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Limits on exposure to carcinogens and mutagens at work: Third proposal

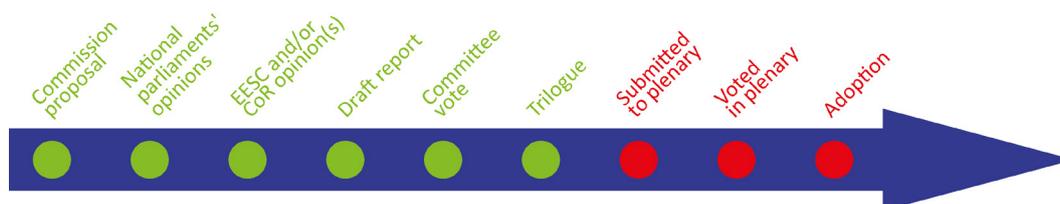
The European Commission has proposed to amend Directive 2004/37/EC by expanding its scope and by including and/or revising occupational exposure limit values for a number of cancer- or mutation-causing substances. The initiative is proceeding in steps. The first proposal of May 2016 covered 13 priority chemical agents, the second, of January 2017, a further seven. The current (third) proposal addresses an additional five. Broad discussions with scientists and the social partners fed into all three proposals. Reacting to the Commission's set of measures as a whole, trade unions have acknowledged the importance of further improving the existing framework. Actors on the employers' side have underlined the need to ensure that values are proportionate and feasible in terms of technical implementation.

Parliament's Employment and Social Affairs Committee voted its report on 20 November 2018. It includes the call to bring cytotoxic medicines, which are used in the treatment of cancer, within the scope of the directive, as well as to grant incentives to businesses that comply. Council agreed on its position on 6 December 2018. Trilogue negotiations gave rise to a provisional agreement in January 2019. Once endorsed by the Council, it will be voted in Parliament's plenary.

Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

COM(2018) 171, 05.04.2018, 2018/0081(COD), Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')

Committee responsible:	Employment and Social Affairs (EMPL)
Rapporteur:	Laura Agea (EFDD, Italy)
Shadow rapporteurs:	Claude Rolin (EPP, Belgium); Marita Ulvskog (S&D, Sweden); Anthea McIntyre (ECR, United Kingdom); Enrique Calvet Chambon (ALDE, Spain); Patrick Le Hyaric (GUE/NGL, France); Karima Delli (Greens/EFA, France); Joëlle Mélin (ENF, France)
Next steps expected:	First-reading vote in plenary



18 February 2019
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The 'EU Legislation in Progress' briefings are updated at key stages throughout the legislative procedure. Please note this document has been designed for on-line viewing.

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Introduction

On 5 April 2018, the European Commission adopted its third proposal to amend [Directive 2004/37/EC](#) (the Carcinogens and Mutagens Directive – CMD). The [third proposal](#) (hereafter referred to as the ‘current proposal’) complements a [first one](#) of May 2016 and a [second one](#) of January 2017¹, by addressing another batch of substances. (For more details, see ‘The changes the proposal would bring’ below.)

According to the Commission, the aims of the current proposal are to:

- > improve workers’ health protection by reducing workplace exposure to five chemical agents that may cause cancer (‘carcinogens’) or mutations (‘mutagens’);
- > provide more clarity for workers, employers and enforcers; and to
- > contribute to a level playing field for economic operators.²

The current proposal is meant to contribute to delivering on the [European Pillar of Social Rights](#) by implementing its [principle 10](#), ‘Healthy, safe and well-adapted work environment’, which expresses workers’ right to a high level of protection of their health and safety. Moreover, as pointed out by the Commission, addressing the social dimension of the EU by means of a directive on protecting workers from health risks in the workplace is part of the [Joint Declaration](#) (European Parliament, Council, European Commission) on the EU’s legislative priorities for 2018-2019.

The Commission is proceeding in steps, and further amendments of the CMD are planned. A proposal covering a fourth batch of substances is envisaged for early 2019.

