We have just received this request for a meeting from AnimalhealthEurope (please see English text below). Did any of you receive the same request?
I don't see any reason to meet with them as we have proposed a derogation for active substances covered by Regulation (EU) 2019/6.

Kind regards
Toke

Fra: P11 < E7 >
Sendt: 23. september 2022 09:54
Til: Mikkel Aaman Sørensen <[redacted]@mim.dk>; Toke Winther <[redacted]@mst.dk>
Cc: P12 < E8 >
Emne: Forespørgsel om møde vedr. PFAS (perflouralkylstoffer)
Prioritet: Høj

Kære Mikkel Aaman Sørensen og Toke Winther!
Denne henvendelse på vegne af AnimalhealthEurope og Veterinary Industry Nordic.
AnimalhealthEurope (https://animalhealtheurope.eu) er den Bruxelles-baserede interesseorganisation for den veterinære del af lægemiddelindustrien og vi hos Veterinary Industry Nordic den nordiske pendant.
Vi er stærkt bekymrede for, at de aktuelle overvejelser vedr. et totalforbud mod anvendelse af perflouralkylstoffer vil få sundhedsmæssige konsekvenser for både dyr og mennesker. Vi redegør for vores bekymringer nedenfor, herunder også, hvordan et sådant forbud efter vores opfattelse vil være i strid med de grundlæggende principper for EU-lovgivning.
I den forbindelse vil vi anmode om et møde – meget gerne *in person* – med jer og på dette forelægge og uddybe disse bekymringer.
Et møde vil have deltagelse af P12 (Ti2 AnimalhealthEurope), P13 (Senior Technical Manager, AnimalhealthEurope) og undertegnede.
Vi har retter samme henvendelse til myndighederne i Norge og Sverige.
Ser frem til at høre fra jer.
Mange venlige hilsner

P11
Ti1

VINORDIC VETERINARY INDUSTRY NORDIC

Direct: T1
Mobile: T2
Switch: T3

Veterinary industry Nordic
Store Kongensgade 81 I 1264 København K I Denmark
vinordic.org

Uddybning

With the new and very recent Veterinary Regulation 2019/6, which came into effect on 28 January 2022, the European Institutions have further finetuned the standards for development, authorisation, manufacturing, and use of Veterinary Medicinal Products (VMPs) for the years/decades to come. The Regulation ensures high protection of human health, animal health and the environment while at the same time aiming to address compelling issues such as the reduction of administrative burden and increasing the availability of VMPs in the Union.

However, in practice, some EU environmental legislations threaten to potentially overlap and conflict with legislation for veterinary medicines. This is in particular the case for:

The REACH Regulation (Reg 1907/2006). Various initiatives under this Regulation are already impacting VMPs either during their manufacture or in their composition, or are imposing labelling requirements which are in direct conflict

with the rules in Reg 2019/6:

- Examples include restrictions on aprotic solvents NMP, DMF and DMAc; rules on labelling and reporting of microplastics in medicinal formulations.
- The recently launched proposal for restriction of per- and polyfluoro alkyl substances (PFAS) which, given its broad definition of PFAS, threatens a ban on specific VMPs or renders their manufacture impossible as there are no alternatives. E.g., this could eliminate all inhalation anaesthetics currently used in both human and veterinary medicine, and it could cause significant treatment gaps in other areas with implications for animal health but also for public health as some of the conditions that are treated by these medicines (e.g., fleas and ticks, and the diseases they carry) can impact human health if the animals are left insufficiently treated, or even untreated.

Human and veterinary medicinal products are regulated by weighing their benefits with the potential risks that might be associated with them and where this balance is positive, the medicines receive a marketing authorisation. This principle which governs the provisions of Regulation 2019/6 is in contrast to the principle of regulating based on the hazard alone, which is at the core of EU environmental legislation. By default, this basic difference in governing principles will ultimately result in serious availability issues with both human and veterinary medicines if the “one substance, one assessment” proposal would be pursued in a non-discriminatory way.

This area of environmental legislation not only causes legal conflicts with regulation 2019/6 but also risks resulting in dual and even conflicting legislation for VMPs which is unacceptable under the basic principles of EU Law.

This situation already causes uncertainty for companies, and we know from experience that the lack of predictability of our legal environment will rapidly result in a decrease in investment and with that of innovation for the EU Medicine sector.

