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Deutsche Sozialversicherung
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Chemicals assessment reform "One substance, one assessment" for faster, simplified and transparent procedures

I. Preliminary remarks

The European Commission published the "One substance, one assessment" reform package on 7 December 2023. This includes the following three legislative proposals:

- Proposal for a Regulation establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals (COM(2023) 779 final)
- Proposal for a Regulation amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals (COM(2023) 783 final)
- Proposal for a Directive amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (COM(2023) 781 final)

The German Social Insurance (DSV) welcomes the European Commission's reform package to establish a standardised platform for chemicals and to reallocate existing tasks and assign new tasks to the EU agencies. By reorganising the cooperation between the EU agencies, duplication of work can be avoided and an efficient way of working in the field of chemicals assessment can be achieved. In addition, the development of a standardised platform for chemicals makes it possible to make the data traceable, accessible, interoperable and reusable for interested parties.

The realisation of the reform package should ensure that all agencies involved and, notably, the European Chemicals Agency (ECHA) can carry out their new scientific and technical tasks. In particular, when assessing the risks posed by a substance, it must be ensured that the risk is adequately assessed on the basis of the hazard and exposure. The necessary human and material resources must be made available to ECHA in good time to enable the agency to provide expert assessments in the new areas. In this context, realistic timelines are required when performing the new tasks so as to avoid negative effects in practice.

II. Opinion

1 _ Extension of the agencies' responsibilities

ECHA has the task of ensuring the safe use of chemical substances and specialises in the assessment of chemicals. With its proposal, the European Commission wants to extend ECHA's powers so that the technical and scientific work on substance assessments is carried out by a central body with proven experience and tried-and-tested instruments. However, this extension of competence presupposes that ECHA can carry out a quality-assured and independent assessment of actual and potential exposures during activities throughout the life cycle of electronic equipment, including disposal or recycling. In order to completely fulfil this task, the implementation of the proposed directive requires not only the expansion of ECHA's expertise in the field of electrical and electronic equipment, but in particular the involvement of appropriate experts with specialist knowledge from various fields. This is the only way to ensure a professional assessment of the release and exposure of hazardous substances throughout their entire life cycle at all times.

In view of the far-reaching changes in the ECHA and its scientific committees, the German Social Insurance believes that the transition periods are too tight. Until all new processes for the implementation of the specific tasks in the procedures for substance authorisations and restrictions and the evaluation of applications for derogations in connection with the restrictions are established, the scientific committees must be given more time for processing. The time limits provided for in Article 6a of the proposed directive should therefore be increased.

The European Commission's proposed changes to the Regulation laying down general principles and requirements of food law aim to promote cooperation between the European Food Safety Authority (EFSA), ECHA, the European Environment Agency (EEA) and the European Medicines Agency (EMA). They allow EFSA to monitor and identify potential divergences between its scientific opinions and those of the other three agencies and to address them in a next step. As only two players will be dealing with disputed points in the expert reports, it must be ensured that the scientific discourse is not curtailed. For this reason, the proposed regulation must ensure that EFSA and ECHA, EMA or EEA also provide each other with all relevant and technical details during their bilateral exchange on the opinions concerned. A comprehensive scientific and technical exchange on the disputed points must be possible.

2 _ Effects of the measures on the chemical safety assessment

The initiative proposed by the European Commission for a single assessment of a substance on the basis of high scientific quality and robustness with a simultaneously low compliance burden in terms of personnel and other costs appears to be extremely sensible. However, from the perspective of the German social insurance system, the results of the hazard and, above all, the risk assessment require a differentiated view depending on the various legal areas. Such an assessment cannot currently be guaranteed by ECHA. The results of the hazard and, in particular, risk assessment of a substance should depend on its various areas of application, such as the safety of toys, cosmetics, biocidal products, plant protection products and foodstuffs or even activities involving carcinogens at work and environmental protection. We consider a standardised and comprehensive assessment of substances without taking into account the circumstances under which they are used to be wrong.

The properties of a substance should not be the sole trigger criterion for a risk assessment, which forms the basis for handling or working with the substance. The risk must be assessed on the basis of the hazard and the exposure. In particular, the safe exposure to different persons (groups) and the possible safe handling of the substance should be taken into account. In addition, the level of exposure and the possible use of protective measures, such as detection at the point of release or respiratory protection, must be addressed. If one followed the hazard-based approach, which is based on the properties of a substance, surface disinfection with formaldehyde-containing cleaners or sterilisation with ethylene oxide (e.g. of medical instruments or infusion tubes) would no longer be possible in the healthcare sector, for example. Both substances are classified as carcinogenic to humans. However, occupational exposure limits for surface disinfection with formaldehyde-containing cleaners and the use of ethylene oxide for sterilisation in closed systems make it possible for both substances to be used by employees with the help of the risk-based approach.

An approach to assessing a substance solely on the basis of its properties could lead to excessive and possibly no longer appropriate restrictions or a complete ban on substances or entire groups of substances. The same applies in the event of an excessive reduction in exposure limits. From an occupational health and safety perspective, such an approach cannot be accepted in view of established risk assessments and tried-and-tested protective measures. The proportionality of protecting vulnerable persons must be taken into account.