Context

Cancer is the leading cause of work-related deaths in the EU. Occupational cancers may be prevented by reducing or eliminating exposure to certain carcinogens or mutagens. Workplace exposure usually involves a [combination of factors](#), however, and it can be difficult to establish a causal relationship between cancer cases and exposure to a specific chemical agent – the time between exposure and onset of the disease can be up to 50 years (‘latency period’).

1 The first proposal was adopted by the co-legislators as [Directive \(EU\) 2017/2398](#) (for further information, see an EPRS [briefing](#) (‘EU Legislation in Progress’), January 2018, or consult the [EP Legislative Train Schedule](#) on the file.) The second proposal was adopted as [Directive \(EU\) 2019/130](#) (see also an EPRS [briefing](#) (‘EU Legislation in Progress’), December 2018, or the corresponding [EP Legislative Train Schedule](#)).

2 An analysis of the objectives of the initiative is provided in an [EPRS initial appraisal](#) of the Commission impact assessment (IA). According to the analysis, it could be assumed (based on the second amendment of the CMD) that ensuring a high level of protection of workers’ health and safety in the EU is the general objective. At the same time, in view of the reference to the Commission’s 2017 communication [‘safer and healthier work for all’](#), modernising the structure of the EU occupational safety and health acquis would appear to be another.

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In addition to cancers, workplace exposure to carcinogens or mutagens can lead to other serious health problems, such as respiratory diseases and neurological disorders. In a bid to raise awareness on the risks associated with the exposure to dangerous substances,³ including carcinogens and mutagens, the European Agency for Safety and Health at Work (EU-OSHA) recently launched the [2018-2019 Healthy Workplaces Manage Dangerous Substances campaign](#). The campaign aims, among other things, to support the exchange of good practices (such as the covenant committing to the [EU roadmap on carcinogens](#)); to provide tailored information and examples of good practices to workers with specific needs and higher levels of risks; and to increase knowledge of the [legislative framework](#) that is already in place to protect workers, as well as highlighting policy developments.

Existing situation

The CMD sets general minimum requirements to eliminate or reduce exposure to the chemical agents falling within its scope. Furthermore, it establishes occupational exposure limit values (OELs) for certain carcinogens and mutagens with a view to protecting workers.⁴ Employers must identify and assess exposure-associated risks for workers; where risk occurs, exposure must be prevented. Where it is technically possible, the process or agent concerned must be substituted with a non-hazardous or less hazardous process or agent. Where substitution is not possible, chemical carcinogens/mutagens must be used in a closed system, or worker exposure must be reduced to as low a level as is technically possible. Employers also have the obligation to ensure that OELs are not exceeded.

The CMD provisions apply to chemical agents that ‘may cause cancer’ or are ‘suspected of causing cancer’ according to the criteria set out in [Regulation \(EC\) No 1272/2008](#) on classification, labelling and packaging of substances and mixtures (the CLP Regulation), and also to the substances, mixtures and processes referred to in annex I of the CMD, which currently – in its amended version – has six entries.⁵ These are what are referred to as [process-generated substances](#) (PGSs) – hazardous chemical agents such as dust, fumes and gases generated during combustion or as by-products during production processes. The provisions also apply to mutagens as per the CLP Regulation, namely, ‘substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans’. According to the CMD, OELs need to be established for those chemical agents for which they do not yet exist, and to be revised whenever this becomes necessary in the light of more recent scientific data. Currently, the CMD – as amended – sets OELs for 14 agents.⁶

3 [Dangerous substances](#) are any liquids, gases or solids that pose a risk to workers’ health or safety.

4 The term ‘limit value’, defined in the CDM, addresses the inhalation route of exposure. It describes ‘a maximum airborne concentration level for a given chemical agent above which workers should not be exposed, on average, during a defined time period’ (see explanatory memorandum, p. 13).

5 These are: 1. manufacture of auramine; 2. work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch; 3. work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes; 4. strong acid process in the manufacture of isopropyl alcohol; 5. work involving exposure to hardwood dusts; and 6. work involving exposure to respirable crystalline silica dust generated by a work process.

