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Subject: Orgalim comments on the draft guidance document on the Product Liability Directive

Dear Mr Ingels,

Having read the report on Liability for Artificial Intelligence¹, I am pleased to provide our views on the Product Liability Directive (85/374/EEC). Please find below our views on the questions raised during the latest meeting of the Product Liability Expert Group on 5 November 2019.

The Product Liability Directive, thanks to its technology-neutral provisions, has created legal certainty while enabling technological innovation over the past years. We do not see a need to revise the Directive at this point in time. We believe that the Directive is fit for purpose and will continue to meet its objective of setting a balanced and fair framework, in terms of liability, for damage caused by a defective product. The upcoming European Commission guidelines, planned for the first semester of 2020, will play a crucial role in clarifying the scope of the Directive for smart products.

I. Product

- *Should the EU's product liability legislation and its strict liability regime cover all tangible or non-tangible items (including software) causing damage? If so, should there be a distinction of types of software that should be included or not, and why?*

The future guidance document on the Product Liability Directive should not explicitly define stand-alone software or pure data as a "product". This would unduly broaden the scope of the Directive and completely change its logic. Moreover, this would raise many practical issues related to other concepts of the Directive, in particular the concept of "defect". Indeed, it is very difficult to define a defective stand-alone

¹ See: European Commission (2019). Liability for Artificial Intelligence and other emerging digital technologies.
<https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=36608>

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software. On the other hand, according to our understanding, embedded software is a product or part of a product within the meaning of the Directive and should be considered as such also in the future.

II. Defect

- *Do you think that it would be necessary to maintain the notion of defect in the Directive? If not, how would you conceive it differently?*

Only if a product is defective it should trigger the strict liability of the producer according to the Product Liability Directive. A non-defective product should not, under any circumstance, be subject to the Product Liability Directive. Therefore, it is necessary to maintain the notion of defect in the Directive. The addressees of the legislation need as much clarity as possible as to the scope of the legislation. The placing on the market of a product should remain the decisive moment for the start of 10 years' limitation period (see article 10 (2) of the Product Liability Directive).

- *If this notion should be maintained, do you consider that there should be situations where the defect is presumed to exist?*

Due to the very broad definition of defect in the actual legislation, a defect should not be presumed to exist.

- *Would other notions, such as a stronger focus on the reasonable or intended use of the product, provide an alternative in your view?*

To our understanding, the focus on the reasonable or intended use of a product is already provided for in the Directive, which mentions "a product is defective when it does not provide the safety which a person is entitled to expect" (see article 6 of the Product Liability Directive). The notion of reasonable or intended use could be further explained in a guideline document.

III. Damage

- *Do you think that the EU's product liability legislation and its strict liability regime should only cover physical damage and damage to private property, including the resulting loss of income? Why?*

The Directive should cover only material damage and be limited to damage caused by death or by personal injuries and damage to private property (see article 9 paragraphs a and b). It has to be highlighted that for other damages, the claimant can request compensation based on the national tort law (see article 13 of the Product Liability Directive). Originally, the PLD filled a gap in the national legislative framework and therefore its scope shouldn't be extended.

- *Should other types of damage be covered and, if so, why?*

No further types of damages. apart from physical damage and damage to private property, should be covered.

IV. Injured person

- *Would it be necessary to specify that closely related persons could claim compensation in the case of death?*

In all European legal systems, it's already the case that the relatives can claim compensation in case of death. Clarifying this in the guidance document about the Product Liability Directive would do no harm.

V. Producer

- *Who should be liable, in your view - producers of the final products and component manufacturers?*

Both the producer of the final product and the component manufactures are jointly liable according to Articles 3.1;5. This should be maintained.

- *Are you of the opinion that refurbishers and repairers whose actions have a substantial impact on product safety should also be liable as producers?*

Normally, the refurbishers and the repairers are not producers in the sense of the Product Liability Directive. However, if the refurbishes and repairers completely change the product, creating a new product, they should be considered producers according to the Product Liability Directive.

- *Would this require any clarification to the current terms of the Directive?*

In our view, there is a need to further clarify the terms of the Directive in the envisioned guidance document on the PLD.

- *Who would be the producer in decentralised manufacturing processes such as e.g. cases where a product is printed using a downloaded CAD file and a 3D-printing service?*

Both the designer of the CAD file as well as the printer should be considered as producer (joint liability). It is the similar situation as when a drawing component is defective, and it is already provided for in the current directive in Article 5. The claimant has the option to file the claim against one or the other. It seems pertinent to analyse the implications case by case as there are significant differences depending on the product and process concerned.

- *Should the liability of suppliers and importers if the producer cannot be identified also apply to online traders having a role in the distribution of that product?*

Online traders should be considered suppliers according to article 3.3 of the directive.

VI. Burden of proof

- *Are you of the opinion that the burden of proof for injured persons should be improved? And, if so, which would be the ways to do it?*

The burden of proof is an essential counterbalance to the strict liability for the producer. This balance shouldn't be changed as it has been proven successful since the implementation of the PLD.

- *Should authorities and businesses be obliged to provide information on risks and potential problems related to the product that caused the damage?*

This is already an obligation under the **Directive 2001/95/EC on general product safety (see article 2)**.

VII. Exemptions to liability

- *Are the existing exemptions to liability sufficient in your opinion?*

Yes, the existing exemptions to liability are sufficient.

- *Do you consider that the later defect defence should be maintained in light of updates/upgrades/etc.?*

The relevant point in time is when the product is placed on the market (see article 10,2). At this time, the product has to be flawless.

- *Should the development-risk clause be maintained?*

The development-risk exemption has proven to enable innovation in Europe and should be kept by all means.

- *Is the 500€ threshold still a useful tool?*

Maintaining a 500€ threshold is necessary, in particular for insurance coverage.

VIII. Timelines

- *Are you of the opinion that the current timelines for liability claims are appropriate?*

The current timelines for liability claims are appropriate. They lead to legal certainty and enable the producer to obtain adequate insurance coverage.

- *What about cases where the damage occurs within the first ten years of placing the product on the market, but effects only become apparent later?*

In the absolute majority of the cases the ten years period is appropriate. If life or health are involved, the time limitation is often longer than 10 years in many Member States.

- *How should continuous software updates be treated in relation to the timelines?*

The case of software updates should be treated as the repair/refurbishing. If the software update creates a totally new product, the timeline should re-start.

IX. Insurance

- *Should there be mandatory insurance or compensation funds for product liability cases?*

No. It should be left up to the producer to make his own risk management. In the technology industries, there is a wide choice of insurance contracts that can be taken on voluntary basis.

We hope that you find these comments helpful and look forward to discussing them with the group at the next Expert Group meeting.

Thank you for taking our views into account.

Sincerely,



Malte Lohan
Director General
Orgalim – Europe's Technology Industries

Cc: Dirk Staudenmayer