
Til: Claus Jørgensen ([redacted]@fbr.dk ([redacted]@fbr.dk), Shima Dobel ([redacted]@mim.dk), Rikke Donchil Holmberg ([redacted]@mim.dk), Dorte Bjerregaard Lerche ([redacted]@mim.dk)
Fra: Henrik Søren Larsen ([redacted]@mim.dk)
Titel: SV: [Chemicals Working Group] Chemical Nation Germany: Chemical Summit at Chancellery
Sendt: 28-09-2023 11:59

Kære Claus
Tak for tippet. Vidste noget var på vej men ikke hvad.
Mvh
Henrik

Fra: Claus Jørgensen <[redacted]@fbr.dk>
Sendt: 28. september 2023 10:24
Til: Henrik Søren Larsen <[redacted]@mim.dk>; Shima Dobel <[redacted]@mim.dk>
Emne: VS: [Chemicals Working Group] Chemical Nation Germany: Chemical Summit at Chancellery

Kære begge,
I ved det måske allerede, men se her fra Tyskland, og deres holdning til PFAS restriction…

Yesterday the German Chemical Industry, Unions, members of the German Federal Government (incl. Kanlzer Scholz) as well as Ministers from the Federal States met at Scholz' chancellery for a "Chemical Summit".

On REACH, the chancellery's press release reads:

3. Balanced European regulatory framework
The protection of the environment and health as well as occupational health and safety are central concerns of the German government. The European Chemicals Strategy for Sustainability (CSS) is intended to improve the existing European framework. At the same time, it must be ensured that the ramp-up of future technologies for the energy transition, the development of innovative materials, products and processes, the production of high-tech goods and the supply of essential goods to the population and industry are not impeded. The CSS should therefore also be the basis for a sustainable and competitive, resilient chemicals sector and lead to an improvement in the competitive position of the European chemicals industry. This is particularly true with regard to regulatory requirements and the declared intention to reduce bureaucracy wherever possible.
The German government is committed to ensuring that the EU's standard for REACH substance restrictions remains risk-based. In the view of the German government, blanket, undifferentiated bans on entire classes of substances are not covered by the existing European legal framework and are not envisaged under the current proposal by the German and other specialist authorities. ***A total ban on PFAS is therefore not planned and would not be supported by the German government****. In the view of the German government, this should remain the case on a permanent basis, particularly in the context of the discussions on the European chemicals strategy and REACH****.*** *In order to avoid negative effects of substances on the environment and health and increasing dependence on non-European suppliers as far as possible, and at the same time to further improve the industry's ability to transform, research into alternatives must also be resolutely pursued. The German government and the chemical industry reaffirm their joint commitment to sustainable international chemicals management. In view of the worldwide interdependencies of the chemical industry and in view of our global responsibility for a sustainable future, the World Chemicals Conference must send out a strong signal for the safe management of chemicals worldwide. At the same time, this will help to create fair competitive conditions worldwide.*

Mh Claus

Til: Magnus Løfstedt ([redacted]@mst.dk), Elisabeth Paludan ([redacted]@MST.DK), Dorte Bjerregaard Lerche ([redacted]@mim.dk), Rikke Donchil Holmberg ([redacted]@mim.dk), Henrik Søren Larsen ([redacted]@mim.dk), Mikkel Aaman Sørensen ([redacted]@mim.dk)
Fra: Toke Winther ([redacted]@mst.dk)
Titel: SV: Dansk holdning til eventuelle undtagelser fra PFAS restriktionen
Sendt: 26-08-2021 11:22

Kære alle

Dorte og jeg forestiller os, at vi følger rækkefølgen i 'Decision document' på mødet i morgen. Dvs. vi begynder med kemisk scope og fortsætter med medicin, biocider og pesticider. Forhåbentligt kan vi også nå at tage hul på snakken omkring F-gasser.