Miljøministeriet
Miljøstyrelsen

Den 12. juli 2024

Aktdetaljer

Akttitel: VB: PFAS-regulation
Aktnummer: 17
Sagsnummer: 2020 - 15422

Akt-ID:	3823244
Dato:	05-10-2021 17:20:08
Type:	Indgående
Dokumenter:	• [1] VB PFAS-regulation.eml • [2] Input from KVI - Swedish trade association for refrigeration importers.pdf

Til: P1 (E1), P2 (E2), Toke Winther ([redacted]@mst.dk), restrictiePFAS (E7)
Cc: DE (E1 (E1)
Fra: ' P3 ' (E3)
Titel: VB: PFAS-regulation
Sendt: 05-10-2021 17:08
Bilag: Input from KVI - Swedish trade association for refrigeration importers.pdf;

FYI (I see that this was sent to SE and DE.
Best regards
P3

P3
Strategic Advisor
Development of Legislation and Other Instruments\Proposals for Classification and Restriction
Swedish Chemicals Agency
Direct: + 46 T2
Phone: + 46 T3
www.kemikalieinspektionen.se

How we treat your personal data

Från: E4 < E4 >
Skickat: den 5 oktober 2021 10:18
Till: E4
Ämne: PFAS-regulation

Input from KVI – Swedish trade association for refrigeration importers

Med Vänlig Hälsning/Best Regards
Lars Jonsson
Projektledare/Kansli

Kyl & Värmepumpimportörerna
Tillinge, Vela 9
SE-745 94 Enköping
Sweden
Phone 0171445129
Cellphone +4 T1
email E4
Internet. www.kvi.se

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KYL och VÄRMEPUMP IMPORTÖRERNA

Enköping 21.10.04

Input from Ti1 – Swedish trade association for refrigeration importers

From the information we have received as a trade association we see and believe not all aspects have been covered in the first step in the process for the project around a change in PFAS-regulation.

From the Swedish side we like to share the light on the fact we have the EU 517/2014 and a very clear and strong Swedish legislation for us in the market to follow. In short for the SE market we have suppliers strict in line with it and under the use for refrigeration and refrigerants Sweden holds a strong position in sales and use only for companies with a F-Gas certificate. The companies with their personnel uphold all aspects such as safe handling and use of refrigerants and this includes a strong position in how SE takes care of used refrigerants and how we scrap used equipment in a good and safe way.

Feel free to reach out to Ti1 if you have further questions on the topic.

Best Regards

P1
Ti1

Sändlista;
E1
E2
E1

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Ti1 Kansli
Tillinge Vela 9, 745 94 Enköping

e-postadress
[redacted]@kvi.se

Telefon
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www.kvi.se

Org.nr.802009–4291

Miljøministeriet
Miljøstyrelsen

Den 12. juli 2024

Aktdetaljer

Akttitel: VS: Letter from Hydrogen Europe and Hydrogen Europe Research to RIVM on the PFAS restriction process
Aktnummer: 61
Sagsnummer: 2020 - 15422

Akt-ID:	4483827
Dato:	26-01-2022 08:58:21
Type:	Indgående
Dokumenter:	• [1] VS Letter from Hydrogen Europe and Hydrogen Europe Research to RIVM on the PFAS restriction process.eml • [2] HE and HER_Letter on PFAS to RIVM_final.pdf

Til: Helle Simon Elbro ([redacted]@mst.dk), P18 ([redacted]@mst.dk)
Fra: Toke Winther ([redacted]@mst.dk)
Titel: VS: Letter from Hydrogen Europe and Hydrogen Europe Research to RIVM on the PFAS restriction process
Sendt: 26-01-2022 08:58
Bilag: HE and HER_Letter on PFAS to RIVM_final.pdf;

Hej P18 og Helle

Denne er relevant for elektronik/energi rapporten.

Venlig hilsen
Toke

Fra: P1 < E1 >
Sendt: 25. januar 2022 12:47
Til: Toke Winther <[redacted]@mst.dk>
Cc: restrictiePFAS < E7 >
Emne: FW: Letter from Hydrogen Europe and Hydrogen Europe Research to RIVM on the PFAS restriction process

Hi Toke,

For info / processing.

