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Fischersgade 56
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6 February 2026

Re: Consultation response – Draft criteria for Nordic Swan Ecolabelling of medical devices (098)

Introduction

We acknowledge Nordic Ecolabelling's ambition to promote more environmentally and health-responsible material choices in the healthcare sector. This is a legitimate and important objective. At the same time, we find it necessary to raise a number of fundamental and principled concerns regarding the way PVC is categorically excluded in the current draft, without this being accompanied by an equivalent, documented, holistic and proportionate assessment of the alternatives.

Our overarching concern is that, in their current form, the criteria risk leading to significant economic and systemic consequences for the healthcare sector, without it being sufficiently documented that a corresponding environmental or health benefit is achieved.

1. Categorical exclusion of PVC without risk-based evidence

PVC is excluded in the criteria as a "halogenated plastic" in a general and categorical manner. The justification, as stated in the background text to criterion 02, refers broadly to waste management, health risks and historical issues associated with PVC.

We find this approach problematic for the following reasons:

- PVC continues to be widely used in critical medical devices precisely because of its well-documented functional, safety and hygienic properties, which in many cases are difficult to replace without extensive re-design and new regulatory approvals.
- PVC in medical devices is subject to very strict regulation in the EU, including REACH, the Medical Device Regulation (MDR), as well as requirements relating to biocompatibility, migration, sterilisation and patient safety.
- Classified phthalates, including DEHP, have already been phased out or heavily restricted in the vast majority of medical devices in the EU, and current use is in practice based on non-classified, regulatorily accepted alternatives. For blood bags, DEHP-free PVC solutions are actively being developed and validated by manufacturers and European blood services, in line with EU regulatory timelines.[1]

[1] https://doi.org/10.1111/vox.13433; http://data.europa.eu/eli/reg/2023/2482/oj; http://data.europa.eu/eli/reg/2023/607/oj;

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- Like all sectors, the healthcare sector must meet European climate targets, aiming for net zero by 2050. PVC has a comparatively low carbon footprint among polymers and a high inorganic content, which reduces its fossil carbon dependency and facilitates decarbonisation without fundamental changes to existing production infrastructure.[2] Furthermore, PVC offers high recyclability and is already integrated into documented recycling initiatives. In parallel, PVC producers and compounders are already offering healthcare-grade materials based on bio-attributed and recycled feedstocks, as well as renewable energy inputs, further improving the carbon footprint of PVC-based medical devices.

If PVC is to be excluded as a material, Nordic Ecolabelling should therefore document why the existing EU regulatory framework is not considered sufficient, and why alternatives are assessed as being environmentally and health-wise superior overall, when evaluated on a comparable and risk-based basis.

It should also be noted that this categorical approach is not applied in a corresponding manner to other plastic materials, which likewise require additives and processing chemicals to achieve the necessary functional properties in medical devices. All plastics – including PP, PE, PET, TPU, TPE and silicone – rely on additive systems and may contain processing aids, catalyst residues, flame retardants, PFAS-based fluoropolymers, as well as non-intentionally added substances (NIAS), which can be difficult to identify and control.[3]

Focusing narrowly on PVC additives without imposing equivalent requirements on alternative materials entails a real risk of regrettable substitution.

This inconsistency is particularly evident when comparing how PVC and silicone are treated in the background analysis. The primary argument used to exclude PVC is its chloride content. However, chloride is also an essential input in the manufacture of silicone, which is explicitly allowed under the criteria.

Notably, the background documentation sets a threshold for chloride emissions during silicone manufacture, based on Best Available Techniques (BAT). An equivalent, BAT-based approach has historically not been accepted or applied to PVC production.

Furthermore, the MECO analysis included in the background material shows that PVC manufacture has the lowest carbon footprint and energy demand among the compared materials. Despite this, a specific CO_2 threshold is established for silicone manufacture — again an approach that has not been applied to PVC.

This selective use of thresholds and BAT-based benchmarks raises questions about the consistency and neutrality of the material assessment.

2. Lack of consideration of economic aspects and healthcare system realities

Sustainability rests on three equally important pillars: environmental, social and economic. In the present draft, however, the economic dimension is largely absent.

