

CHAIR'S WELCOME



The next ENVI meeting will take place on 19 March 2024.

First, I would like to update you on the latest development since last newsletter. On Monday 11 March, during an extraordinary ENVI meeting in Strasbourg, Members exchanged with Commissioner Kyriakides on the implications of €1.0 billion funding cut for the EU4Health Programme, decided in the revision of the 2021-2027 Multiannual Financial

Framework (MFF). In its resolution of 24 February 2024 on the draft Council regulation amending Regulation (EU, Euratom) 2020/2093 laying down the multiannual financial framework for the years 2021 to 2027, the Parliament has expressed its concerns on this decision which risks to undermine preparedness for any further pandemic and curtail the Union's ability to support public health systems. During the same meeting, we have also voted on important provisional agreements reached with Council, such as on the Mercury Regulation, the Directive on the treatment of Urban Wastewater, the Union Certification Framework for Carbon Removals and the revision of the Ambient Air Quality and Cleaner Air Directive. Members also voted on the draft report on the Soil Monitoring Law to promote healthy soils in Europe by 2050, in line with the EU Zero pollution ambition.

On 19 March, we will start with the presentation by the Commission of the so-called "One substance, one assessment package", a legislative package of three proposals which aims to improve the consistency, efficiency and transparency of chemical risk- and safety assessments across EU legislation, strengthening the knowledge base on chemicals and ensuring early detection and action on emerging chemical risks. The package is a pillar of the EU Chemicals Strategy for Sustainability and it will continue to be one of the key priorities in the ENVI committee. ENVI has also invited European Chemicals Agency (ECHA) to present its investigation report on PVC and PVC additives and their effects on the environment and human health. Members will have the opportunity to exchange views with ECHA and the Commission on the outcome and follow-up of this important report.

We will continue our work on climate, with the presentation by the European Environmental Agency (EEA) of the European Climate Risk Assessment (EUCRA), the very first assessment of its kind, to help identify policy priorities for climate change adaptation and for climate-sensitive sectors in the EU.

ENVI will also hold a busy voting session. We will vote on the long-awaited revision of the pharmaceutical framework, with the adoption of the drafts reports on both the Pharma Directive and Pharma Regulation proposals. The aim of this important revision is to ensure greater accessibility, affordability, and availability of medicinal products for all patients across the EU, combat medicines shortages and boost research and innovation in the Union. We will also vote on the provisional agreement reached by co-legislators on the Packaging and Packaging Waste as well as on the draft report on preventing plastic pellet losses to reduce microplastics pollution.

Finally, ENVI will hold the Hearing of Dr Pamela Rendi-Wagner, the candidate-nominee for the function of the Director of the European Centre for Disease Prevention and Control (ECDC), as the mandate of the current Director, Dr Andrea Ammon, will end in June 2024. During the hearing, Members will be able to ask questions on her experience, knowledge and views on the main priorities and activities of the ECDC.

As always, you can follow the ENVI Committee meeting live at: <http://www.europarl.europa.eu/committees/en/envi/home.html>

You can also follow the activities of the ENVI Committee on its official Twitter account @EP_ENVIRONMENT.

MEETING ITEMS

Exchanges of views:

- Joint presentation and exchange of views with the Commission on the "one substance, one assessment" package:
 - Re-attribution of scientific and technical tasks to the European Chemicals Agency
 - Re-attribution of scientific and technical tasks improving cooperation among Union agencies in the area of chemicals
 - Common data platform on chemicals, establishing a monitoring and outlook framework for chemicals
- Exchange of views with the European Chemicals Agency (ECHA) and the Commission on the ECHA Investigation report on PVC and PVC additives
- Exchange of views with the European Environment Agency (EEA) on the European Climate Risk Assessment (EUCRA)- Building resilience of European Societies to climate change risks)
- Exchange of views on the presentation by the European Commission on "Managing risks - protecting people and prosperity"

Hearings:

- Hearing of the nominee for the function of the Executive Director of the European Centre for Disease Prevention and Control (ECDC)

Votes:

- Provisional agreement on the Packaging and Packaging waste (RIES)
- Draft report on preventing plastic pellet losses to reduce micro-plastic pollution (ALBUQUERQUE)
- Draft report on the Union code relating to medicinal products for human use (Pharma Directive) (WEISS)
- Draft report on Union procedures for the authorisation and supervision of medicinal products for human use and rules governing the European Medicines Agency (Pharma Regulation) (WÖLKEN)

ENVI IN THE NEXT PLENARY

Draft agenda of the Plenary available [here](#).