6 In accordance with annex III of the [consolidated version](#) of the CMD, for hardwood dusts, chromium VI compounds, refractory ceramic fibres, respirable crystalline silica dust, benzene, vinyl chloride monomer, ethylene oxide, 1,2-epoxypropane, acrylamide, 2-nitropropane, o-toluidine, 1,3-butadiene, hydrazine and bromoethylene.

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For the carcinogens and mutagens considered in this proposal, no EU-level OELs exist, and the situation as regards national OELs is diverse: several Member States have not yet set national limit values for any of the substances under consideration; where national OELs exist, they differ in range.⁷ As the Commission explains in the [explanatory memorandum](#) of the current proposal, diverging national OELs lead to different levels of workers' protection across the EU, as well as creating different competing conditions ('distorted competition'): companies operating in one Member State may need to comply with OELs that are many times lower (that is, stricter) than companies based in other Member States and may face increased costs in terms of investments in protective measures or equipment. In addition, these national differences may lead to legal, administrative and/or organisational complications for businesses that operate simultaneously in different Member States.

Parliament's starting position

In its [resolution](#) of 14 March 2013 on asbestos-related occupational health threats, Parliament called on the Commission to put forward a proposal to amend Directive 2004/37/EC as a matter of urgency, so that 'the health of workers at risk of being exposed to carcinogens be protected and safeguarded through the promotion and exchange of best practices in prevention and diagnosis'.

In its [resolution](#) of 25 November 2015 on the 'EU strategic framework on health and safety at work 2014-2020', Parliament highlighted the importance of protecting workers against exposure to substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs). It reiterated its calls on the Commission to present a proposal to amend Directive 2004/37/EC on the basis of scientific evidence, add more binding limit values, and develop an assessment system based on clear and explicit criteria. Furthermore, Parliament underlined the need for more stringent protection of workers, taking into account not only exposure periods, but also the mix of chemical and/or toxic substances to which workers are exposed. It also called on the Commission to take action on the exposure of chemical risk factors in the healthcare sector.

⁷ For an overview of all national OELs for the substances considered, see [table 36 in annex 5](#) to the IA.



Preparation of the proposal

The changes the proposal would bring

Proposal

Preparation of the proposal

The current proposal is accompanied by a Commission [impact assessment](#) (IA) and its [executive summary](#), which received a positive [opinion](#) from the Regulatory Scrutiny Board. The IA covers the expected costs and benefits from the five chemical agents included in the proposal. According to the Commission, the IA should be read in conjunction with the [earlier IA for the first proposal](#), where the CMD and its context are considered exhaustively.

The November 2017 [inception impact assessment](#) (IIA) on the intended initiative recalled that stepping up the fight against occupational cancer through legislative proposals, accompanied by increased guidance and awareness-raising, is among the three priorities for action identified under the Commission's [action to promote occupational safety and health](#). The proposal would aim to tackle three problems: 1) exposure of workers to carcinogens represents a significant risk to workers' health; 2) the CMD is not up-to-date considering most recent information; and 3) the lack of OELs has negative consequences for workers and their families as well as for businesses and social security systems across the EU. According to the IIA, new scientific evidence is available that allows the Commission to present the next proposal for new OELs for the substances in question.

The selection of the specific five agents considered in the IA was based on a consultative approach, which included opinions on each of the agents by the tripartite Advisory Committee on Safety and Health at Work ([ACSH](#)) and a formal two-stage consultation of the social partners. The first phase of the consultation closed on 30 September 2017, the second phase on 22 December 2017. The scientific advice for the chemical agents covered in the IA was provided by the Scientific Committee on Occupational Exposure Limits ([SCOEL](#)) and the Committee for Risk Assessment ([RAC](#)).⁸ (For an analysis of the quality of the impact assessment, see the [EPRS initial appraisal](#).)⁹

The changes the proposal would bring

The measures put forward

Continuing on from the two previous legislative amendments to the CMD, which addressed 20 priority chemical agents,¹⁰ the current proposal would introduce OELs for an additional five (three groups of substances and two individual substances). These are:

8 SCOEL: cadmium, beryllium and formaldehyde; RAC: arsenic acid and 4,4'-methylene-bis(2-chloroaniline) (MOCA).

9 Following an EPRS initial appraisal of the Commission IA, the EMPL committee requested in October 2018 a more detailed appraisal focused on the process and evidence base used for setting the limit values for cadmium and beryllium, notably in light of some knowledge gaps and methodological challenges regarding the number of workers exposed and the estimation of the burden of disease. The resulting EPRS [study](#) finds that the Commission's overall analysis is convincing and robust. The values considered appear to be plausible and justified, based on the availability of data; the full current and future disease burden is however not captured, a weakness acknowledged in the IA.

