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CHAIR'S WELCOME



At its next meeting in Brussels on 29 January 2015, the ENVI Committee will deal with a very broad range of issues. Members will vote on an opinion on the European Semester as well as on opinions on the 2013 discharge for the general budget of

the European Commission and for the budget of the five Agencies under ENVI's remit (EMA, ECDC, EFSA, ECHA and EEA).

Most of the debates on the agenda will concern food safety and health: Members will consider a draft motion for resolution on a new alcohol strategy and vote on the related question for oral answer, and will consider a draft report on caseins and caseinates; they will also examine a draft opinion on the Ebola crisis, hold the annual exchange of views with Mr Marc Sprenger, Executive Director of ECDC, and discuss clinical trials in third countries with representatives from EMA and the Commission.

Finally, opinions on the state of play of the regulatory fitness and performance programme (REFIT) and on energy security will be considered, and the Committee will hold a debate with young participants in last May's European Youth Event.

Giovanni La Via

MEETING PREVIEW

Discharge 2013: EU general budget, European Commission

Vote on draft opinions (EC, ECHA, EEA, EMA, EFSA, ECDC)



Once a year,
Parliament grants
discharge to the
Commission,
other institutions
and the agencies
in respect of
implementation of
the budget for the

year n-2, after having examined the European Court of Auditors' annual report and the replies from the Commission and the other institutions to its questions. The discharge reports are drawn up by the

budgetary control committee and comprise the **opinions** of the committees concerned.

ENVI will vote on **six opinions** on the annual discharges for the financial year 2013: an opinion for each **agency** that fall under its remit (EEA, ECHA, EMA, EFSA, ECDC) and one opinion on the general budget of the **European Commission**. In all six draft opinions, the Rapporteurs recommended the discharge to be **granted**. In total, 23 amendments were tabled to the draft opinions.

Rapporteur: La Via (EPP)

Shadows: <u>Kadenbach</u> (S&D), <u>Girling</u> (ECR), <u>Gerbrandy</u> (ALDE), <u>Javor</u> (Greens/EFA), Konečná (GUE/NGL), Evi (EFDD)

European Semester for economic policy coordination: Annual Growth Survey 2015

Vote on draft opinion



opinion will The contribute to the owninitiative report by ECON (rapporteur Dariusz EPP), Rosati, which Parliament's provides input into the first phase of the annual cycle of economic policy guidance and

surveillance for 2015, namely the Spring European Council on the Annual Growth Survey (AGS) 2015.

The draft opinion stresses that moving towards a truly sustainable economy will contribute to achieving the Union's environmental goals, giving back the European economy its competitive edge and creating quality jobs. It calls for incorporating a European strategy for sustainable development into the Semester and for stronger investments to achieve the 2020 sustainable growth targets and the 2030 climate and energy targets.

40 amendments have been tabled, mainly relating to using the new **investment plan** in support of the EU's climate and environment policies and exploiting the employment potential of those investments. Other amendments focus on the role of European Semester in guaranteeing **sustainability**, **accessibility and efficiency of healthcare services**. The Rapporteur proposed 2 compromise amendments as regards sustainability of healthcare services and its recognition in European Semester as contributing factor to jobs and growth as well as to improved social cohesion.

Rapporteur: <u>Grammatikakis (</u>S&D) <u>Procedure file</u> Shadows: <u>Melo (EPP), Girling (ECR), <u>Faria</u> (ALDE), <u>Konečná (</u>GUE), <u>Škrlec</u> (Greens/EFA), <u>Mazuronis (</u>EFDD)</u>

Alcohol strategy

Vote on <u>question for oral answer</u> and consideration of <u>motion for a</u> resolution



A first oral question on the alcohol strategy was tabled and debated in ENVI on 25 April 2013, then, in reaction to the Commission's

reply, a resolution on the issue was adopted in ENVI on 12 February 2014. However, the procedure lapsed as the previous legislature ended. In that resolution, the Commission was asked to review its decision to not update the alcohol strategy, to explain whether additional actions are being taken and to produce a report on the application of the requirements to provide information on ingredients and nutrition information to alcoholic beverages by December 2014, as foreseen by Regulation 1169/2011 on the provision of food information to consumers.

The purpose of this additional oral question with resolution is to obtain more information on possible future proposals for a new alcohol strategy, especially as regards the reasons why the abovementioned separate report has not yet been published.

The deadline for amendments is 12 February 2015 and the vote in ENVI is envisaged for 31 March 2015.

Co-rapporteurs: <u>Cirio</u> (PPE), <u>Willmott</u> (S&D), <u>Pretzell</u> (ECR), <u>Faria</u> (ALDE), <u>Omarjee</u> (GUE/NGL), <u>Pedicini</u> (EFDD)

Caseins and caseinates intended for human consumption

Consideration of draft report

The Commission proposes to replace the directive on the approximation of the laws of the Member States relating to caseins and caseinates intended for human consumption with a new directive, in order to align to the Lisbon Treaty the powers conferred to the Commission (delegated/implementing acts), adapt existing provisions to the further developments of food legislation, and adjust the composition requirements of edible caseins to the international standard (Codex Alimentarius).