A general shift away from PVC in medical devices entails:

[2] https://pvc.org/wp-content/uploads/2023/06/230628_Eco-profile-PVC_june23.pdf
[3] https://zenodo.org/records/17208791; https://doi.org/10.1016/j.jfca.2025.108371; https://echa.europa.eu/documents/10162/2082415/flame_retardants_strategy_en.pdf

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- significant costs for manufacturers related to material substitution, re-design, new production processes, revalidation, biocompatibility testing, sterilisation validation and renewed regulatory approvals under the MDR
- indirect, but real, costs for hospitals and healthcare systems if the Nordic Swan Ecolabel becomes influential in public procurement or political prioritisation

This creates a tangible risk of more expensive products, reduced availability and longer implementation timelines, without documented evidence of a corresponding improvement in patient or environmental safety. Without a systematic cost–benefit assessment, the proposed approach does not appear proportionate.

At the same time, it must be recognised that increased costs in healthcare systems can have knock-on effects on overall resource allocation and thus on the social sustainability of publicly funded healthcare systems, such as those in the Nordic countries.

3. Circularity is addressed insufficiently and unrealistically

It is particularly concerning that circularity does not form a core and operational criterion in the assessment of materials for medical devices.

The background documentation states that medical devices covered by the criteria are generally incinerated after use, regardless of which materials they consist of. While this may reflect current practice for a large share of medical devices, it does not provide a complete picture and risks obscuring relevant differences between materials.

A modern ecolabel should, as a minimum:

- set requirements for design for recycling, including mono-material solutions and traceability, where technically feasible
- consider which materials can, in practice, be integrated into functioning and documented recycling systems

In this context, it is important to note that the only documented, operational recycling initiatives for medical devices in Europe today are PVC-based, developed and implemented through VinylPlus Healthcare. These initiatives demonstrate that post-use recycling of selected medical devices is technically and organisationally feasible within existing healthcare systems.[4]

It is therefore paradoxical that a material already integrated into concrete circular solutions is excluded, while materials without documented circularity are accepted. PVC can also be treated through pyrolysis and physical recycling based on selective dissolution.[5]

It is also important to underline that many PVC alternatives achieve the required functional properties through complex multi-material solutions, combinations of different polymers, and permanent coatings or layered structures. These constructions cannot be mechanically separated and recycled and therefore typically end up in incineration. An ecolabel that favours products solely based on polymer type ("PVC-free") thus risks unintentionally promoting solutions with poorer recyclability and lower actual circularity.

[4] https://vinylplushealthcare.eu/sustainability/vinylplus-med
[5] https://www.vinylplus.eu/resources/arcus-greencycling-technologies-pyrolysis; https://www.vinylplus.eu/circular-economy/recycling-options

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4. ECHA's assessment of PVC should be explicitly included

In the assessment of materials for medical devices, existing EU authority evaluations should serve as a central and normative reference point. The European Chemicals Agency (ECHA) published its comprehensive PVC assessment in 2023, conducted on a mandate from the European Parliament. This assessment represents the most up-to-date and consolidated technical review of PVC at EU level.[6]

ECHA concludes, inter alia, that:

- PVC production in Europe can today be considered safe under the current regulatory framework
- there is insufficient evidence to conclude that PVC in medical devices is, overall, environmentally inferior to alternative materials when assessed across the full life cycle
- PVC possesses a combination of functional properties – including flexibility, durability, chemical stability, weldability and transparency – that are, in practice, difficult to achieve collectively in alternative materials
- substitution of PVC in medical devices often leads to functional compromises or the need for more complex product designs, including thicker materials and multi-layer or multi-material solutions
- such design changes may increase material consumption, reduce recyclability and, in some cases, lead to a higher overall environmental footprint
- substitution entails significant economic consequences for manufacturers in the form of re-design, testing, revalidation and new regulatory approvals
- security of supply and stable access to materials are relevant considerations, as PVC is largely produced in Europe, whereas several alternative materials are more specialised and dependent on global supply chains
- modern European waste incineration plants are technically capable of handling waste streams containing up to approximately 2% PVC without negative effects on operation or emissions

ECHA further notes that classified phthalates have to a large extent been substituted in medical PVC, and that current use is largely based on alternative plasticisers such as DOTP, DINCH, BTHC and TOTM. These are approved under the MDR and comply with relevant requirements in the European Pharmacopoeia. On this basis, ECHA finds no grounds to conclude that the use of PVC in medical devices based on these alternative plasticisers constitutes an unacceptable risk.