EXCHANGES OF VIEWS

Joint debate on the "one substance, one assessment" package



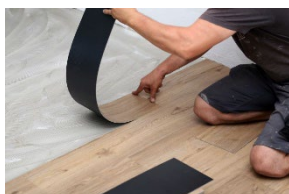
ENVI will hold a joint presentation by the Commission of the "one substance, one assessment" package, followed by an exchange of views. This package comprises three legislative proposals which aim to streamline assessments of chemicals across EU legislation, strengthen the knowledge base on chemical, and ensure early detection and action on emerging chemical risks. It is a

deliverable of the Chemicals Strategy for Sustainability, and the new measures aim at shortening the gap between the identification of a possible risk and the necessary regulatory action.

Under this package, significant tasks are reallocated between four EU agencies. Thus, in this exchange on views, the Commission is expected to focus on three

main topics: Re-attribution of scientific and technical tasks to the European Chemicals Agency; re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals; and a common data platform on chemicals, establishing a monitoring and outlook framework for chemicals. The "one substance, one assessment package" will be further analysed by ENVI in the new legislature term.

Exchange of views and presentation of the investigation report on PVC and PVC additives



ENVI will hold a presentation by the European Chemicals Agency (ECHA) of the investigation report on PVC and PVC additives, and an exchange of views with the ECHA and the European Commission.

This report was prepared following a request by the Commission to ECHA to collect information on the potential risk to human

health and the environment posed by PVC additives and PVC itself. PVC is used in various sectors and uses, including building and construction, electrical and electronic equipment, health services, plastic products, textiles, leather and fur, other miscellaneous consumer articles and vehicles. The investigation focused on a list of 63 PVC additives, the so called 'prioritised additives', out of 470 PVC additives identified as currently in use. According to the report, some substances added to PVC plastic may pose risks to human health and the environment. The conclusions also stress that to reduce risk, regulatory action would be necessary.

Presentation by the Commission of the Communication on "Managing risks - protecting people and prosperity"



The Commission will present its Communication "Managing climate risks - protecting people and prosperity". The Communication underlines the importance of building climate resilience of both EU society and economy. It aims to enable better adaptation and preparation for climate risks to safeguard citizens, their livelihoods, the

competitiveness of our industries and ensure future prosperity.

Specifically, in response to the EU Climate Risk Assessment (EUCRA) report, which will also be presented during the meeting, the Communication outlines several horizontal measures across four categories - including improved governance, tools for risk-owners, harnessing structural policies, and financing climate resilience - to make decision-making processes fit for addressing climate risks. In addition, the Commission proposes a systemic approach to tackle climate risks introducing key actions targeting various impact clusters, such as ecosystems, health, food, infrastructure and built environment, economy and water.

EEA EU Climate Risk Assessment (EUCRA) report



ENVI will exchange views with the European Environment Agency (EEA) on its first-ever assessment of climate change risks facing the EU.

The EUCRA report - released on 11 March - not only highlights 36 major climate risks across every sector such as ecosystems, food, health,

infrastructure, economy and finance, but also outlines priorities for EU policy action, with the aim to support strategic policy making and enhance social preparedness. In this regard, it emphasises that the implementation of effective policies and actions at both European and national level can help reduce potential damages.

Nevertheless, the main findings underline that Europe's climate is changing rapidly and that climate change is a risk multiplier, exacerbating existing risks and crises. Additionally, climate risks are determined by the interaction of climate-related hazards with non-climatic risk drivers and differ substantially within and across regions, sectors and vulnerable groups. In conclusion, the assessment reveals that the EU is unprepared and risks catastrophic losses over the coming decades if action is not taken promptly.

HEARINGS

Hearing of the nominee for the Director of the European Centre for Disease Prevention and Control (ECDC)



After 7 years as Director of the European Centre for Disease Control and Prevention (ECDC), Dr Andrea Ammon's mandate will end in June 2024. Thus, a procedure for future replacement of the Director was initiated. According to the ECDC founding Regulation, the Commission shall propose to the ECDC Management Board a list of candidates,

based on which the Management Board shall make a nomination. This nomination took place in February 2024. The candidate-nominee is Dr Pamela Rendi-Wagner.

The candidate-nominee will appear before the ENVI Committee and present her views regarding the mission of the ECDC, as well as answer Members' questions.

VOTES

Preventing plastic pellet losses to reduce microplastic pollution



ENVI members will vote on the draft report on the proposal on preventing plastic pellet losses to reduce microplastics pollution. On 16 October 2023, the Commission adopted a proposal to address the issue of plastic pellet losses, which are a major source of unintentional microplastics releases into the environment. The text sets out mandatory

requirements, with lighter requirements for micro and small companies, and it aims to ensure that all operators handling pellets in the EU take the necessary precautionary measures at all stages of the supply chain to prevent losses. The proposal is expected to decrease pellet losses to the environment by up to 74%, reducing the burden on environment and human health. In the draft report, among other changes, the rapporteur proposes to better define pellet losses, to add the objective of achieving zero pellet losses, instead of just preventing losses, to add a labelling obligation for all storage and transport containers containing plastic pellets, and to better frame the flexibilities and obligations set to micro and small enterprises.