Best regards, P1

From: restrictiePFAS < E7 >
Sent: dinsdag 25 januari 2022 10:05
To: P2 < E2 >
Subject: FW: Letter from Hydrogen Europe and Hydrogen Europe Research to RIVM on the PFAS restriction process

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From: P3 < E3 >
Sent: dinsdag 25 januari 2022 10:02
To: restrictiePFAS < E7 >
Cc: P4 < E4 >; P5 < E5 >; P6 P9 < E6 >
Subject: Letter from Hydrogen Europe and Hydrogen Europe Research to RIVM on the PFAS restriction process

Dear Madam or Sir,

You will find attached a joint letter from the European hydrogen industry and research associations, Hydrogen Europe and Hydrogen Europe Research, addressed to Mr. P7 , Director Environment and Safety, Dr. J.M. (P8) Roles, Head of Centre for Safety of Substances and Products, and Dr. P2 , Head of the REACH Bureau, at the Dutch National Institute for Public Health and the Environment (RIVM).

The letter follows up on the published report summary on PFAS in the electronics and energy sectors (following the Regulatory Management Option Analysis (RMOA) of summer 2021) and outlines the sector's positions and concerns on the upcoming PFAS restriction proposal.

Hydrogen Europe (HE) is the leading organisation representing European based companies and stakeholders that are committed to moving towards a (circular) carbon neutral economy. With more than 300 companies and 30 national associations as members, we encompass the entire value chain of the European hydrogen and fuel cell ecosystem. Hydrogen Europe Research (HER) is an international non–profit association composed of 103 universities and Research & Technology Organisations (RTO) from 25 countries all over Europe and beyond. Our members are active

within the European hydrogen and fuel cell sector.

We remain available to continue this dialogue, whether by written or via a meeting.

Best regards,

***

P3
Officer, Industry Policy
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Secretariat: +32 2 540 87 75
E3
www.hydrogeneurope.eu
Learn more about our activities also on Instagram, LinkedIn and Twitter!

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Belgium

EU Transparency Register: 77659588648-75

RIVM National Institute for Public Health and the Environment
Kingdom of the Netherlands

P1 , Director Environment and Safety
Dr. J.M. (P2) Roles, Head of Centre for Safety of Substances and Products
Dr. P3 , Head of the REACH Bureau

CC: E1

Brussels, 25th January 2022

Subject: The use of PFAS in the hydrogen sector and on the report summary for the electronics and energy sectors

P1 Wijnker, Dr. J.M. (P2) Roles, and Dr. P3 ,

Hydrogen Europe and Hydrogen Europe Research are writing to you to share their reaction on the published report summary on PFAS in the electronics and energy sectors (following the Regulatory Management Option Analysis (RMOA) of summer 2021) and their concerns on the upcoming restriction proposal.

Our sector is fully supportive of the Fit-for-55 package and the ambitious targets it sets for increasing the uptake of renewable hydrogen technologies by using demand and supply side mechanisms and targeting rollout in end use sectors in addition to scaling up production.

The way the restriction is shaped will be a decisive factor determining whether the EU and the Netherlands will achieve their Hydrogen Strategies' targets in installed electrolyser capacity of 6GW and 0.5GW by 2024, and 40GW and 3-4 GW by 2030, respectively. The restriction proposal could also put at stake the feasibility of complying with the binding target of 50% for renewable fuels of non-biological origin (RFNBO) used in industry and the 2.6% sub-target for RFNBOs in transport, as currently proposed by the European Commission in the revision of the Renewable Energy Directive. This restriction also has the potential to hinder the general achievement of the carbon neutrality by 2050 objective fixed by the European Union.

In this context and whereas a restriction proposal is being drafted following the publication of the sectoral reports, we would like to point out the following key elements:

Regarding the purpose of using PFAS in the hydrogen sector:

- Electrolysers and fuel cells are principally concerned by the PFAS restriction proposal. The core of both proton exchange membrane (PEM)[1] water electrolysers and PEM fuel cells is an electro-chemical reaction through a membrane in which certain types of PFAS are used. A very large proportion of planned projects involving electrolysers and fuel cells (and in some applications, 100% of them) are based on this PEM technology. Amongst tracked water electrolysis projects to be completed by 2030 in EU/EEA/UK for which information is available, PEM electrolysis accounts for 55% of the projects and 20% of the capacity[2]. In the case of alkaline water electrolysis (ALK), a diaphragm (e.g., Zirfon) which does not contain PFAS is used instead of a membrane. Yet, like for the PEM technology, PFAS types (i.e., PTFE)

[1] The PEM acronym also sometimes stands for "polymer electrolyte membrane," which essentially refer to the same membrane type.
[2] Hydrogen Europe data.

are used in the product, e.g., as sealing materials and gaskets. ALK electrolysis accounts for 38% of the projects and 73% of the capacity. The remaining shares belong to solid oxide technology projects and projects combining multiple technologies for which the capacity cannot be split.[3]

- The PFAS membranes act as a barrier to gases (H2 and O2), an electrical insulator, and a conductor of protons (H+), providing essential hydrogen impermeability and oxygen permeability. Furthermore, it is durable in the chemically and mechanically harsh environments of the devices.
- In that sense, PFAS are currently essential to both fuel cells and electrolysers.

