

ENVI-News

Newsletter from the European Parliament Environment, Public Health and Food Safety Committee

Meeting in Brussels

Monday 25 January 2010, 3.00 - 6.30 p.m.
 Tuesday 26 January 2010, 9.00-12.30 p.m.
 and 3.00-6.30 pm
 Wednesday 27 January 2010, 9.00 - 12.30 p.m.



**WE WOULD LIKE TO WISH
 ALL OUR READERS A HAPPY
 AND HEALTHY 2010!**

LEGISLATIVE WORK

ENVIRONMENT

➤ **PROTECTION OF THE COASTS AND WATERS OF THE NORTH-EAST ATLANTIC AGAINST POLLUTION**

*Consultation (2009/0120(CNS))
 Consideration of draft report*

The ENVI committee will consider a draft report on the 'Additional protocol to the cooperation agreement for the protection of the coasts and waters of the North-East Atlantic against pollution' (Anna Rosbach, EFD, DK).

The Lisbon Agreement on the mutual assistance and cooperation between Member States in the case of marine pollution was signed on 17 October 1990 by Portugal, Spain, France, Morocco and the European Community but

Morocco and Spain never ratified it because of a territorial dispute over the southern borders in Western Sahara (Article 3(c)). Consequently, the Agreement never entered into force.

This dispute has been settled recently in an Additional Protocol which has been signed by all the Contracting Parties but should now also be ratified.

Vote in plenary: April 2010

PUBLIC HEALTH

➤ **PHARMACOVIGILANCE (AMENDMENT OF REGULATION (EC) No 726/2004 and AMENDMENT OF DIRECTIVE 2001/83/EC)**

*Co-decision - first reading
 (2008/0257+ 0260(COD))
 Consideration of draft reports*

The ENVI Committee will consider two draft reports on Pharmacovigilance (Linda McAvan, S&D, UK).

The Commission aims at strengthening and rationalizing the Community pharmacovigilance system of medicinal products for human use through the amendment of the two legal acts governing this field, Regulation (EC) No 726/2004 and Directive 2001/83/EC.

The Commission proposals ensure clearer roles, responsibilities and obligations for the different actors. They rationalise the EU decision-making, enhance transparency and communication on medicines in order to improve trust and understanding of patients, health care professionals, companies and all the other parties involved. They also ensure a proactive and proportionate collection of high quality data which are relevant to the safety of medicines. Finally they also involve stakeholders in the pharmacovigilance process and simplify the procedures.

In his report, the rapporteur proposes amendments aiming at keeping the national

authorities as key players, strengthening the role of the EUDRAVIGILANCE database, strengthening the role of the patients enhancing the transparency and improving the communication on adverse reactions.

Vote in plenary: 15-16 March or 6-7 April 2010

➤ **FALSIFIED MEDICINAL PRODUCTS
(AMENDMENT OF DIRECTIVE
2001/83/EC)**

*Co-decision - first reading (2008/0261(COD))
Consideration of draft report*

The ENVI Committee will consider a draft report on falsified medicinal products (Marisa Matias, GUE/NGL, Portugal).

There is an increase in the EU of medicinal products which are falsified in relation to their identity, history or source. The existing provisions of Directive 2001/83/EC on the Community code relating to medicinal products for human use are in some respects insufficient to address this problem. The Commission therefore inter alia proposed certain obligations for other players than wholesale distributors; a legal basis for the Commission to render obligatory specific safety-features; a prohibition in principle of manipulating safety features on the packaging; obligatory audits of supplying wholesale distributors of medicinal products; strengthened rules for imports from third countries and for inspection.

The draft report inter alia better clarifies the definitions and responsibilities, it proposes sanctions equivalent to sanctions against other organised criminal activities, and it aims at also preventing the export of falsified medicines from the European Union. Furthermore it includes provisions to deal with the selling of falsified medicines through the internet, which is considered to be a key source and which is not covered by the Commission proposal.

Deadline for amendments: 9 February

Vote in committee: 7 April 2010

Vote in plenary: May II 2010

➤ **STANDARDS OF QUALITY AND
SAFETY OF HUMAN ORGANS
INTENDED FOR
TRANSPLANTATION**

*Co-decision - first reading (2008/0238(COD))
Consideration of draft report*

The ENVI Committee will consider a draft report on standards of quality and safety of human organs intended for transplantation (Miroslav Mikolášik, PPE, Slovakia).

The regulatory approach of this proposed directive is based on a framework model, ensuring that national legislation is put in place to deal with key aspects of organ donation and transplantation but without prescribing detailed policy measures. The Directive will ensure that quality and safety structures are in place. These will facilitate the conditions for organ exchanges and ensure a basic level of quality and safety for all patients in Europe. The Directive, given its binding nature, will support and trigger the implementation of key priority actions of the *Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States* (See further down).