In his draft report, the Rapporteur broadly endorses the proposal, but suggests to "fine tune" it by means of 5 amendments.

The deadline for amendments is 3 February 2015 and the vote in ENVI is envisaged for 24 February 2015.

Rapporteur: <u>La Via</u> (EPP) <u>Procedure file</u> Shadows: <u>Melior</u> (S&D), <u>Girling</u> (ECR), <u>Huitema</u> (ALDE), <u>Eickhout</u> (Greens/EFA) The Ebola Crisis: the long-term lessons and how to strengthen health systems in developing countries to prevent future crises

Consideration of draft opinion

An outbreak of Ebola virus disease (EVD) has been ongoing in West Africa since December 2013, and the overall situation of the Ebola outbreak in the affected



countries remains **critical**. As of 12 January 2015, WHO has reported 21 427 confirmed, probable, and suspected cases of EVD, with **8 459 deaths**.

According to WHO, in week two of 2015 Guinea reported its lowest weekly number of new confirmed EVD cases since mid-August 2014. Case numbers remain low in Liberia, and Sierra Leone has now reported a decline in case incidence for the second week running. Mali was declared Ebola-free on 18 January 2015.

In its opinion, the rapporteur congratulates the United Nations Mission for Ebola Emergency Response, partner organisations and nongovernmental humanitarian organisations for their work done on the ground, and calls on the Commission to put in place control systems to ensure appropriate allocation of the budget devoted to stop the Ebola outbreak and to strengthen the health systems in the West African countries affected. A particular emphasis is also given to educational and informative actions to raise awareness of symptoms and preventive measures.

The deadline for amendments is 10 February 2015 and the vote in ENVI is envisaged for 26 March 2015.

Rapporteur: <u>Juaristi Abaunz (GUE/NGL)</u> <u>Procedure file</u> Shadows: <u>Collin-Langen</u> (EPP), <u>Cabezón Ruiz (</u>S&D), <u>Piecha (</u>ECR), <u>Bearder</u> (ALDE), <u>Pedicini</u> (EFDD)

European Energy Security Strategy

Consideration of draft opinion



The Commission
Communication on
a European Energy
Security Strategy
outlines a series of
measures to
strengthen the
EU's energy

resilience and reduce its import dependency, in view of the crisis in the Ukraine as well as of the overall importance of security of supply (currently,

the EU imports 53% of the energy it consumes, for about €400 billion).

The rapporteur in her draft opinion stresses that the energy security strategy must include climate and sustainability objectives and calls for a comprehensive approach, linking increased energy security to the transition to a low-carbon economy. The Commission should adopt measures to increase energy efficiency and fully implement existing measures. The rapporteur also emphasises the need to further develop renewable energy sources and related grid and storage infrastructure. She calls for prompt action in transport regarding efficiency and alternative fuels and to cease subsidies for fossil fuels.

The deadline for amendments is 3 February 2015 and the vote in ENVI is envisaged for 18 March 2015.

Rapporteur: <u>Kyllönen</u> (GUE/NGL) <u>Procedure file</u> Shadows: <u>Melo (EPP)</u>, <u>Dalli</u> (S&D), <u>Wiśniewska</u> (ECR), <u>Torvalds</u> (ALDE), <u>Eickhout</u> (Greens/EFA), <u>Pedicini</u> (EFDD)

Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook

Consideration of draft opinion



The REFIT programme is a major Commission initiative aiming to simplify and rationalise the EU regulatory framework. JURI's own-initiative report relates to a

Commission communication which reports on the state of play in implementing the REFIT programme and identifies new actions, and which is accompanied by the first edition of an annual REFIT scoreboard which monitors REFIT initiatives through the legislative process and at the level of Member States implementation. A number of actions mentioned in the communication fall within ENVI competence, such as the withdrawal of the proposal for a soil directive and of the proposal on access to justice in environmental matters; the on-going fitness checks concerning the protection of birds and habitats (Natura 2000) and the General Food Law; and the announced new evaluations and fitness checks on carbon capture and storage, CO2 emissions of vehicles, the noise directive and chemicals legislation other than REACH.

The Rapporteur welcomes the REFIT programme and the scoreboard, as well as the aim of removing unnecessary regulatory burden, but expresses his concern about potential deregulation in the fields of environment, food safety and health. He criticizes the Commission's announcement to withdraw the

proposal on the revision of waste legislation and to modify the proposal on the reduction of national emissions.

The deadline for amendments is 5 February 2015 and the vote in ENVI is envisaged for 26 March 2015.

