ENPC
European Nursery Products Confederation

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The **European Nursery Products Confederation** would like to comment on the order specifying the substances contained in mineral oils prohibited for use on packaging and for printed matter distributed to the public (TRIS notification 2022/0004/F).

Our sector welcomes initiatives aimed at supporting the transition to a greener economy. However, we believe this draft order represents a severe barrier to trade, has a potential negative environmental and economic impact and is incompatible with EU law.

We call on the European Commission to present a detailed opinion, to extend the standstill period and to ask France to bring the draft order in line with EU-requirements.

Specific concerns and impacts

Likely impossibility of compliance

It appears impossible to comply with this decree as drafted. In Article 2 of the order, the testing timeline is outlined. From 2023, the level of aromatic hydrocarbons (MOAH) must be lower than 0.1% and saturated hydrocarbons (MOSH) must be lower than 1%. From 2025, the level of MOAH must be lower than one part per billion and for MOSH, lower than 0.1%. This presents three problems. Firstly, the 2025 level of MOAH is too low to be detected via tests. This means that producers cannot test for these mineral oils in 2025 and therefore cannot comply with this decree. Secondly, the low limits mean that even contamination at trace level will result in the packaging or product not being compliant, even if they comply with all other EU laws. Thirdly, the testing must be done on the ink, not on the finished packaging or printed paper. Testing on the finished product may result in a non-compliant result because adhesives can be a source of mineral oils.

This also means that enforcement is not possible. This will put companies aiming to comply with the measures at a serious competitive disadvantage vis-à-vis rogue traders who disregard the rules.

Negative environmental impact

Firstly, Article 5 of the draft order stipulates that packaging and printed material manufactured or imported before 1 January 2023 shall be granted a period of not more than 12 months from that date for the disposal of stocks. This shall result in destruction of unsold products or shipment to other Member States (with additional transport and labelling for example, leading to additional waste and carbon footprint).

Secondly, the draft order also encourages manufacturers to use virgin cardboard instead of recycled cardboard, to ensure that there is no contamination trace of mineral oils from recycled materials. This runs counter to the circular economy objectives.

Thirdly, the use of alternative inks will require longer time periods to dry, leading to additional energy consumption.

Proportionality and justification of the measure

The proposal is disproportionate to the level of toxicity in the mineral oils. We call on France to provide further evidence showing that these mineral oils in ink for packaging provide a threat to public health and that this ban would constitute defending the consumer.

The basis for this measure is the ANSES opinion on the migration of mineral oil compounds into food from recycled paper and cardboard packaging from 8 March 2017. However, the ANSES opinion does not provide a concrete justification for the ban (see annex).

MOSH accounts for 80% of mineral oil hydrocarbons found in packaging. ANSES recommends additional testing and data on the toxicity of MOSHs before any measures**.** Therefore, bans on MOSH should not be introduced in this draft order until more data is available.

For MOAH, the ANSES opinion was not able to propose toxicity reference values due to a lack of data and so risk assessment was not possible. ANSES recommends limiting consumer exposure to MOAHs by acting initially on the sources of mineral oils in paper and cardboard packaging. The ANSES opinion does not provide an express recommendation to ban all mineral oils. The concentration limits proposed are arbitrary and not based on any risk assessment.

Also, ANSES explicitly recommends an alternative, which is the use of a functional barrier between recycled food contact material and the food product, which would prevent migration of mineral oils from the recycled food contact material into the food product. The definition of a functional barrier is provided for in Article 3(15) of the Plastics Regulation *No 10/2011/EC.*

The evaluation of the Food Contact Material Framework regulation (1935/2004) is ongoing. This could be an appropriate framework to address mineral oils in food-contact material.

Negative economic impact

The measure would impact an enormous number of packages, with at least 220 million pieces of toy packaging per year (source: NPD), 35% is imported from other EU countries and 50% from third countries (Source: French Customs) to give you one example. It is unlikely that global manufacturing will be able to comply with the French requirements within the timeframe, regardless of their willingness to do so, which is questionable. This will put at risk any export of toys to the French market, creating a competitive disadvantage for EU operators. Companies that will be able to provide separate packaging for the French market will also be faced with additional costs.

Scope

The scope is unclear with regards to “printed material destined for public”, referred to in Article 4 of the order (and Article 112 of the Law AGEC). No clear definition is provided.

Timeline

The measure obliges printers using mineral oil-based inks to replace their machines without delay, regardless of their geographical location. The timeline foreseen is too short for manufacturers to be able to change inks or for printers to change their printing machines. The willingness to change machines or inks only for the French market is questionable. This will be especially problematic for SME childcare product manufacturers. However, also it is also not possible within the timeline to change the global manufacturing process of an international company. A longer timeline is needed to find ink sources that

are free from these mineral oils.