Deadline for amendments: 11 February

Vote in committee: 16 March

Vote in plenary: April

FOOD SAFETY

➤ **FOOD INFORMATION TO
CONSUMERS**

*Co-decision - first reading (2008/0028(COD))
Consideration of amendments*

The ENVI Committee will consider amendments to a draft report on Food information to consumers (Renate Sommer, PPE, Germany).

The proposal is aiming at modernising, simplifying and clarifying the current food labelling scene, in particular: Recasting of the different horizontal labelling provisions by merging various directives into a single piece of legislation (regulation); Introduction of clear principles to draw a clearer borderline between mandatory and voluntary information, including clarification of the responsibilities regarding

food labelling for the different food business operators along the supply chain; Introduction of a minimum print size for mandatory information on the label; Introduction of a requirement that information on allergenic ingredients should be available for non-pre-packed foods sold through retail and catering outlets; Differentiated provisions regarding labelling of the country of origin or place of provenance of a food.

The proposal makes nutrition labelling mandatory in the principal field of vision of a food label. It allows for the development of best practice in the presentation of nutrition information, including alternative forms of expression of the nutrition information in relation to overall daily nutrient requirements or graphical forms of presentation.

The main controversial political issues are related to mandatory and/or voluntary information and the design of labelling.

After the vote in ENVI, a number of technical adaptations to the Lisbon Treaty need to be implemented, such as adaptation of the legal basis and adaptation to the delegated and implementing act procedures.

Vote in committee: 15-17 March

Vote in AGRI (associated): 27 January

Vote in IMCO (associated): 8 February

Vote in plenary: May

NON-LEGISLATIVE WORK

➤ ADAPTING TO CLIMATE CHANGE

Consideration of draft own initiative report (2009/2152(INI))

The ENVI Committee will consider an own initiative draft report on the White Paper: 'Adapting to climate change: Towards a European framework for action' (Vittorio Prodi, S&D, Italy).

The White Paper sets out a framework to reduce the EU's vulnerability to the impact of climate change. The draft report focuses on the following points: Developing the knowledge base; integrating adaptation into EU policies, such as Water, Agriculture, Soil, Health, Infrastructure, Biodiversity and Cultural Heritage; Structure and governance; Financing.

Deadline for amendments: 12 February

Vote in committee: 16 March

Vote in plenary: April

➤ ACTION PLAN ON ORGAN DONATION AND TRANSPLANTATION

Consideration of draft own initiative report (2009/2104(INI))

The ENVI Committee will consider a draft own initiative report on the 'Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States' (Andrés Perello Rodríguez, S&D, Spain). Large differences in organ donation and transplant rates exist within the EU, ranging from 34-35 donors per million people (pmp) in Spain to less than 1 pmp in Bulgaria. These differences cannot be easily explained and it is clear that some organisational models are performing better than others. Cooperation between Member States should focus on identifying the most efficient systems, sharing experience and promoting best practice as well as supporting Member States whose transplant systems are not yet sufficiently developed. The Action Plan sets out a collaborative approach with ten priority actions. It is based on the identification and development of common objectives, agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.

Deadline for amendments: 11 February

Vote in committee: 16 March

Vote in plenary: April

OPINIONS

➤ SUSTAINABLE DEVELOPMENT OF EUROPEAN AQUACULTURE

Consideration of draft opinion (2009/2107(INI))

The ENVI Committee will consider a draft opinion (Kartika Tamara Liotard, GUE/NGL, the Netherlands) to the Committee on Fisheries' own initiative report on 'A new impetus for the Strategy for the Sustainable Development of European Aquaculture'.

The rapporteur highlights in her opinion the fact that several forms of aquaculture have a serious impact on the environment (chemicals, destruction of habitat, competition for space, nutrient contamination etc) and asks the Commission to propose legislation in this field.

She also insists on the animal welfare aspects linked to aquaculture as well as a certification system for sustainable aquaculture. She finally draws the attention to the fact that new production methods or new species used for aquaculture could require a marketing authorisation under the Novel Food Regulation.

Deadline for amendments: 2 February
Vote in committee: 23 February
Vote in plenary: possibly April

➤ **AGRICULTURAL PRODUCT QUALITY POLICY**

Consideration of draft opinion (2009/2105(INI))

The ENVI Committee will consider a draft opinion (Pilar Ayuso, PPE, Spain) to the Committee on Agriculture's own initiative report on the 'Agricultural product quality policy: what strategy to follow?'

The Communication sets out strategic orientations for a framework to simplify future policy on agricultural product policy since the present policy has been developed on "piecemeal" basis. It is, therefore, suggested to develop horizontal guidelines for agricultural product quality certification schemes and to prepare legislative initiatives on geographical indications, traditional specialities guaranteed and marketing standards, including optional reserved terms.