Rapporteur: [ALBUQUERQUE \(S&D\)](#)

Shadows: [CLUNE \(PPE\)](#), [CHABAUD \(RENEW\)](#), [KELLER \(Greens/EFA\)](#), [KARSKI \(ECR\)](#), [GRISSET \(ID\)](#), [VILLANUEVA RUIZ \(THE LEFT\)](#)

Packaging and Packaging Waste Regulation: Vote on the outcome of the interinstitutional negotiations



ENVI will vote on the provisional agreement, reached on 4 March 2024, on the regulation establishing rules to reduce, reuse and recycle packaging in the EU. The regulation – part of the new Circular Economy Action Plan – aims to address the increase in packaging waste in the EU, enhance safety and boost the circular

economy. The new measures, which cover the entire packaging cycle, include set targets for packaging reductions (5 % by 2030, 10 % by 2035, and 15 % by 2040), banning certain formats of single-use plastic packaging in 2030, as well as prohibiting the use of PFAS chemicals in food-contact packaging. It also introduces reuse targets for several alcoholic and non-alcoholic beverages and refill obligations for operators in the food sector by 2030, including the possibility for consumers to bring their own containers. Other measures include minimum recycled content targets for plastic packaging, increased recyclability requirements, and the establishment of deposit-return systems (DRSs), with the aim of ensuring the annual collection rate of at least 90% of single-use plastic bottles and metal beverage containers by 2029.

Rapporteur: [RIES \(RENEW\)](#)

Shadows: [SALINI \(EPP\)](#), [BURKHARDT \(S&D\)](#), [O'SULLIVAN \(GREENS/EFA\)](#), [SARDONE \(ID\)](#), [FIOCCHI \(ECR\)](#), [PIMENTA \(THE LEFT\)](#)

Pharma Directive: a Union code relating to medicinal products for human use.



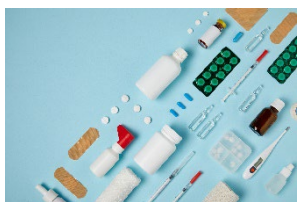
ENVI Members will vote on the draft report on the proposal for a Directive on the Union code relating to medicinal products for human use (Pharma Directive), setting rules for the marketing of medicines in the European Union both at national and Union level. The directive, together with the proposal on Union procedures for the authorisation and supervision of medicinal

products for human use and establishing a European Medicines Agency, is part of the long-awaited Pharmaceutical Package Revision adopted by the Commission on 26 April 2023. 1636 AMs were tabled on the file, while ITRE and JURI adopted an Opinion. Several Compromise Amendments were reached in the negotiations covering the vast majority of the AMs, in particular on access to medicines, the procedures for the environmental risk assessment of medicines (ERA), hospital exemption, enhanced consultation with stakeholders, including pharmacists and patient organisations, and increased transparency of the procedures.

Rapporteur: [WEISS \(PPE\)](#)

Shadows: [GONZÁLEZ CASARES \(S&D\)](#), [AMALRIC \(RENEW\)](#), [AUKEN \(GREENS/EFA\)](#), [KOPCIŃSKA \(ECR\)](#), [KONEČNÁ \(THE LEFT\)](#)

Pharma Regulation: Union procedures for the authorisation and supervision of medicinal products for human use and rules governing the European Medicines Agency,



ENVI Members will vote on the draft report on the proposal for a regulation on Union procedures for the authorisation and supervision of medicinal products for human use and rules governing the European Medicines Agency. The Regulation is part of the long-awaited Pharmaceutical Package Revision adopted by the Commission on 26

April 2023. 1927 AMs were tabled and ITRE, BUDG and AGRI committees delivered opinions. Several Compromise amendments were reached during the

negotiations, covering the vast majority of amendments tabled and covering, *inter alia*, the establishment of an ad-hoc Environmental Assessment working group, the creation of a new European Health Emergency Preparedness and Response Authority (HERA) within the ECDC to boost European research, strengthened provisions to prevent and manage shortages of medicines, increased consultation processes with stakeholders, including patient organisations, regulatory sandboxes to boost innovation, and strengthened provisions on transparency and conflicts of interests.