Regarding where PFAS are used and the types of used PFAS in the hydrogen sector:

- The report summary omits the use of PFAS in Membrane Electrode Assemblies (MEAs) (consisting of the membrane, a gas diffusion layer, and a microporous layer) for PEM electrolysis in Table 2 (p. 3) and of Perfluorosulfonic acid (PFSA) ionomers in the catalyst layer of PEM fuel cells (e.g., p. 6 and Table 4 p. 13).
- Besides, it should be flagged that PFAS (especially PTFE) is also used in hydrogen transmission and distribution technologies (not least in compressors).
- The definition between sealing components and membrane needs to be made clearer.
- It is not clear in which section (energy or fuel cell section) electrolysis falls. It should fall under the energy section.
- The paragraph on the top of p. 8 on the "global fuel cell market …" refers to material handing vehicles, light-duty vehicles, buses and aerospace. On top of those, it should be ensured that other heavy-duty vehicle types (trucks, trains, coaches, etc.) as well as maritime transport applications (especially small vessels) are clearly considered in those forecasts. The HDV and maritime sectors are clearly to be two major end-uses for hydrogen (which is also highlighted in the Work Programme of the EU's Clean Hydrogen Partnership). Likewise, it omits stationary application market of PEM fuel cells.
- Appendix I of the report summary should also include Nafion (CAS: 31175-20-9), Aquivion (CAS: 1163733-25-2) and 3M Ionomers (CAS: 913556-90-8).

Regarding the potential for PFAS alternatives in the hydrogen sector:

- No alternative to PFAS today comes close to the same KPIs – research can play a role but there is no foreseen fluorine-free breakthrough in the near future.
- The alternative sealing materials need to be looked at more loosely to assess if they are technically feasible to meet the product requirements.
- Under Section 8 "Alternatives", the text refers only to the semiconductor manufacturing industry. For fuel cells and electrolysers, there is also no drop-in replacement, neither for the PFSA ionomer (membrane and catalyst layer) nor for PTFE.
- Research has evaluated the potential of sulfonated hydrocarbon membranes mentioned in Table 4 p. 13; e.g., sulphonated polyetheretherketone (sPEEK) or polysulfone (e.g., seminal work on BPSH polymers by J. E. McGrath). While conduction properties and performance of these materials can be reasonably good, mechanical stability and durability are extremely poor, as oxidation by oxygen radicals, occurs. All non-fluorinated membrane concepts are still highly immature against minimum lifetime requirements of >25,000 hours. In a nutshell, they are not even close to meeting any durability requirements in a lab testing environment (10x better radical scavenging strategy or reversable degradation[4]) and even less so in a real operation environment. Therefore, they should not be considered today as ready

[3] Hydrogen Europe data.

[4] https://iopscience.iop.org/article/10.1149/2.0131806jes/pdf

"alternatives" to marketable fluorinated current technology. Although there would be an economic advantage to finding performant fluorine-free materials, there is no alternative today to replace PFAS (PFSA, PTFE) in the hydrogen industry (both electrolyser and fuel cell).

At disposal stage, recycling of MEAs at end of life, while maximising the recovery rate and minimising incineration should be a best practice. Building on recommendations set forth in Integrated Environmental Assessment and Management (Henry et al., 2018), "responsible incineration of fluoropolymers, adhering to regulatory guidelines, at the end of their life cycle," as well as "recycling, reuse, and closed loop systems" should pave the way forward to regulate PFAS at end of life. Those recycling practices of fuel cells and electrolysers will enable to "control" the PFAS risk at end-of-life stage and recover the contained fluorine (which is a critical raw material identified by the EU). The precious metal content of PEM fuel cells and electrolysers and the inherent economic value are an incentive as such to put forward recycling habits. There should be an economical imperative to do this, preventing that none of the fluorinated material in the stack be released into the environment by use or disposal of the stack.