Materials containing asbestos have been used in the construction industry for many years and should be gradually removed. Asbestos is carcinogenic to humans. Removal is therefore carried out exclusively under strict conditions and by industrial employees who are appropriately trained to avoid exposure. If the hazard-based approach were to be implemented, it would no longer be possible to remove materials containing asbestos. This renders the EU's initiative to make Europe asbestos-free impossible. The use of certain hazardous substances in the workplace by trained and adequately protected personnel should not be made virtually impossible by an inappropriate assessment. This could lead to activities in which exposure limits are inevitably exceeded being carried out outside the EU and certain sectors of the economy possibly moving to non-European countries. For the DSV, it is not acceptable to outsource health, environmental and labour protection from the EU.

3 _ Data platform for chemicals

The DSV welcomes the move to make the assessment of chemicals more transparent and comprehensible by standardising terminology and providing information within the newly created database. The principles that lead to an assessment of chemicals are currently not publicly available. In this respect, the initiative could contribute to greater acceptance. In particular, the DSV expressly supports the request to the European Environment Agency (EEA) to compile and/or collect more data on human biomonitoring and the request to ECHA to collect data on air monitoring. The collection of this data can help to better verify the state of the art and serve to increase efforts to raise occupational health and safety to a higher and more uniform level across the EU.

With the help of the common data platform, the European Commission wants to concentrate and consolidate information on chemicals at EU level in a centrally accessible IT infrastructure. Its administration provides for the establishment of a steering committee in which the European Commission is allocated the same number of seats as the members from the EU agencies. The participation of the European Commission in the steering committee makes sense. However, the number of representatives from the agencies and consequently from the specialist area should be higher. Advice, for example on the standard data formats used and scientific vocabulary, should be provided by those who use the information on the data platform in practice. The structure of the steering committee, which is to advise on the structure of the data platform, can be improved. The same applies with regard to access rights for the data platform. Scientific bodies such as the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the

Work Area of the German Research Foundation (MAK Commission) as well as statutory insurers should be granted full access comparable to that of the authorities. In contrast, limited public access to the data platform is justifiable from the DSV's point of view.

It must be ensured that the independence of ECHA and its processes is maintained and that the necessary expertise is available to evaluate a substance in relation to all of the different areas. One example of this is the tasks of the former Scientific Committee on Occupational Exposure Limits (SCOEL). In addition to the risk assessment of a substance, its assessments also include comprehensive expertise regarding exposure to hazardous substances in companies as well as occupational medical and epidemiological expertise.

One of the proposed regulations in the package provides for the establishment of an early warning system to identify (new) hazards from chemicals based on improved data availability. An early warning system can only work if qualitative and usable data is available. Therefore, data generation should be reviewed and the inclusion of incomplete data should be avoided. For this reason, ECHA should also be authorised to commission scientific studies if the data available is limited, incomplete or restricted to a specific area.

4 _ Timing and personnel-related implementation of the reform package

The tasks of the ECHA are not only being massively expanded by the reform package, but also by other legal acts. The planned entry into force of the Regulation on the re-attribution of tasks to the agencies in the third quarter of 2025, which coincides with the start of the assessment of substances under the Persistent Organic Pollutants Regulation and that of medical devices, may have an impact on the objective and robust assessment of substances. This will be exacerbated if, as planned, ECHA also starts the technical and scientific work under the proposed directive on the re-attribution of tasks to ECHA just twelve months later, i.e. from the third quarter of 2026. This contrasts with the relaxed deadline of ten years envisaged for the provision of all relevant data via the common data platform by 2035. If the final transparency of the chemicals assessment can only be achieved after a period of ten years, the deadlines for starting the various technical and scientific activities should also be adjusted with a view to a coordinated and established working method and staggered more generously accordingly. This would enable an appropriate allocation of resources within ECHA.

Finally, it should be pointed out that the additional workload resulting from increased tasks and responsibilities, in particular at ECHA and the EEA, will be recognised and taken into account with appropriate funding for staff and other costs. Accordingly, the EFSA, EMA and the Commission's Joint Research Centre also see and pay for additional work. The DSV believes that this should also apply to the European Agency for Safety and Health at Work (EU-OSHA). The EU-OSHA should therefore be strengthened on an equal footing and be appropriately staffed and funded. Only joint and comprehensive consideration of all areas involved can ensure that the reform package is a success.

Article 4 Proposal for a Regulation on the data platform - Implementation plan and management of the common data platform

Proposed new regulation
Article 4 of the proposed regulation regulates the establishment and composition of the steering committee.

	Commission proposal		Proposed amendments
Art. 4 para. 2	(2) The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.	>	(2) The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and ~~five~~ ***two*** representatives from the Commission.

Justification
The steering committee should be made up predominantly of representatives of the agencies, as these experts can make valuable contributions to the use of the data platform in routine practice.

