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NOTE

From: To:	General Secretariat of the Council Delegations
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Subject:	Directive of the European Parliament and of the Council on liability for defective products - Non-paper on special liability systems

Delegations will find in Annex a non-paper from the German delegation on special liability systems.

16 March 2023

German Non Paper

Product Liability Directive

Article 2 para. 3

This Directive shall not affect:

(d) any rights which an injured person may have under any special liability system that existed in national law on ~~30 July 1985~~ **[date of entry into force of this Directive]**.

Recital 10

In certain Member States, injured persons may be entitled to make claims for damages **for example** caused by pharmaceutical products **or products containing genetically modified organisms** under a special national liability system, with the result that effective protection of consumers in the**se** ~~pharmaceutical~~ sector**s** is already attained. ~~The right to make such claims~~ **Such special liability systems that existed in national law on [date of entry into force of this Directive]** should remain unaffected by this Directive **and can be subject to further amendments to keep them viable in the future**.

Article 3 of the Commission's proposal explicitly provides for full harmonisation. In principle we support this approach as the proposal will have a significant impact on the internal market. However, it is necessary to ensure that Member States can **maintain special liability systems** in certain areas to avoid significant disadvantages for the injured parties. In Germany, this applies to sections 84 et seqq. of the Medicinal Products Act (Arzneimittelgesetz – AMG) and sections 32 et seqq. of the Genetic Engineering Act (Gentechnikgesetz – GenTG).

The **German liability regime for pharmaceuticals** was introduced in 1976 in response to the thalidomide scandal which had caused numerous cases of death and serious birth defects of children in the 1960s. This special liability regime provides for a specific balance between the interests of injured parties and pharmaceutical companies and has been adapted several times since its introduction. An obligation to provide coverage — implemented by the "pharma pool" of German insurers — ensures that the **injured parties always face a solvent debtor** in Germany. This high level of protection should be maintained and, if necessary, adapted to further developments in the future.

Moreover, the German law contains specific rules on liability for **products containing genetically modified organisms** (e.g. food made of GM maize). It provides in particular that manufacturers who have been granted authorisation for placing the product on the market are also liable for so-called **development risks** if the product error is based on genetic engineering (section 37 para. 2 sentence 2 GenTG). Under the existing PLD, the development risk defense was optional for Member States. According to the Commission's proposal, development risks are to be fully exempted from product liability, which could mean a considerable reduction in liability under the German Genetic Engineering Act, which has existed since 1990. Especially in the field of genetic engineering, it is conceivable that damage can occur which was not yet foreseeable at the time of development. In such cases, injured persons should also be able to bring claims for damages.

As it is the first time that the PLD explicitly orders full harmonisation, Article 2 para. 3 (d) should not refer to 1985 but to the date of entry into force of the new PLD. This would also allow other Member States to retain their special liability regimes which might provide a higher level of protection for injured parties. Outside of these existing regulations, the PLD would still ensure a full harmonization in the future.

The corresponding recital 10 should also be further clarified in this respect to enable a further development of such special national systems to keep them future-proof.