10 Chemical agents considered by the Commission as being a priority for protection of workers. The selection was made on the



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- > cadmium and its inorganic compounds
- > beryllium and its inorganic compounds
- > arsenic acid and its salts, as well as inorganic arsenic compounds
- > formaldehyde
- > 4,4'-methylene-bis(2-chloroaniline) (MOCA).¹¹

The limit values would be supplemented by a skin notation¹² in the case of MOCA; a notation for skin sensitisation¹³ in the case of formaldehyde; and a notation for both skin and respiratory sensitisation¹⁴ in the case of beryllium and its inorganic compounds.

Transition periods for all sectors would be established for beryllium and cadmium (five and seven years, respectively).¹⁵ For arsenic acid, a two-year transition period is envisaged for copper smelting only, given the technical challenges the sector might face in complying with the retained OEL.

The impact

The chemical agents considered in the current proposal are used across a [wide range of sectors and activities](#), including: cadmium production and refining; nickel-cadmium battery manufacture; mechanical plating; zinc and copper smelting; foundries; glass; laboratories; electronics; chemicals; construction; manufacturing of leather and fur, pulp and paper, textiles, wood and wood products; healthcare (pathology departments and autopsy rooms); plastics; and recycling.

According to the Commission's explanatory memorandum, the measure would contribute to lowering the risk for **workers** of getting avoidable work-related cancer (including lung, bladder, kidney, skin, prostatic and nasopharyngeal cancers¹⁶), as well as other significant health problems¹⁷ caused by exposure to the five substances under consideration. In the longer term, the current proposal would prevent over 22 000 cases of ill health and benefit over 1 million EU workers in terms of improved prevention of and protection, while reducing effects such as the suffering of workers and their caring families, a reduced quality of life or undermined wellbeing. The [greatest benefits](#) would be expected in relation to formaldehyde, to which an

basis of stakeholders' views (see IA, [annex 6](#)).

11 Arsenic acid and MOCA are included in annex XIV of Regulation (EC) No1907/2006 ([REACH](#)), i.e., are subject to authorisation before being placed on the market. Cadmium has been identified as a 'substance of very high concern' and is on the [candidate list](#) for possible inclusion in annex XIV. A restriction of formaldehyde is under consideration.

12 A skin notation indicates the possibility of significant uptake of a substance through the skin. In many European countries, skin notations [are used](#) to warn against the [potential health effects](#) associated with such uptake, in addition to inhalation exposure.

13 [Skin sensitisers](#) are agents that cause over-reactivity, or allergy, in skin. They are also referred to as 'contact allergens'.

14 [Respiratory sensitisers](#) are agents that can induce allergic respiratory diseases in humans.

15 Meaning that during these periods, transitional measures would apply that provide for higher (that is, less strict) limit values (see [annex III](#) to the proposal).

16 Cancer of the [nasopharynx](#), the upper part of the throat behind the nose.

17 For a list of adverse health effects due to the substances under consideration, see IA, [p.7](#). By way of example, as the Commission points out, exposure to beryllium causes not only lung cancer, but also [chronic beryllium disease](#).



estimated 990 000 workers are exposed. According to the Commission, the quantified benefits linked to the prevention of ill health (nasopharyngeal cancer and sensory irritation only) among workers exposed to formaldehyde range between €1-5 billion. The Commission also states that the proposal would provide more clarity for workers, employers and enforcers regarding the acceptable levels of exposure.