We remain at your disposal to continue this dialogue to ensure hydrogen can play its central role in delivering the net zero targets by 2050.

Sincerely,

P4 P5

Ti1 Ti2

Hydrogen Europe Hydrogen Europe Research

Miljøministeriet
Miljøstyrelsen

Den 12. juli 2024

Aktdetaljer

Akttitel: VS: Spørgsmål ang. forbud mod brug af kemiske stoffer på EU-plan
Aktnummer: 51
Sagsnummer: 2020 - 15422

Akt-ID:	3994113
Dato:	04-11-2021 09:23:42
Type:	Indgående
Dokumenter:	• [1] VS Spørgsmål ang. forbud mod brug af kemiske stoffer på EU-plan.eml (MEDTAGES IKKE) • [2] Letter P31 - Denmark.pdf

Honeywell

Honeywell Fluorine Products Europe B.V.
Stationsplein Zuid-West 961
1117 CE Schiphol-Oost
The Netherlands
Tel. [redacted]
www.honeywell.com

Ministry of Industry, Business and Financial Affairs
Attn.: P1
Ti1 , Regulation of Business and International Relations

E1

Dear P2 ,

We are writing you in relation to the PFAS REACH restriction proposal that was entered into the registry of restriction intentions of the European Chemicals Agency (ECHA) on 15 July 2021 by five EU/EEA countries and the unintended impact that this restriction may have on the Danish economy and on achieving the objectives under the Paris Agreement and the EU Green Deal. Decarbonization and the reduction of the emission of greenhouse gases (thereby limiting global warming to less than 2 degrees centigrade) are key interlinked global policy objectives.

Honeywell is a strong supporter of these objectives, and we believe that we make an important contribution to achieving them. For example, to date, the use of our Solstice HFO refrigerants and blowing agents has helped avoid the release of nearly 250 million metric tons of CO2e1 into the atmosphere so far, an equivalent to removing over 50 million cars from the road, more than all passenger cars registered in Germany. Furthermore:

- Honeywell is a recognized and established B2B supplier of innovative chemicals to various enterprises in Denmark.
- Our customers use our products to manufacture various *high added value* final products (including air-conditioning and refrigeration systems, medical packaging and devices, various electronics, building insulation foams, etc.). Our business partners in Denmark are leading suppliers and manufactures including SMEs and start-ups.
- Honeywell's products contribute to the important innovative downstream projects in sectors such as pharmaceuticals, automotive (incl. electric vehicles), refrigeration, renewable energy, construction, as well as electronics.

The expected approach of the proposing countries, confirmed in the recent registration of the intent, is to expand the current definition of what constitute a PFAS, and to regulate thousands of substances never before considered as PFAS as one single group. In our view, this approach does not sufficiently consider the recently issued OECD guidelines, which emphasizes that PFAS is a broad, general, nonspecific term, which does not inform whether a compound is harmful and is not a basis for regulation.[2]

The new definition would, amongst others, include HFOs (a refrigerant with low global warming potentials that are used in applications such as refrigeration, air conditioning, building insulation, personal and household care) and PCTFE (a fluoropolymer that is used in high-barrier pharmaceutical packaging). In our view, capturing these two substances under the definition of PFAS is not scientifically justified, because they do not pose a risk to human health or the environment. The total costs for society should such a blanket ban be enacted would be extremely high (particularly for SMEs) and disproportionate to the alleged health and environmental risks which are being used to justify this future possible restriction.

[1] HFO Climate Impact (fluorineproducts-honeywell.com)

[2] OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris.

The proposed restriction would prohibit Honeywell from continuing to supply any HFOs and PCTFE to their partners and customers in Denmark. It could consequently have a negative impact on the businesses of these customers and (consequently) on the employment provided by these customers in Denmark.

Most importantly we believe the restriction could negatively impact the ability of Europe and its countries to achieve the ambitious decarbonisation and energy efficiency objectives already agreed in particular in the Paris Agreement and the EU Green Deal. For example, it would lead to the replacement of HFOs by alternatives with a greater environmental impact from reliability or safety issues and often with more indirect emissions, resulting largely from the energy used.

As we know these matters are important to you, we would very much value the opportunity to discuss the impact of the PFAS REACH restriction proposal on the Danish economy and on achieving the objectives set out in the Paris Agreement and the EU Green Deal with you.

Kind regards,

P3

Ti2 and Ti3 for Advanced Materials EMEA