The draftswoman of the opinion takes a critical stand on the proposals regarding geographical indications and obligatory marketing rules. She also criticizes the lack of ideas to promote quality products.

Vote in committee: 25-27 January
Vote in lead committee (AGRI): 22/23 February
Vote in plenary: probably March

➤ **DISCHARGE 2008**

Consideration of draft opinions

The ENVI Committee will consider draft opinions (Jutta Haug, S&D, Germany) to the Budget Committee on the EC general budget, the European Environment Agency, the European Medicine Agency, the European Food Safety Authority, the European Centre for Disease Prevention and Control and the European Chemicals Agency.

The rapporteur in her draft opinion considers the implementation of the general EU budget in the fields of environment, public health and food safety. In overall terms, the implementation rates in 2008 have been satisfactory. She is therefore in favour of granting discharge to the Commission.

Deadline for amendments: 1 February
Vote in ENVI committee: 23 February

➤ **SECURITY OF GAS SUPPLY**

Consideration of draft opinion (2009/0108(COD))

The ENVI Committee will consider a draft opinion (Bogusław Sonik, PPE, Poland) to the Industry, Research and Energy Committee on the security of gas supply.

The Russian-Ukrainian gas crisis in January 2009, when 30% of Europe's import was cut off for two weeks, made it clear that under the present circumstances of increasing import dependence and growing supply and transit risk, the current Directive on the security of gas supply is no longer sufficient and its review is necessary. The current proposal aims at increasing the security of gas supply by creating incentives for investment into the necessary interconnections to meet the N-1 indicator and the reverse flows. (The N-1 indicator refers to the situation where "in the event of a disruption the of the largest gas supply infrastructure, the remaining infrastructure has the capacity to deliver the necessary volume of gas to satisfy the demand (...)".)

The proposal was based on Article 95 of the "old" Treaty. On 2 December 2009 the Commission adopted a communication to adjust certain pending proposals to the Lisbon Treaty and changed the legal base of this proposal to Article 194(2) of the TFEU.

Vote in lead committee (ITRE): 22 February
Vote in plenary: March II

➤ **INVESTMENT PROJECTS INTO ENERGY INFRASTRUCTURE**

Consideration of draft opinion (2009/0106(CNS))

The ENVI Committee will consider a draft opinion (Mario Pirillo, S&D, Italy) to the

Industry, Research and Energy Committee on Investment projects into energy infrastructure within the European Community.

The proposal is to revise the current system of notification on energy investment projects: it aims at gathering adequate information on planned investments and major decommissioning projects in order to enable the Commission to monitor the situation of the infrastructure and to forecast potential problems.

The proposal was based on Article 284 of the "old" Treaty. On 2 December 2009 the Commission adopted a communication to adjust certain pending proposals to the Lisbon Treaty but this proposal was left unchanged. Following the renumbering of the Treaty articles, the legal base of the proposal is now Article 337 of the TFEU.

Vote in lead committee (ITRE): 4 February

Vote in plenary: February II (tbc)

ORAL QUESTIONS

- **ORAL QUESTION 2010/03 ON EU MANAGEMENT OF THE PANDEMIC (H1N1)**

Exchange of views with Commission representatives

RESOLUTIONS

- **CONVENTION ON INTERNATIONAL TRADE IN ENDANGERED SPECIES OF WILD FAUNA AND FLORA (CITES) - COP 15**

Adoption of motion for resolution

EXCHANGE OF VIEWS

On **Tuesday afternoon at 3.00 p.m.** the ENVI Committee will hold an exchange of views with **Trinidad Jiménez**, Spanish Minister for **Health**.

On **Wednesday morning at 11.00 a.m.** the ENVI Committee will hold an exchange of views with **Elena Espinosa**, Spanish Minister for **Environment and Agriculture**.

DELEGATIONS

- **REPORT BACK OF THE EP DELEGATION TO THE UN CLIMATE CHANGE CONFERENCE IN COPENHAGEN**

EUROPEAN ENVIRONMENT AGENCY

- **INTERNATIONAL YEAR ON BIODIVERSITY**

Biodiversity is life. Biodiversity is our life. To celebrate the launch of the International Year of Biodiversity on 11 January, the European Environment Agency (EEA) is commencing a series of concise, thematic assessments of biodiversity. The first of these '10 messages for 2010' presents the interaction between climate change and biodiversity.

Read more ...

http://www.eea.europa.eu/highlights/biodiversity-is-life-biodiversity-is-our-life?&utm_campaign=biodiversity-is-life-biodiversity-is-our-life&utm_medium=email&utm_source=EEASubscriptions

Dates of next meeting:

- Brussels, 23 February 2010, 9.00-12.30 and 3.00-6.30 pm