Venlig hilsen
Toke

-----Oprindelig aftale-----
Fra: Toke Winther
Sendt: 9. august 2021 14:32
Til: Toke Winther; Magnus Løfstedt; Elisabeth Paludan; Dorte Bjerregaard Lerche; Rikke Donchil Holmberg; Henrik Søren Larsen; Mikkel Aaman Sørensen
Emne: Dansk holdning til eventuelle undtagelser fra PFAS restriktionen
Hvornår: 27. august 2021 10:00-11:00 (UTC+01:00) København, Stockholm, Oslo, Madrid, Paris.
Hvor: Skype-møde

Kære alle

Hermed indkaldelse til det første møde omkring Dansk holdning til eventuelle undtagelser fra PFAS restriktionen. I forhold til det jeg sendte til nogle af Jer tidligere i dag, er der ændret i rækkefølgen (se nedenor), så det første der skal diskuteres mellem de 5 lande er F-gasser. Jeg har netop modtaget en opdateret version af 'Decision document' (vedhæftet), der er udgangspunkt for diskussionen.

- Friday, 10 September, 9.00 – 12.00
  Discussion and possible decision on the F-gasses; in my view the F-gasses are a specific case given its properties and the separate legislation. Maybe we do not see the need to already decide on this and leave it open for the moment (no decision is in my view: part of the restriction dossier)

- Friday, 17 September, 9.00 – 12.00
  Discussion on possible (general) exemption for PPP, BP and medicinal products: we probably need two meetings for this decision

- Friday, 24 September, 10.00 – 13.00
  Discussion on restriction options for (mostly) consumer uses:ski wax, FCM, cosmetics, textiles, consumer mixtures

- Friday, 1 October, 9.00 – 12.00
  Discussion on restriction options (mostly) industrial/professional applications: petroleum and mining, medical devices, lubricants and construction, electronics and energy, transportation

- Friday, 8 October, 9.00 – 12.00
  Discussion on restriction options for manufacture/production and waste (setting conditions to the

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Til: Rikke Donchil Holmberg ([redacted]@mim.dk), Dorte Bjerregaard Lerche ([redacted]@mim.dk)
Cc: Sandi Muncrief ([redacted]@mst.dk), Grete Lottrup Lotus ([redacted]@mst.dk), Peter Juhl Nielsen ([redacted]@mst.dk), Peter Hammer Sørensen ([redacted]@mst.dk)
Fra: Sehbar Khalaf ([redacted]@mst.dk)
Titel: Vs: INFO - CW: German government is against ‘blanket, undifferentiated’ bans on chemical classes (MST Id nr.: 8569643)
Sendt: 12-10-2023 10:54

Kære alle,
hvis ikke I allerede har set den, så var denne i Chemical Watch i sidste uge.

Bh Sehbar

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https://chemicalwatch.com/843983/german-government-is-against-blanket-undifferentiated-bans-on-chemical-classes

German government is against ‘blanket, undifferentiated’ bans on chemical classes

05 October 2023

September statement reiterates opposition to 'total PFAS ban'

The German government has said that it does not support "blanket, undifferentiated bans of entire classes of substances", including this approach being taken for PFAS.

The government told Chemical Watch the comments do not reflect a change in its position and align with the PFAS restriction dossier (see box). However, the statement followed a 27 September meeting with representatives from the country’s chemicals industry, signalling its willingness to listen to the sector's concerns about "overregulation" and action targeting large groups of substances.

Chancellor Olaf Scholz organised the meeting after continued pressure from the domestic chemicals industry to address the "burden of overregulation". Germany is one of the five European authorities that prepared the PFAS restriction dossier, alongside Denmark, the Netherlands, Norway and Sweden.

The September statement sets out the government’s position on certain points of the EU’s plans to regulate chemicals, saying that total bans on chemical groups are not covered by the existing European legal framework and "not envisaged" by the German authorities.

Germany also wants the EU's restriction process to remain risk-based, according to the statement.

Its reference to ‘undifferentiated bans’ refers to the case, often made by the industry, that substance groups such as per- and polyfluoroalkyl substances (PFASs) comprise different sub-classes that do not always have the same concerning properties. Therefore they may not fit the scope of a group restriction.