Article 16 Proposal for a Regulation on the data platform - access rights and transparency

Proposed new regulation
Article 16 of the proposed Regulation regulates access to information stored in the data platform.

	Commission proposal		Proposed amendments
Art. 16 para. 1	(1) The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.	>	(1) The Authorities***, scientific bodies and institutions having obligations and rights under social security schemes*** shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.

Justification
The scientific bodies, such as the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area of the German Research Foundation (MAK Commission) and the organisations that have obligations and rights under the social security schemes, must be granted full access to the information in the data platform, as they need it to carry out their work.

Article 21 Proposal for a Regulation on the data platform - data generation mechanism

Proposed new regulation
Article 21 of the proposed Regulation regulates the generation of new data by ECHA.

	Commission proposal		Proposed amendments
Art. 21 para. 3	(3) The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.	>	(3) The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I ***or where the data are limited, incomplete or sector-specific***. It shall not commission

			studies with a predominant research objective.

Justification
For the early warning system to be fully utilised, it must be ensured that the data included is complete. Therefore, ECHA should also be able to commission scientific studies if the data basis is limited, incomplete or sector-specific.

Article 6a Directive 2011/65/EU - Initiation of a procedure to review and amend the list of restricted substances

Proposed new regulation
The newly created Article 6a of Directive 2011/65/EU regulates the procedure for the list of substances subject to restrictions.

	Commission proposal		Proposed amendments
Art. 6a para. 5	[...] Within 30 days of receipt of the restriction dossier, the respective Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.		[...] Within 30 days of receipt of the restriction dossier, the respective Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. ***During the first 3 years after the entry into force of this Directive, notification shall be made within 60 days.*** If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. ***During the first 3 years after the entry into force of this Directive, written notification shall be made within 90 days of receipt.*** The Agency or

			the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated. ***During the first 3 years after the entry into force of this Directive, the dossier shall be brought into conformity with the requirements within 120 days of receipt of the committee's statement of reasons. Otherwise, the proceedings under this Article shall be discontinued.***

Justification

The new processes at ECHA following the reorganisation and the appointment of experts to carry out the assessments of hazardous substances in electrical and electronic equipment first have to become established. The deadlines should therefore be doubled in the first three years after the directive comes into force.

Article 6b Directive 2011/65/EU - Opinion of the Agency's committees

Proposed new regulation

The newly created Article 6b of Directive 2011/65/EU regulates, among other things, the deadlines for the opinion of the Agency's committees in the procedure for the list of restricted substances.

	Commission proposal		**Proposed amendments**
Art. 6b para. 1	(1) Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is	>	(1) Within 12 months ***or 18 months during the first 3 years after the entry into force of this Directive*** from the date of publication referred to in Article 6a(6), the Committee for

	appropriate in reducing the risk to human health or the environment, specifically by reference to the risks set out in Article 6(1), third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a). […]		Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically by reference to the risks set out in Article 6(1), third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a).
Art. 6b para. 2	(2) Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. […]		(2) Within 15 months ***or 21 months during the first three years after the entry into force of this Directive*** from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. […]

Justification

The new processes at ECHA following the reorganisation and the appointment of experts to carry out the assessments of hazardous substances in electrical and electronic equipment first have to become established. The deadlines should therefore be extended by 6 months in the first three years after the directive comes into force.

Article 2 Proposal for a Directive on the data platform

Proposed new regulation
Article 2 regulates the transitional period from the entry into force of the Directive amending the procedural provisions of Directive 2011/65/EU.

	Commission proposal		Proposed amendments
Art. 2 para. 2	The provisions under this Directive shall be applicable from [OJ: 12 months after the publication of this Directive].	>	The provisions under this Directive shall be applicable from [OJ: ~~12~~ ***24*** months after the publication of this Directive].

Justification
The envisaged transitional period of 12 months from the entry into force of the directive amending the procedural provisions of Directive 2011/65/EU is too short to allow an appropriate distribution of resources and tasks for ECHA. It should be at least doubled.

Article 30 Regulation (EC) No 178/2002 - Divergent scientific opinions

Proposed new regulation
The newly created Article 30 of Regulation (EC) No 178/2002 regulates the procedure in the event of divergent scientific opinions.

	Commission proposal		Proposed amendments
Art. 30 para. 2	(2) Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned	>	(2) Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned

are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available. [...]	are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues ***using all relevant and technical details available*** and identify the relevant uncertainties in the data and be made publicly available. [...]

Justification

In order not to curtail the scientific discourse, EFSA and the other EU agencies concerned (ECHA, EEA or EMA) must provide each other with all relevant and technical details underlying the opinions in order to resolve divergences.

About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations of statutory health and longterm care insurance funds as well as the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance – Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e.V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union and other European institutions and advises the relevant players in the context of current legislative projects and initiatives. As part of a statutory insurance system, health and long-term care insurance with 74 million insured people, pension insurance with 57 million insured people and accident insurance with more than 70 million insured people in 5.2 million member companies, citizens in Germany are provided with effective protection against the consequences of major life risks.