CAS Numbers

The draft order lists MOAH and MOSH as substances covered by a ban. However, the relevant Chemical Abstracts Service (CAS) Registry Numbers are not listed. As a result, companies will struggle to identify the relevant substances in their supply chain. This will further hamper the possibility for companies to ensure compliance.

Listing the CAS numbers of the mineral oils specified in the ban would make it easier for producers to identify the relevant mineral oils. It would also facilitate the work of market surveillance authorities.

Precedent

If adopted by France, the order will set a very negative precedent and other Member States may follow suit with imposing diverging and arbitrary limit values for mineral oils in printing ink. This will lead to even more fragmentation of the internal market.

Breaches of EU law

Packaging & Packaging Waste Directive (94/62/EC)

The European Packaging & Packaging Waste Directive (PPWD) has as an "objective to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community". By intruding specific requirements for the French market, the draft order does not conform with this objective.

Furthermore, Article 18 of the PPWD states that "Member States shall not impede the placing on the market of their territory of packaging which satisfies the provisions of this Directive". Article 18 comprises a free movement clause and constitutes maximum harmonization because the provision does not enable Member States to lay down more restrictive or simply different rules from those of the Directive. This means that, because of Article 18, the Directive's provisions are the floor and the ceiling, and therefore national legislation cannot deviate from this Directive.

The draft order would impede the placing on the market of packaging that meets the essential requirements as laid down in Article 9 of the PPWD. Moreover, the proposed ban on mineral oils goes beyond the preventive measures mentioned in Article 4.1, which are to be implemented by Member States to prevent generation of packaging waste and to minimize the environmental impact of packaging.

REACH Regulation 1907/2006/EC

According to Article 128 on free movement, Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a mixture or in an article, falling within the scope of the REACH Regulation, which complies with the REACH Regulation and, where appropriate, with Community acts adopted in implementation of the REACH Regulation. The only exceptions are to protect workers, human health and the environment. As pointed out above, we believe there is no valid justification on these grounds.

If the substances covered by the draft order are authorized under the REACH Regulation, the restrictions imposed by the draft order on these substances would be illegal. Substances authorized by the REACH Regulation do not fall within the scope of the exception provided for under Article 4 of the draft order.

Plastics Regulation No 10/2011/EC

According to Article 5, only substances included in the Union list of authorized substances may be intentionally used in the manufacture of plastic layers in plastic materials and articles.

Prohibiting the use of a substance explicitly authorized by this Regulation would constitute a violation. However, that is why in Article 4 of the draft order would have an exception for "packaging… for which a Community provision expressly authorizes the use of inks containing mineral oils, subject to compliance with the limits and conditions of use by the said provision."

This Regulation refers to white mineral oils (95883) in its Annex I (number 95 on the list) and it is permitted for use as an additive or polymer production aid. According to the test method and concentration threshold set by the draft order, this is likely to be identified as a prohibited substance.

Other substances, likely to be identified as prohibited substances are: number 93 waxes (95858), number 94 waxes (95859), number 97 petroleum hydrocarbon resins (72081/10), number 549 polyethylene wax (80000), number 550 polypropylene wax (81060).

It is therefore necessary that the exception provided for in Article 4 of the draft order will apply to substances whose use is authorized under this Regulation.

General - EU treaties

Regarding all matters and products not covered by the PPWD and TSD, we must consider whether the draft order qualifies as an obstacle to trade contrary to EU primary legislation, i.e., the TFEU. The measure might nevertheless be justified by France pursuant to any of the exemptions foreseen by the Treaty on the Functioning of the EU (TFEU) or the EU case law, such as the protection of the environment. Such justification is not relevant for those products where EU secondary legislation amounts to full harmonization (packaging and toys) but is decisive in those cases where EU secondary legislation does not amount to full harmonization or for those products where there is no EU legislation addressing the concerns covered by the Draft order.

Articles 34-36 TFEU which guarantee the free movement of goods, are intended to "eliminate all barriers, whether direct or indirect, actual or potential, to trade flows in intra-[EU] trade". Therefore, any measure introducing an unnecessary and unjustified technical barrier against the free movement of goods which are lawfully produced and marketed in another Member State is contrary to EU law. The principle of mutual recognition requires Member States to authorize in their territory goods that are legally sold in other Member State.

The requirements are specific for the French market. Companies will therefore need to create separate accompanying documents to be provided just with goods sold on the French market. The Draft order will therefore constitute an obstacle to trade. The requirements will render the marketing of products more difficult or more expensive.