"In this respect, a total ban on PFAS would not be supported by the federal government," it said, adding that avoiding such class bans should "remain the case on a permanent basis".

Two options under PFAS proposal

The authorities' restriction proposal sets out two options:

- a 'full ban' with no derogations and transition period of 18 months after the regulation enters into force; or
- the dossier submitters' preferred choice – a full ban with use-specific time-limited derogations that would carry an 18-month transition and a five- or 12-year derogation period, depending on the application.

'Not a change in thinking'

A spokesperson for Germany's Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV) told Chemical Watch that the government's statement is not a change in thinking and simply reiterates the country's position.

"There are certain misconceptions in the discussion … some actors think that a blanket, undifferentiated ban of the whole substance group is discussed by the authorities while they actually argue for a use-differentiated approach," the spokesperson said.

They added that in some instances, grouping may be the faster and better approach, for example to stop regrettable substitution. But when deciding on a regulatory strategy the "individual situation at hand has to be analysed before deciding on the way forward".

They also said it is necessary for the government to clarify the legal situation on risk-based approaches for restrictions under REACH "in light of voices claiming that a targeted REACH revision might lead to giving [this] up".

The statement highlights the German chemicals industry's "major challenges" and the increasing "international competitive pressure" it is experiencing, specifically due to the war in Ukraine, weak demand and high energy and raw material prices.

Industry welcomes risk-based commitment

German chemicals industry association VCI, which attended the meeting, released its own statement saying that it welcomed the "clear commitment of the federal government to a risk-based substance policy and against blanket substance bans".

VCI has called on the European Commission to pause work on the EU's chemicals strategy for sustainability to allow for a "reassessment" of its priorities and implementation.

This is because the global political and economic situation has "changed fundamentally" since the announcement of the EU's Green Deal and the CSS, it said.

'Truly ambitious'

The day after the government released its statement, Chancellor Scholz addressed delegates at last week's fifth International Conference on Chemicals Management (ICCM5), where a global framework to manage chemicals was agreed. The meeting took place in Bonn, Germany from 25-29 September.

Referring to a high-level document that was agreed on, alongside the framework text, Scholz urged the room to set "clear commitments, agreed by all stakeholders, that are truly ambitious".

"You have the opportunity to define how the global community will manage chemicals and waste in the future. I would therefore like to encourage you to make ambitious commitments," he told attendees.

Til: Sehbar Khalaf ([redacted]@mst.dk)
Cc: Peter Juhl Nielsen ([redacted]@mst.dk)
Fra: Dorte Bjerregaard Lerche ([redacted]@mim.dk)
Titel: Spørgsmål om PFAS og aktivstoffer i lægemidler
Sendt: 20-11-2023 13:27

Kære Sehbar

Da vi talte sammen om mødet i Dortmund om det generelle PFAS-forslag, fortalte du, at ECHA juridiske tjeneste havde fundet ud af og gjort jer opmærksom på, at ift. lægemidler er det ikke kun aktivstoffet, der vurderes, men hele produktet ifm. deres godkendelsessystem. Du sagde også, at det ville betyde, at I som dossier submitter ville genoverveje formuleringen om at aktivstoffer i lægemidler skal undtages.

Jeg har forsøgt at ringe for at høre, om I har fundet ud af, hvad I vil gøre.

For det andet vil jeg høre, om I også overvejer at undtage de kemiske stoffer der anvendes i produktionen af lægemidler (precursors) og produktionsanlæg. Ved du, om de kemiske stoffer, der anvendes i produktionen af lægemidler, og produktionsanlæg er en del af den godkendelse, som medicinalvirksomhederne får ifm. godkendelse af lægemidler?

Venlig hilsen

Dorte Bjerregaard Lerche
Specialkonsulent | Rent drikkevand og sikker kemi
+45 22 38 51 82 | [redacted]@mim.dk

Miljøministeriet
Departementet | Frederiksholms Kanal 26 | 1220 København K | Tlf. +45 38 14 21 42 | [redacted]@mim.dk | www.mim.dk
Facebook | Twitter | Instagram I LinkedIn

Til: Sehbar Khalaf ([redacted]@mst.dk)
Fra: Dorte Bjerregaard Lerche ([redacted]@mim.dk)
Titel: SV: Høringssvar fra EFPIA om PFAS begrænsning (MST Id nr.: 8617702)
Sendt: 20-10-2023 10:07

Alle tiders, mange tak. Jeg ser på det.

