU. This exchange of views with the Commission will allow to address ongoing and possible future initiatives on TSE, and to discuss the current challenges linked to the implementation of the TSE Regulation and the two TSE roadmaps.

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NEWS FROM THE POLICY DEPARTMENT

Recent Publications

- Implementing the Paris Agreement – Issues at Stake in View of the COP 22 Climate Change Conference in Marrakesh
- Links between Pharmaceutical R&D Models and Access to Affordable Medicines

Upcoming Publications

- Briefing on Climate action and the Emissions Trading System in China
- Proceedings of the Workshop on The fight against cancer is a team sport: The role of education and sport
- Comparative study on the differences between the EU and US legislation on emissions in the automotive sector (for EMIS)

Upcoming event

- 29 November 2016, 12:45-14:45, Workshop on "Exchange of good practice in the field of health promotion and primary prevention". Paul-Henri Spaak 5B001 (ENVI Working Group on Health)

To request hard copy of publication please contact:
Poldep-Economy-Science@ep.europa.eu

NEWS FROM THE AGENCIES

European Environment Agency (EEA)

With fossil fuels still contributing to roughly half of the electricity generated in Europe, moving away from a carbon-intensive power supply will require a commitment to increase investment in clean technology, restructure the fossil fuel energy infrastructure and ensure a secure and affordable power supply. EEA report fills an important information gap by looking at the hypothetical evolution of fossil fuel capacity by 2030 in the absence of strong drivers to counter present trends, and how this evolution would fit in with the need to create a different EU power sector by 2030 and beyond, in line with EU climate goals. More

European Chemicals Agency (ECHA)

ECHA organised its 2016 workshop for Accredited Stakeholder Organisations on 21 October, in Brussels. 48 organizations, comprising of NGOs, trade unions, customer and industry associations, discussed with ECHA what will success look like in meeting the World Summit for Sustainable Development 2020 goals on the sound management of chemicals throughout their lifecycle. The proceedings of the workshop will be published on ECHA's website.

European Food Safety Authority (EFSA)

Building on recent international developments and previous work on pesticides and contaminants, EFSA's scientists have started to develop new approaches for assessing risks to humans and the environment from exposure to multiple chemicals in the food chain: "chemical mixtures" and their "cocktail effects". EFSA is also developing new scientific tools for modelling combined toxicity through joint research projects involving several institutions. More

European Centre for Disease Prevention and Control (ECDC)

ECDC is in charge of the coordination of the European Antibiotic Awareness Day (EAAD), which will be held on 18 November from 09:30 - 13:00 at Residence Palace, 155 Rue de la Loi, Brussels. Speakers will include Commissioner Andriukaitis, and representatives from WHO, ECDC, EMA and EFSA. More

European Medicines Agency (EMA)

Opening up clinical data on new medicines. EMA provides public access to clinical reports for new medicines for human use authorised in the EU. Clinical reports give information on the methods used and results of clinical trials conducted on medicines. "Transparency on clinical data is a longstanding commitment from EMA and today, we are delivering on our promise to give access to the data on which our recommendations are based", explained EMA's Executive Director Guido Rasi. More

About the editor
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