Companies might need separate packaging for the French market or might not be able to sell certain products in France even if they are fully compliant with the EU legislation. This results in a severe barrier to trade within the EU. This is an infringement of Article 34 of the Treaty on the Functioning of the European Union (TFUE), which prohibits any measure likely to hinder, directly and indirectly, actually or potentially, intra-Community trade (*C-8/74 Dassonville*).

No valid justifications have been brought forward by France to deviate from the principle of free movement of goods. As highlighted above, the measure appears disproportionate to the level of toxicity in the mineral oils. Moreover, other, potentially less restrictive measures, more appropriate to attain the objective could have been considered, such as a functional barrier between recycled food contact material and the food product.

Call for Action

We call on:

- The European Commission and EU Member States to present a detailed opinion asking Franceto address the above-mentioned concerns;
- The French Government to provide evidence that these mineral oils present a threat to public health – and if so, at what threshold - and justifications to deviate from the principle of free movement of goods in the internal market;
- The French Government to change the draft Ordinance to address the above-mentioned concerns, such as proportionality, compliance with EU rules, achievable limit values, include CAS numbers, longer implementation deadlines and clarify the scope of this measure.

About the European Nursery Products Confederation

The ***European Nursery Products Confederation (ENPC)*** is the trade association for childcare product manufacturers in Europe. It is composed of national associations representing small and medium-size enterprises (SMEs) and large companies playing a key role in the European single market.

ENPC was established in May 2011 in Brussels with the aim of speaking with a united voice and guaranteeing an active participation of its members in European policy developments.

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Annex: Toxicologist assessment

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ANSES Opinion of MOSH and MOAH and proposed French ban on packaging inks

ANSES were charged to provide an opinion on the migration of mineral oil compounds from recycled cardboard and paper packaging. Consequently, mineral oils will be banned for use on packaging in France and from 2025 the ban will extend to printed material for the general public.

Mineral oils used in packaging inks have been associated with migration of MOSH and MOAH into foodstuffs, particularly where recycled paper has been used to manufacture the packaging materials.

The ANSES Opinion, while recommending that consumer exposure is minimized, does not provide a concrete justification for the ban.

For MOSH, little new data has been provided since the original EFSA Opinion on mineral hydrocarbons with the exception of one new study that indicates that adverse effects in the liver are more likely to occur at higher doses than suggested in the EFSA Opinion. Adverse effects in the male rat kidney were considered species specific and not relevant for humans.

MOSH account for approximately 80% of mineral oil hydrocarbons found in packaging.

MOAH are more problematic, as MOAH with at least three aromatic rings and little or no alkylation can be metabolically activated to potentially genotoxic carcinogens. ANSES however state that it is difficult to predict the mutagenic nature of mineral oils. MOAH have been associated with carcinogenicity by the dermal route, but evidence is lacking for the oral route. Adverse effects on reproduction and endocrine disrupting potential cannot be ruled out.

ANSES were not able to propose toxicity reference values due to the lack of data on the composition of MOAH fractions, toxicity and insufficiently characterized human exposure. Risk assessment was therefore not possible.

The ESPA WG and the CES ERCA believe that priority should be given to reducing the contamination of food by MOSH and MOAH. This makes sense, as the available data does indicate that the presence of non-threshold genotoxic substances in food is a potential, but as yet unquantifiable risk.

ANSES therefore recommend additional steps that include examining the feasibility of using MOAH free additives and processing aids in the printing sector and examining how the mineral oil hydrocarbon content could be reduced in the processing of recycled paper material. A further practical step is to include a barrier material into food packaging to reduce migration.

The ANSES opinion therefore does not provide an express recommendation to ban all mineral oils from packaging material but focusses on the MOAH fraction as this is likely to have the most significant adverse effect on health. The French ban proposes different limits for MOSH and MOAH in printing ink, bit the concentration limits are arbitrary and not based on any risk assessment. The limit for MOAH of 1 ppb reflects the precautionary principle and it is questionable whether this is measurable. When this limit is reviewed in the context of food analysis for mineral oil hydrocarbons where the detection limits are 2.0 mg/kg to 0.5 mg/kg, depending on the matrix it is clearly over-protective.

Applying a ban only to printed material in France is not justified at all by the ANSES Opinion and would have limited impact on consumer safety, as clearly this will have no effect on feedstocks supplied from other Member States. The French ban is also disproportionate when viewed in the context of actions being taken by other Member States. In Germany, a regulation is being prepared to regulate migration

into food which is a practical solution and does not involve a ban on MOSH/MOAH printing inks. BfR also recommend that exposure can be prevented by using virgin fiber, using mineral oil free printing inks in food packaging and the use of functional barriers.

In other words, in Germany the focus is being placed at the end of the supply chain to protect consumers which is logical. In my view a general French ban on mineral oil in inks for all purposes will have virtually no effect on food safety.

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