Fra: Sehbar Khalaf <[redacted]@mst.dk>
Sendt: 20. oktober 2023 09:59
Til: Dorte Bjerregaard Lerche <[redacted]@mim.dk>
Emne: Sv: Høringssvar fra EFPIA om PFAS begrænsning (MST Id nr.: 8617702)

Kære Dorte
jeg har ikke tid til at se nærmere på de høringssvar aktuelt, men kan se, at der er indsendt 2 høringssvar fra EFPIA. Måske du selv kan se nærmere på dem, så du får lige lidt info til at finde dem.
De har ID nr. 4455 og 9063 og findes i hhv. part 19 og 109 på ECHAs side
her: https://echa.europa.eu/da/restrictions-under-consideration/-/substance-rev/72301/term
Har også vedlagt de to dokumenter her, så du har dem.

Bh
Sehbar

Til: Sehbar Khalaf ([redacted]@mst.dk)
Fra: Dorte Bjerregaard Lerche ([redacted]@mim.dk)
Titel: Høringssvar fra EFPIA om PFAS begrænsning
Sendt: 20-10-2023 09:37

Kære Sehbar

Vi har fundet ud af at Novo Nordisk har indsendt høringssvar sammen med deres interesseorganisation EFPIA.

Tror du kan finde deres høringssvar og se hvad det handler om?

Venlig hilsen

Dorte Bjerregaard Lerche
Specialkonsulent | Rent drikkevand og sikker kemi
+45 22 38 51 82 | [redacted]@mim.dk

Miljøministeriet
Departementet | Frederiksholms Kanal 26 | 1220 København K | Tlf. +45 38 14 21 42 | [redacted]@mim.dk | www.mim.dk
Facebook | Twitter | Instagram I LinkedIn

Til: Rikke Donchil Holmberg ([redacted]@mim.dk)
Cc: Elisabeth Paludan ([redacted]@MST.DK)
Fra: Toke Winther ([redacted]@mst.dk)
Titel: SV: Indstilling om bredt EU forbud for per- og polyfluorerede stoffer (PFAS) (oversendt til DEP) (MST Id nr.: 634072)
Sendt: 20-02-2020 09:49

Hej Rikke

Det lyder godt. Tak for info.

Venlig hilsen
Toke

Fra: Rikke Donchil Holmberg <[redacted]@mfvm.dk>
Sendt: 20. februar 2020 09:36
Til: Toke Winther <[redacted]@mst.dk>; Elisabeth Paludan <[redacted]@MST.DK>
Cc: Magnus Løfstedt <[redacted]@mst.dk>; Shima Dobel <[redacted]@mfvm.dk>; Henrik Søren Larsen <[redacted]@mfvm.dk>; Sandi Muncrief <[redacted]@mst.dk>
Emne: VS: Indstilling om bredt EU forbud for per- og polyfluorerede stoffer (PFAS) (oversendt til DEP) (MST Id nr.: 634072)

Kære Toke og Elisabeth

Ministeren har godkendt jeres mandat til at være "medafsender på forslaget om et EU-forbud mod PFAS og derfor nedprioriterer eller udskyder udvalgte planlagte EU-reguleringsforslag for at frigøre tid og ressourcer til arbejdet med PFAS-forslaget i 2020-2021", herunder specifikt, at:
"Prioriteringen af arbejdet vil betyde, at Miljøstyrelsen vil være nødsaget til at udskyde eller nedprioritere en række andre planlagte EU-reguleringsforslag. EU-begrænsningsforslag af klorede flammehæmmere udskydes, da der stadig afventes resultater af igangværende testning fra de amerikanske myndigheder, og antallet af klassificeringsforslag for allergifremkaldende stoffer nedskaleres fra 3 til 2 stoffer. Derudover omprioriteres arbejdet med regulering af hormonforstyrrende stoffer. Nominering af triclosan til Kandidatlisten som hormonforstyrrende stof nedprioriteres, da data om stoffets mulige hormonforstyrrende effekter ikke er entydige, og i stedet prioriteres begrænsning af PFAS-stoffer, som mistænkes for at være hormonforstyrrende."