As an official, legally anchored ecolabel widely used in both markets and public procurement, Nordic Ecolabelling bears a particular responsibility to base its criteria on objective, documented and proportionate assessments. In this context, it is problematic if positions put forward by US-based non-governmental organisations, such as Health Care Without Harm, or considerations related to materials' historical reputation, as referenced in previous responses from Nordic Ecolabelling during consultation processes, are given greater weight than central EU authority assessments without explicit and technical justification.[7]

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[6] https://echa.europa.eu/documents/10162/17233/rest_pvc_investigation_report_en.pdf; https://echa.europa.eu/documents/10162/17233/rest_pvc_investigation_report_appendix_a_b_en.pdf; https://echa.europa.eu/documents/10162/17233/rest_pvc_investigation_report_appendix_c_en.pdf

[7] " … [T]here is a risk that the trustworthiness of the Nordic Ecolabel could be undermined if Nordic Ecolabelled PVC based exterior panels were to be found on the market, as many NGOs still advise to avoid the use of PVC products." https://www.nordic-swan-ecolabel.org/4ab625/contentassets/432a01492e0d4656894881210ba27abb/consultation-responses-114_114_exterior-panels-and-cladding-114_english.pdf, p. 7

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If Nordic Ecolabelling chooses to adopt an assessment that differs from ECHA's conclusions, this should be clearly justified and supported by newer and more robust evidence. An ecolabelling scheme should not implicitly set aside comprehensive EU authority assessments without a solid technical basis, as this risks undermining the scientific credibility of the criteria.

5. Waste, incineration and historical problem framing

The background text to criterion 02 places emphasis on historical issues related to PVC, including additives and waste management.

We find it important to clarify that emissions of polychlorinated dibenzodioxins and dibenzofurans, acid gases, and other undesirable combustion products today are primarily a matter of process control and compliance with BAT requirements, not the presence of a specific plastic material per se. Under inadequate or uncontrolled incineration conditions, a wide range of materials – including polyolefins, polyurethanes, textiles and composite materials – can give rise to problematic emissions.

Modern European waste incineration plants, however, operate under very strict emission limits and technical requirements specifically designed to prevent such conditions. Within this system, PVC, as confirmed by the ECHA report, does not in itself constitute an unacceptable risk, and plants are technically capable of handling waste streams with a controlled PVC content.

Using waste and incineration arguments as a general justification for material bans therefore appears to reflect a historical and oversimplified problem framing that does not correspond to current technical and regulatory realities.

6. Inspiration from Nordic Swan Ecolabelling of floor coverings

In this context, we would point out that Miljömärkning Sverige has already proposed a more nuanced and technology-neutral approach in its work on Nordic Swan Ecolabelling of floor coverings.[8]

Under this proposal, PVC is not excluded per se, but assessed against concrete and stringent requirements covering the entire product life cycle – including production, raw materials, use and waste management. This approach ensures a level playing field, high environmental ambition and technical credibility.

Although the proposal was not adopted at Nordic level, it demonstrates that it is both feasible and credible to apply strict, objective and life-cycle-based criteria to PVC-based products.

We believe that a similar model could beneficially be applied to medical devices.

7. Proposal for more targeted criteria

Instead of a general exclusion of PVC, we propose that Nordic Ecolabelling consider a more precise and technically robust approach, for example:

- allowing PVC in medical devices provided that the material is produced in compliance with applicable European standards and demonstrably meets EU chemicals and product legislation, including being free from classified phthalates and other regulated substances of concern
- requiring design for recycling and documented compatibility with existing or feasible recycling systems

[8] Nordic Swan Ecolabel's position on PVC in floor coverings, 2023. Internal memo.

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- applying the same circularity and chemical requirements to all materials, not only PVC

This would promote technology neutrality, genuine innovation and actual circularity.

Concluding remark

We urge Nordic Ecolabelling to reconsider the categorical exclusion of PVC and instead develop criteria that are proportionate, evidence-based and technology-neutral, that integrate circularity and economic aspects as core elements, and that build on current knowledge and existing EU assessments.

Only in this way can the Nordic Swan Ecolabel function as a truly modern, credible and effective environmental tool for the healthcare sector.

/Ole Grøndahl Hansen & Tobias Johnsen, VinylPlus Healthcare, 6 February 2026

Signatories

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