Rapporteur: [WÖLKEN \(S&D\)](#)

Shadows: [SOKOL \(PPE\)](#), [RIES \(RENEW\)](#), [METZ \(Greens/EFA\)](#), [SLABAKOV \(ECR\)](#), [VISTISEN \(ID\)](#), [KONEČNÁ \(THE LEFT\)](#)

NEWS FROM THE POLICY DEPARTMENT

Recent publications:

- Briefing on [progress on implementing the Kunming-Montreal Global Biodiversity Framework](#)
- Study on [the COP28 climate change conference: status of climate negotiations and issues at stake, Dubai \(UAE\), 30 Nov - 12 Dec 2023](#)
- Briefing on the [commitments made at the hearing of MAROŠ ŠEFČOVIČ Executive Vice-President of the Commission on the European Green Deal](#)
- Briefing on the [commitments made at the hearing of WOPKE HOEKSTRA, Commissioner-designate on Climate Action](#)
- Briefing on [the UN High Level Political Forum on Sustainable Development Goals, New-York, 17-19 July 2023](#)

Upcoming publication:

- Study on Issues at stake at the COP 29 Climate Change Conference in Baku, Azerbaijan, November 2024

NEWS FROM THE AGENCIES

European Environment Agency (EEA)

Europe is not prepared for rapidly growing climate risks



Europe is the fastest warming continent in the world, and climate risks are threatening its energy and food security, ecosystems, infrastructure, water resources,

financial stability, and people's health. The EEA has published the first ever European Climate Risk Assessment (EUCRA) to help identify policy priorities for climate change adaptation and for climate-sensitive sectors. It identifies 36 climate risks with potentially severe consequences across Europe. The risks are evaluated in the contexts of risk severity, policy horizon (lead time and decision horizon), policy readiness and risk ownership. Many of these risks have already reached critical levels and could become catastrophic without urgent and decisive action. More information can be found [here](#).

European Food Safety Authority (EFSA)



EFSA's annual report for 2022 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products was published on 6 March. The results confirm that veterinary drug residues in animals and

foods remain low. This report looks at variety of substance groups, including hormones, antibacterials, environmental contaminants, prohibited substances, and other veterinary drugs. The results can soon be explored through an interactive dashboard. The comprehensive dataset for the report, totalling approximately 13 million analytical results, will soon be made available through the EFSA Knowledge Junction. This open repository is designed to enhance transparency, reproducibility, and the usability of evidence in food and feed safety risk assessments. More info [here](#).

European Medicines Agency (EMA)

Multi-agency report highlights importance of reducing antibiotic use



Countries that have decreased their consumption of antibiotics in both animals and humans have seen a reduction in antibiotic-resistant bacteria. This is according to the fourth joint report on the integrated analysis of the consumption of

antimicrobial agents and occurrence of antimicrobial resistance (AMR) in bacteria from humans and food-producing animals (JIACRA IV), published by the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), and the European Medicines Agency (EMA).

Taking a One Health approach, which recognises the connection between the health of people and animals, the report presents data primarily collected between 2019 and 2021 on antibiotic consumption and AMR in Europe. AMR is a serious threat to public and animal health. It is estimated that, every year, AMR causes the death of more than 35,000 people in the European Union and the European Economic Area (EU/EEA) and puts a significant burden on European healthcare systems. The One Health approach implemented through the cooperation of ECDC, EFSA and EMA, and the results presented in this report call for: continued efforts to tackle AMR at national, EU and global levels across the human and food-producing animals sectors; harmonised surveillance of antimicrobial consumption and AMR in the human and animal sectors; targeted studies to further understand the spread of AMR. More information is available [here](#).

European Chemicals Agency (ECHA)



ECHA launches new chemicals database ECHA's database, the largest chemicals database in the EU, combines industry-submitted data with information generated in the EU's regulatory processes. ECHA has recently revamped its database, to make it future-proof and to be able

to better share with the public the growing amount of information it hosts. In the first version of ECHA CHEM, you can find information from all the over 100 000 REACH registrations that companies have submitted to ECHA since 2007. ECHA Chem website

European Centre for Disease Prevention and Control (ECDC)

ECDC Evidence brief: Progress towards reaching the Sustainable Development Goals related to HIV in the EU/EEA



The United Nations Sustainable Development Goal (SDG) 3.3 aims to end AIDS by 2030. This brief provides an update on the progress in relation to HIV prevention, testing and treatment, the number of new HIV infections, AIDS-related deaths and HIV-related stigma and

discrimination in the EU/EEA. Annex 1 provides country-level progress towards meeting these targets. The EU/EEA is on track to meet the 95-95-95 targets set by UNAIDS, with 91% of all people living with HIV (PLHIV) knowing their status, 93% of people who know their status on treatment, and 91% of those on treatment being virally suppressed. However, nearly one in four of all PLHIV (23%) in the 23 EU/EEA countries with available data had still not achieved viral suppression and only two countries have achieved the overall 86% target of ensuring that all PLHIV are virally suppressed by 2025.

More than 10% of people living with HIV report experiencing HIV-related stigma and discrimination in healthcare and community settings, indicating that further work is required to reach the goal of zero stigma. More [here](#).

Next meetings of the ENVI Committee: 19 March 2024.

Future meetings: [ENVI Committee meetings 2024.pdf](#)

Watch online the Committee meeting on the [EP website](#) 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.

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