Ring, hvis det er. Bliver spændende!
Mvh Rikke

Rikke Donchil Holmberg
Teamleder | Kemikalier
+45 22 35 23 90 | [redacted]@mfvm.dk

Miljø- og Fødevareministeriet
Departementet | Slotsholmsgade 12 | 1216 København K | Tlf. +45 38 14 21 42 | [redacted]@mfvm.dk | www.mfvm.dk

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Fra: Andreas Juhl <[redacted]@mst.dk>
Sendt: 6. februar 2020 14:44
Til: Henrik Søren Larsen <[redacted]@mfvm.dk>; Rikke Donchil Holmberg <[redacted]@mfvm.dk>; MIM - Ministersager <[redacted]@mfvm.dk>
Emne: Indstilling om bredt EU forbud for per- og polyfluorerede stoffer (PFAS) (oversendt til DEP) (MST Id nr.: 634072)

Venlig hilsen

Andreas Juhl
Direktionssekretær | Direktionssekretariatet
+45 20 90 68 92 | +45 20 90 68 92 | [redacted]@mst.dk

22 September 2023
HEWE

DI-2023-02302

Dansk Industri
Confederation of Danish Industry

Consultation response from Confederation of Danish Industry for the public consultation on the restriction proposal on PFAS under REACH

Confederation of Danish Industry (DI) is a private business and employers' organisation representing more than 20,000 companies employing approx. 600,000 employees in total. 38 per cent of our members are in the manufacturing industry or in the energy and supply sector corresponding to approx. 7,600 companies.

Among our member companies are large and globally recognized Danish companies supplying specialized components and technologies essential for use in sectors as energy, production equipment for the food industry, the defense industry, medical devices and pharmaceuticals.

Today, almost every one of them depend on some kind of production equipment containing a variation of PFAS.

First of all, DI supports the direction put forward in the restriction proposal in order to avoid emissions of PFAS to the environment. We support a restriction to be put on PFAS in consumer products and substitution where possible, and we recognise the importance of prioritising research and development to find the alternatives to the use of PFAS. However, we also strongly support the risk-based approach to chemical legislation rather than a hazard-based one. Furthermore, we have to stress that there is a need for realistic transition periods.

The proposed restriction includes a very broad definition of PFAS and aims at restricting the manufacture, import, use and marketing of PFAS in the EU. The broad definition comprises smaller molecules as F-gasses as well as very large molecules as fluorpolymers. As a consequence, the use of PFAS is varying across all sectors and product groups.

Some industries will be affected by the proposed PFAS restrictions more than others, and some industries may already be well on their way towards finding suitable alternatives. After the publication of the PFAS restriction proposal by ECHA in February 2023 we have been in contact with several hundreds of our member companies to initiate a mapping of the present use of PFAS and to get feedback from companies on where the use can be substituted and where it is not possible. Our interaction with our members on this topic included webinars, member association meetings, company visits and feedback as well as bilateral meeetings and consultation with member companies.

H. C. Andersens Boulevard 18
1553 København V
Danmark

(+45) 3377 3377
di@di.dk
di.dk

CVR: 16 07 75 93

The work related to mapping and possible substitution
A number of the larger companies have done – or have started – a mapping of their use of PFAS in cooperation with their suppliers, and some have started substitution processes where possible. However, there are still a lot of uses which are not replacable with other products or technologies – and which will be crucial for the ability to have a production to be leak-tight to avoid emissions from hazardous substances, being able to supply compliant products, fulfill guarantees of products and contract services and being able to supply products for the common good including hospital equipment and medicines and last but not least: technologies essential for the green transision of Europe.