Moreover, it claims that for **employers**, the proposal would reduce costs due to work-related ill health and cancer in terms of absenteeism, lost expertise, insurance payments and productivity losses. It would contribute to a more level playing field for **companies** in the form of EU-wide minimum standards of protection. Since national OELs already exist for several of the chemical agents covered by the proposal, establishing the limit values provided for would not impact companies in those Member States that have equal or lower (that is, stricter) limit values. The Commission states that, for the majority of chemical agents covered by the current proposal,¹⁸ the impact on operating costs for businesses would be limited to minor adjustments that would need to be done in specific cases to ensure full compliance. For **small and medium-sized enterprises** (SMEs), which are considerably represented in the industries dealing with beryllium, formaldehyde and MOCA, the costs incurred would be 'affordable for the companies concerned'.¹⁹ There would be no increase in administrative burden on companies, and the transition periods envisaged for some of the substances would allow companies to address any specific technical challenges.

Furthermore, the Commission argues that the proposal would help to mitigate financial losses incurred by the **Member States'** social security and healthcare systems, which bear the burden and cost of occupational ill health resulting from workers' exposure to dangerous substances (such as healthcare costs for treatment and rehabilitation as well as expenditure on inactivity and early retirement and compensation for recognised occupational diseases). Enforcement costs would not be significant; neither would additional administrative costs, which might be incurred, among other things, in relation to staff information and training.

18 As pointed out in the IA, for some of the chemical agents, in particular formaldehyde and cadmium, the preferred option would entail operating costs for enterprises that would have to put in place additional protective and preventive measures. However, since in case of formaldehyde, the number of companies is very high, and in case of cadmium, mainly large companies would be affected, 'the cost per company in relative terms for both substances is expected to be modest' (see IA [executive summary](#), p. 2).

19 The most significant costs would be incurred by SMEs dealing with formaldehyde and beryllium, and in particular those companies that have not yet invested in closed systems or substitution; these costs would nevertheless remain 'well below 1% of their turnover' (see IA executive summary, p. 2).



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The European Economic and Social Committee (EESC) adopted its [opinion](#) on 19 September 2018. The EESC welcomes the proposal. Among other things, the EESC finds it important that, given the reprotoxic (that is, toxic to reproduction) effects of many carcinogens and mutagens, further revisions and amendments to the CMD 'pay more attention to occupational exposures affecting women and men regarding reproductive aspects'. Moreover, the EESC 'considers it necessary to set up pilot research programmes and, in a second phase, EU-wide programmes to develop life-long health surveillance in the framework of national social security or public health systems for all those who have been exposed to carcinogens, mutagens and reprotoxic compounds'.

National parliaments

The [deadline](#) for national parliaments to submit comments on the current proposal was 5 June 2018, and none submitted a reasoned opinion.

Stakeholders' views²⁰

While not reacting expressly to the current proposal, stakeholders have given their opinions at various steps throughout process of amending the CMD.²¹ Stakeholders nevertheless expressed their views in preparation of the current proposal, during the first and second phases of the social partner consultation (see also 'Preparation of the proposal' above). According to the Commission's [account](#) of the consultation, the three workers' organisations that replied to the first phase of the consultation – the European Trade Union Confederation ([ETUC](#)), the European Confederation of Independent Trade Unions ([CESI](#)) and the European Federation of Building and Woodworkers ([EFBWW](#)) – acknowledged the importance of the existing legislation and the need for further action, but had differing views as to the approach to be followed and the factors to be taken into account. ETUC and EFBWW found it necessary to extend the scope of the CMD to substances that are reprotoxic (that is, toxic to reproduction), and insisted that the fourth amendment be expanded to reach the target of 50 OELs in 2020. ETUC proposed a priority list of such substances. With regard to process-generated substances, ETUC considered it important that, for instance, diesel engine exhaust emissions be considered as a candidate for the fourth amendment of the CMD.

The four employers' organisations that replied to the first phase of the consultation – [BusinessEurope](#), the European Association of Craft Small and Medium-sized Enterprises ([UEAPME](#)), the European Chemical Employers Group ([ECEG](#)) and the Council of European Employers of the Metal, Engineering and Technology-

²⁰ This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'EP supporting analysis'.

