The PFAS Restriction proposal is flawed on three points

The PFAS Restriction proposal is flawed on three points:
1. The Annex XV report fails to demonstrate that PFAS fluoropolymers and fluoroelastomers pose any environmental toxicity concerns beyond their basic property of persistence, nor that they are mobile in the environment, nor lead to bioaccumulation in the food chain, nor that these polymeric PFAS themselves or any breakdown product, if any, are associated with health effects on aquatic organisms, terrestrial organisms or humans. The mere association on the basis of terminology of PFAS fluoropolymers and fluoroelastomers to other types of PFAS that do pose some or all of these concerns is not sufficient grounds to extend the Restriction proposal to fluoropolymers and fluoroelastomers.
2. The Annex XV report is poorly informed about the current availability of PFAS-free alternatives that actually work to replace the fluoropolymers and fluoroelastomers used in the manufacturing of flexible packaging materials such as supplied by our member companies to business operators packaging food and feed. As such alternatives are not currently available, and any future solutions requires time to implement at scale in the whole supply chain, we believe a time derogation for packaging materials for food and feed is justified.
3. The Annex XV report is missing to identify certain uses of PFAS fluoropolymers and fluoroelastomers that are important to our member companies and the supply chains in which they operate. Consequently, the availability of alternatives for these uses, or the time and effort needed to implement them at scale in all stages of our supply chain, have also not been addressed. Therefore, we ask for exemptions or derogations for the following applications:
a. packaging materials for non-sterilised medical devices
b. packaging materials for pharmaceutical products for human and veterinary use
c. manufacturing equipment needed to make packaging materials for food, feed, medical devices, pharmaceutical products and other goods
d. equipment needed for the supply of raw materials to our production plants

The document attached to our response on this consultation gives more information on these three points. In addition, it provides information on the following topics:
support for the proposed derogations for packaging of terminally sterilized medical devices as included in the Annex XV report
• the use of PFAS in laboratory equipment needed for R&D and quality control purposes
• the specific circumstances of the recycled plastics supply chains that justify an additional time derogation

Answer to specific info request 1:

sector: Food contact materials and packaging sub-uses: paper and board packaging, plastic packaging, other packaging

Answer to specific info request 4:

A lot of PE and PP flims collected for recycling do currently contain PFAS (fluoropolymers of fluoroelastomers). There is no practical way for recyclers to find out if the recycled plastic will be below the 50 ppm limit (total fluorine content) except by testing on their finished product, with currently high probability of exceeding the limit. This situation will persist somewhat longer than the time period over which the virgin PE and PP have a derogation for continued PFAS use, as there is a delay until the last of those materials can no longer be returned to the recycling stream. In order to have

a viable plastics recycling industry to meet the sustainability targets of our industry, we therefore need a time derogation that allows extra time for the plastic recycling loops to end. The same is valid for paper recycling streams. As long as PFAS containing paper and board goes into paper recycling streams, recycled paper/board will contain PFAS - maybe exceeding the applicable limits. A time derogation is needed that allows extra time for the paper recycling loops to end. Examples where recycled paper/board are used in our industry are mainly transport packaging and cardboard cores. Recyclable paper is used for industrial packaging. However the use in packaging for food and pharma products is limited today, but might increase in the future due to proposed recycling targets.

Answer to specific info request 5:

Our company is purchasing about 900.000 kg of PE film with a PFAS processing aid. We laminate this film to aluminium foil. This laminate is used as seal closure for 10 billion HDPE bottles for milk, other dairy products and juices.

Answer to specific info request 6:

Our suppliers of the PE film are currently testing alternatives for the PFAS processing aids. Several commercial available alternatives have been tested, however non of these were effective. We laminate these films to aluminium. the laminate is used as lidding film for HDPE bottles for milk, other dairy products and juices. So currently no PFAS free alternative to pack 10 billion HDPE bottles.

Answer to specific info request 10:

To our knowledge ther are currently no analytical methods available for the specific quantification of fluorpolymers in materials and articles - this is only possible for volatile and semi-volatile substances that can be analyzed by liquid chromatography. TF (total fluroine content or TOF (total organic fluorine content) measurements are performed by oxidising the sample by combustion in a bomb with oxygen under pressure (Bomb calorimetry(. After combustion the fluorine is determined by ion chromatography or by ion selective elctrodes. If a sample cannot be introduced into the bomb calorimeter or cannot be completely burned - as in the case with aluminium - content of fluorine or TOF cannot be determined accurately. THis will pose a problem in enforcement/controlling this limit.

中文翻译文本：

6177	日期： 2023/07/11 13:17 内容： 危险或暴露 关于替代品的信息 其他社会经济分析（SEA）问题 过渡期 豁免请求 类型： 代表组织 组织类型： 公司 组织名称： <redacted> 组织所在国家： 荷兰 公司名称保密：	一般性评论： PFAS 限制提案在三点上存在缺陷： 1. 附件十五报告未能证明 PFAS 含氟聚合物和含氟弹性体除了其持久性的基本特性外，还构成任何环境毒性问题，也未能证明它们在环境中具有移动性，也未能导致食物链中的生物积累，也未能证明这些聚合 PFAS 本身或任何分解产物（如果有的话）与水生生物、陆生生物或人类的健康影响有关。仅仅根据 PFAS 含氟聚合物和含氟弹性体的术语与确实引起部分或全部这些问题的其他类型的 PFAS 相关联，不足以成为将限制提案扩展到含氟聚合物和含氟弹性体的理由。 2. 附件 XV 报告对目前无 PFAS 的替代品的可用性知之甚少，这些替代品应该实际上可以替代软包装材料制造中使用的含氟聚合物和氟橡胶，例如我们的成员公司向包装食品和饲料的企业经营者提供的含氟聚合物和氟橡胶。由于目前尚无此类替代品，并且任何未来的解决方案都需要时间在整个供应链中大规模实施，我们认为对食品和饲料包装材料的时间豁免是合理的。 3. 附件 XV 报告缺少确定 PFAS 含氟聚合物和含氟弹性体的某些用途的信息，这些用途对我们的成员公司及其运营所在的供应链很重要。因此，这些用途的替代品的可用性，或者在我们供应链的各个阶段大规模实施它们所需的时间和精力，也没有得到考虑。因此，我们要求豁免或排除以下用途： A. 非灭菌医疗器械的包装材料 B. 人用和兽用药品包装材料 c. 制造食品、饲料、医疗器械、医药产品和其他商品包装材料所需的制造设备 D. 为我们的生产工厂供应原材料所需的设备 我们关于这次磋商的答复所附文件提供了关于这三点的更多信息。此外，它还提供有关以下主题的信息： 支持附件 XV 报告中所列的终端灭菌医疗器械包装的拟议豁免 • 在研发和质量控制所需的实验室设备中使用 PFAS 的程度

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