Mapping the uses of PFAS in raw materials, equipment etc. is not a simple task as a lot of uses have not been known. It is a time consuming task as a lot of suppliers and sub-suppliers in the value chain are involved. Some of our member companies have reported up to 7000 suppliers globally. The time being spent on this communication and mapping process is time being taken from other important work related to improving the environmental impact of the company.

Most of our members are contributing to sector specific responses in European organisations attending to their specific uses and interest. In the present response we focus on giving feedback related to production companies across all sectors as they all face corresponding challenges with the proposed restrictions.

Use of PFAS in production companies
A number of PFAS substances are used, but especially the use of flurorpolymers and fluorelastomers are critical in an industrial production. As an example PTFE is used in plastic compounds due to their low friction, chemical resistance, high temperature resistance, electrical insulation, flame retardancy, chemical inertness, etc; which makes them hard to be substituted in many cases.

Some PFAS applications are reported to be partially replaceable with other tribological combinations e.g. in lubricants. PTFE, used to reduce friction, has possible alternatives depending on specific requirements and applications. However, those have not been fully tested yet.

In other cases, PFAS are considered irreplaceable due to outstanding chemical resistance; Substitution of PFAS does not seem possible for applications requiring exceptional chemical resistance.

Fluorpolymers are being used in components for e.g. heating for buildings and district energy including heat pumps and include materials as PTFE, FEPM, PVDF, PFA and a lot of other materials are being used e.g. in valves.

As an example the following fluoropolymers have been reported as used in engineering polymer shapes for machining:

- PTFE (EC number: 618-337-2; CAS number: 9002-84-0);
- PFA (EC number: 682-550-7; CAS number: 26655-00-5).

The applications where these substances are used include:

- Wide range of applications (automotive/chemical industries/food contact/medical/parts in machines);
- PTFE as lubricant for semi-finished products. The technical application of the products;
- PTFE based coatings needed in a wide range of tooling systems.

The main concern for all PFAS in the restriction proposal is the very high persistence and potential accumulation in the environment and in humans.

As most industrial uses of fluorpolymers do not lead to emissions in the use phase other possibilities to mitigate the exposure from this use should be explored.

We believe that the risk of exposure of PFAS to the environment, to a large extent, can be mitigated by ensuring well-establised processes for handling products in the production and in the waste phase. Danish production companies are sorting their waste streams in a large number of fractions – adding a category for PFAS materials will not be a big hazzle.

Consequences by the proposal and possibilities for enforcement
By publishing the restriction proposal the Commission introduced a very large room for hesitation when considering investments in European industries. This uncertainty and room for hesitation need to be closed as soon as possible, in order to attract investors and companies' belief in the possibility of having production based in the EU.

To politicians and the population transition periods for up to twelve years + a year and a half may seem as long and sufficient time for the transition. In reality it is not possible to develop new technological solutions, test them to ensure reliability and to implement such solutions in production environments within this time frame. A long-term general derogation with review before exuration of fluorplymers without relevant risk is necessary.

Companies planning to establish new production facilities will plan years ahead – and they will need environmental permits by national authorities before new facilities can be built and taken into use. A process which may take years. Facilities will only be built if the companies can trust in a certain period of having a production at the site. However, it is not possible to plan and build a production site for a technology not yet developed.

As PFAS are used due to their strong resistance to harsh environments, it will not be possible to replace with other substances having the same characteristics without the same (eco)toxicological concerns – nobody is in favor of regrettable substitutions. As a consequence new technological solutions are expected to be developed during the next 10-20 years for specific uses – and those cannot be planned when building new production sites, yet.

Furthermore, we are concerned about the authorities ability to enforce a broad restriction covering more than 10,000 substances. How will it be possible to check a possible content of these substance in imported goods? In addition, we do not see the laboratory capacity to perform relevant tests and the analytical methods are not yet developed. Further no laboratory will be able to work without PFAS materials in their analytical equipment.

A proper enforcement is crucial to ensure a fair level playing field for European manufactures in order to ensure that the competitiveness of the European industry will not be compromised.