²¹ For stakeholders' views on the two previous legislative amendments, see the corresponding EPRS 'EU Legislation in Progress' briefings on the first and second proposal, respectively.



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based industries ([CEEMET](#)) – in principle supported further revisions of the CMD, including by setting binding OELs at EU level, subject to certain conditions. In their view, binding OELs should be set for priority substances only, and the process of OELs setting should be based, among other things, on sound scientific evidence and on the criteria of technical and economic feasibility.²²

As regards the second phase of the consultation, the Commission states in the explanatory memorandum that the three workers' organisations recognised the importance of further improving the existing framework and reiterated the need to reach the objective of 50 OELs by 2020. The four employers' organisation confirmed their support to the actions, while underlining the need to ensure that values are proportionate and feasible in terms of technical implementation.

22 For more information, see also the EPRS initial appraisal of the Commission IA.

Legislative process

In Parliament, the EMPL committee is considering the current proposal. Laura Agea (EFDD, Italy) was appointed rapporteur for the file on 16 May 2018. In her [draft report](#) of 29 June 2018, she proposes 25 amendments. The main points are:

- > Businesses that comply with the CMD should be given proportionate **incentives, such as grants and** tax relief, and granted a **transition period** (seven years instead of five for beryllium) to allow for the completion of the necessary organisational and technical changes.
- > Annex I to the CMD should include work involving exposure to carcinogens or mutagens arising from the preparation, administration or disposal of **hazardous medicines (including cytotoxic ones)** that are [classified](#) by the International Agency for Research on Cancer (IARC) as carcinogenic, probably carcinogenic or possibly carcinogenic.

The EMPL committee adopted its [report](#) on 20 November 2018. The main elements of the committee report, as amended, include:

- > **Medical surveillance:** may include biological monitoring ('[biomonitoring](#)') where appropriate;
- > **Occupational exposure limit values:** OELs need to be evidence-based, proportionate and measurable; where a limit value has been set, workers' exposure should be reduced as far as technically possible below that value;
- > **Review:** by the fourth quarter of 2019, the Commission should assess the possibility of widening the scope of the CMD to hazardous medicines, including cytotoxic ones;
- > **Formaldehyde:** a three-year transitional period should be introduced for the funeral sector;
- > **Cadmium:** in Member States that implement biomonitoring, a biological limit value should be introduced (no transitional period required); the Commission should draw up guidelines for the implementation of such biological monitoring;
- > **More flexible rules for small businesses:** compliance of SMEs and micro-enterprises should be facilitated, with measures such as incentives and digital tools.

The Council reached a [general approach](#) during the Employment, Social Policy, Health and Consumer Affairs Council session of 6 December 2018. In a [statement](#) annexed to the general approach, France, Finland, Italy, Lithuania, the Netherlands, the United Kingdom and Slovakia express their regret that the alternative option including complementary biomonitoring for cadmium compounds could not be retained.

The decision to enter into interinstitutional trilogue negotiations was confirmed by Parliament's plenary on 30 November 2018. A first trilogue meeting took place on 16 January 2019. Council, Parliament and Commission reached a [provisional agreement](#) at the second trilogue meeting, on 29 January 2019. It sets new limit values and invites the Commission to assess, by mid-2020, the possibility to extend the scope of the CMD to a list of hazardous medicines, including cytotoxic ones. As regards cadmium, the Commission is requested, within three years after entry into force of this third amendment to the CMD, to consider a



further amendment, which would add the combination of an airborne occupational exposure limit value with a biological limit value.

According to the [Commission](#), the new rules will improve working conditions for over 1 million EU workers and prevent over 22 000 cases of work-related illness. Sectors that will benefit include nickel-cadmium battery manufacture, zinc and copper smelting, laboratories, electronics, funeral and embalming, construction, healthcare, plastics and recycling sectors.

The provisional agreement now needs to be examined by the Council's Permanent Representatives Committee. Once endorsed by Council, and then by the EMPL committee, it will be subject to a vote in Parliament's plenary.



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EP supporting Analysis

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