Rapporteur: <u>La Via</u> (EPP) <u>Procedure file</u> Shadows: <u>Caputo</u> (S&D), <u>Girling</u> (ECR), <u>Meissner</u> (ALDE), <u>Eickhout</u> (Greens/EFA), <u>Affronte</u> (EFDD)

Exchange of views with Marc Sprenger (Executive Director of ECDC)



The Executive Director of the European Centre for Disease Prevention and Control was invited for the annual exchange of views with the ENVI Committee. He will give an overview on the Agency's activities in 2014 and an outlook for 2015.

The topics for discussion may include:

- the activities related to the ebola crisis;
- ECDC's "Rapid Risk Assessments" published in 2014;
- budgetary issues.

Exchange of views with representatives from the European Commission and the European Medicines Agency (EMA) on clinical trials in third countries

A big scandal concerning pharmaceutical products was recently discovered in several EU member states: the company GVK Biosciences in Hyderabad (India) has obviously faked clinical trials on a big scale- a discovery made following an inspection of the company's site by the French medicines agency. Several national authorities have suspended many authorisations of pharmaceutical products in the European Union which have been authorised on the basis of studies carried at the GVK Biosciences site between 2008 and 2014. The suspensions are temporary national measures until the EMA finalises

its review which it commenced in September 2014 and is expected for end of January 2015. The ENVI committee dealt with the issue of clinical trials in



third countries and the lack of surveillance back in 2012, following publications by the British newspaper "The Independent" of investigations revealing that vulnerable populations in India participated in certain drug trials without their informed consent, casting a doubt on both the scientific and ethical value of these tests.

During that debate, members encouraged the European Commission to better control clinical trials in third countries. The **new regulation** on clinical trials that entered into force on 16 June 2014 helps towards solving the problem, as clinical trials in third countries will have to be registered. However, the regulation will be applicable only as of 28 May 2016, so one should make sure that in the meantime the necessary **inspections** are properly done in accordance with the new rules. The ENVI Members will exchange views with representatives from the European Commission and the European Medicines Agency on the current state of the matter. More

Follow-up to the European Youth Event (EYE) - "Ideas check" with young people



The European Youth Event took place for the first time at the European Parliament last May, with the participation of 6000 young Europeans who discussed their ideas for a better

Europe. Seven of the Parliament's committees, including ENVI, have been hosting **follow-up events** in order to exchange views and ideas between young participants in the initiative and Committee Members.

The main topics of discussion will be:

- a zero waste society;
- innovation on new recycling methods;
- changing consumption and production patterns;
- consumer education and citizens' responsibility.



NEWS FROM THE AGENCIES

European Environment Agency (EEA)



Waste prevention: decoupling waste generation from economic growth

Preventing waste is a top priority of waste policy in the European Union with potential

economic and environmental benefits. A new European Environment Agency (EEA) report reviews the state of play in the EU Member States, Iceland, Liechtenstein and Norway. More

European Chemicals Agency (ECHA)



In its **REACH 2018 Roadmap**, ECHA outlines the milestones and support services it plans to give to registrants in the run up towards the final REACH

registration deadline of 31 May 2018. The deadline concerns companies that manufacture or import substances in low volumes, between 1-100 tonnes per year. For this last REACH registration deadline, the Agency is expecting a significant amount of small and medium-sized enterprises to register for the first time. More

European Centre for Disease Prevention and Control (ECDC)



The influenza season has started in Europe, is the conclusion of "Flu News Europe" a joint weekly influenza bulletin published by ECDC and WHO/Europe with the

A(H3N2) virus being the dominant virus which has been associated with more severe diseases than A(H1N1). More

European Medicines Agency (EMA)



In 2014, the European Medicines Agency recommended the highest number of orphan designated medicines for marketing

authorisation in a year. Out of the 82 medicines for human use recommended in 2014, 17 are intended for the treatment of a rare disease among which "Holoclar", the first advanced therapy medicinal product containing stem cells, for approval in the European Union (EU). Holoclar is a treatment for moderate to severe limbal stem cell deficiency (LSCD) due to physical or chemical burns to the eye(s) in adults, a rare eye condition that can result in blindness. More

European Food Safety Authority (EFSA)



EFSA has performed an in-depth reevaluation of Bisphenol A (BPA) exposure and toxicity and published

its results on 21 January. After weighing up a significant body of **new scientific information on its toxic effects**, experts concluded that high doses of BPA (hundreds of times above the tolerable daily intake) are likely to adversely affect the kidney and liver; it may also cause effects on the mammary gland in animals. Experts found, that exposure from the diet or from a combination of sources are considerably under the tolerable daily intake. EFSA concludes that BPA poses **no health risk** to consumers of any age group at current exposure levels. More

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Do you need more information?

 ${\it Contact\ the\ ENVI\ Secretariat:}\ \underline{\it envi-secretariat@europarl.europa.eu}\ or\ visit\ the\ \underline{\it website}\ of\ the\ ENVI\ Committee.$

Next meeting of the ENVI Committee

23-24 February 2015 (Brussels)

See also the <u>2015 meeting dates</u> for future meetings.

Further information sources

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