Finally, we would like to stress one more time that DI supports a constructive regulatory approach for industrial use of PFAS and especially fluorpolymers and fluorelastomers, which seems to be crucial for all production environments.

A swift decision on how the industrial uses can be handled in a future regulation is also needed in order not to harm the Green Transition and possible investments in European production facilities. We would like to know what kind of data the European Commission needs to address as soon as possible.

Kind regards,

Helle Westphal
Head of Chemicals Policy,
Confederation of Danish Industry

Til: Riccardo Corridori ([redacted]@cocir.org)
Cc: Rikke Donchil Holmberg ([redacted]@mim.dk), Dorte Bjerregaard Lerche ([redacted]@mim.dk)
Fra: Henrik Søren Larsen ([redacted]@mim.dk)
Titel: SV: COCIR - Letter on the PFAS restriction proposal and the impact on availability of critical medical devices
Sendt: 20-03-2023 12:35

Dear Mr. Riccardo Corridori,
Thank you very much for your inquiry.

At this moment in time there is a public hearing coming up in near future, and the proposal is undergoing scientific scrutiny in the Committees of ECHA. The Danish EPA is responsible for this step in the procedure together with sister agencies in Germany, the Netherlands, Sweden and Norway.

The Ministry do not form its policy position until the proposal has been forwarded to the Commission for political adoption. For that reason we do not see a need for a meeting at this moment in time.

Kind regards,
Henrik

Med venlig hilsen

Henrik Søren Larsen
Kontorchef | Grøn velfærd – Rent drikkevand - Sikker kemi
+45 23 31 40 37 | [redacted]@mim.dk

Miljøministeriet
Departementet | Frederiksholms Kanal 26 | 1220 København K | Tlf. +45 38 14 21 42 | [redacted]@mim.dk | www.mim.dk
Facebook | Twitter | Instagram I LinkedIn

Fra: Riccardo Corridori <[redacted]@cocir.org>
Sendt: 20. marts 2023 10:38
Til: Henrik Søren Larsen <[redacted]@mim.dk>
Emne: COCIR - Letter on the PFAS restriction proposal and the impact on availability of critical medical devices

Dear Mr Hesla,

Please find attached a letter, on behalf of the COCIR Secretary General, Annabel Seebohm, about the recently released proposal for a restriction of PFAS under the REACH Regulation and the concerns of the medical imaging and radiotherapy industry in Europe.
If a proper transition time is not granted to this sector, via a derogation, critical medical devices will not be available for EU hospitals and clinics with the entry into force of the restriction.

Please do not hesitate to contact us for any additional information.

I also attach to this message the initial “COCIR contribution to the Call for Evidence on PFAS” that is mentioned in the letter.

Best regards,

Riccardo Corridori
Senior Manager
Environmental, Health and Safety Affairs
COCIR
BluePoint - 80 Bd A. Reyers - 1030 BRUSSELS (B)
Tel.: +32 (0) 2 706 89 66 - Fax: +32 (0) 2 706 89 69
http://www.cocir.org

Til: Rikke Donchil Holmberg ([redacted]@mim.dk), Dorte Bjerregaard Lerche ([redacted]@mim.dk)
Fra: Henrik Søren Larsen ([redacted]@mim.dk)
Titel: VS: COCIR - Letter on the PFAS restriction proposal and the impact on availability of critical medical devices
Sendt: 20-03-2023 12:30
Bilag: COCIR contribution to Call for evidence for PFAS.27072020.pdf; 2023-03-20_COCIR.draft.Letter.on.PFAS.restriction.to.REACH&Health.Authorities-DKMinEnv.pdf;

Med venlig hilsen

Henrik Søren Larsen
Kontorchef | Grøn velfærd – Rent drikkevand - Sikker kemi
+45 23 31 40 37 | [redacted]@mim.dk

Miljøministeriet
Departementet | Frederiksholms Kanal 26 | 1220 København K | Tlf. +45 38 14 21 42 | [redacted]@mim.dk | www.mim.dk
Facebook | Twitter | Instagram I LinkedIn

Fra: Riccardo Corridori <[redacted]@cocir.org>
Sendt: 20. marts 2023 10:38
Til: Henrik Søren Larsen <[redacted]@mim.dk>
Emne: COCIR - Letter on the PFAS restriction proposal and the impact on availability of critical medical devices

Dear Mr Hesla,

Please find attached a letter, on behalf of the COCIR Secretary General, Annabel Seebohm, about the recently released proposal for a restriction of PFAS under the REACH Regulation and the concerns of the medical imaging and radiotherapy industry in Europe.
If a proper transition time is not granted to this sector, via a derogation, critical medical devices will not be available for EU hospitals and clinics with the entry into force of the restriction.

Please do not hesitate to contact us for any additional information.

I also attach to this message the initial “COCIR contribution to the Call for Evidence on PFAS” that is mentioned in the letter.

Best regards,

Riccardo Corridori
Senior Manager
Environmental, Health and Safety Affairs
COCIR
BluePoint - 80 Bd A. Reyers - 1030 BRUSSELS (B)
Tel.: +32 (0) 2 706 89 66 - Fax: +32 (0) 2 706 89 69
http://www.cocir.org

COCIR CONTRIBUTION TO THE PUBLIC CALL FOR EVIDENCE ON PFAs

COCIR[1], the European Association of the Radiological, Electromedical and Healthcare IT Industry, is pleased to submit the following contribution to the call for evidence supporting an analysis of restriction options for PFAS.

USE OF PFAs IN MEDICAL TECHNOLOGY

In the medical imaging devices sector the experience with the RoHS Directive teaches that a minimum of 18 months is required to collect information on a new substance due to the complexity of the supply chain and only if the substance had previously been widely restricted for other sectors already. In this case the scope of substances is new, the number of substances is huge and a full list of CAS numbers is missing, making the task even more complicated.

Most medical imaging devices manufacturers count up to 11000 suppliers in 5 to 7 tiers. Most of the supply chain moreover is located outside Europe thus making the collection of information even more difficult and slower (especially as medical devices are not mass-produced-goods and therefore manufacturers of those do have a very limited purchase power).

The complexity of the involved technology (MRI, CT, Beam/particle Therapy, X-ray, etc) also implies that some applications of the targeted substances may be discovered even at a later stage and substitution might turn out to be not possible in a short period of time if not compromising with clinical results.

Therefore, in the limited time given for this public call, we can only confirm that the proposed restriction is going to have a negative impact on the EU healthcare system, which is impossible to quantify.

AVAILABILITY OF ALTERNATIVES

As the applications of PFAs in the medical technology sector are not fully known today it may be assumed that alternatives are not available for all the applications. But even when alternatives are available, substitution of substances in the medical sector is far different from the same process in other sectors.
The EU and global frameworks on the safety of medical devices ensure that no applications of a substance can be substituted without extensive testing on a part-, component-, sub-assembly- and then at system-level.

TIME REQUIRED FOR SUBSTITUTION OF PFAS IN MEDICAL DEVICES

When a substitution is required, this may involve redesign, testing for reliability and for patient safety and to obtain the data needed to gain approval in the EU and in the rest of the world. This can take many years especially if the change in design is significant, which is very likely to occur when material properties are changing.

COCIR did a study to assess the time needed by the sector to substitute the 4 phthalates proposed for a ban under the RoHS Directive, concluding a minimum of 5 years was needed. The report assessed 4 phthalates, but the results are easily applicable to PFAs as the substitution process and the testing phases oftentimes do not depend on the substance

[1] *www.cocir.org*

itself. However, with the increased complexity due to the high number of substances involved and with the low transparency on the usages across all industries, this time is considered to be the far minimum of what might be needed (4 well-known-substances vs 4700 unknown substances).

Testing alternatives: rarely there is a ready-available alternative with the same physical, chemical and mechanical properties for each application.

Redesign: very often the identified alternative requires changes in design at component or system level.

Resource limitation: limited availability of specialised engineers with the experience and expertise to carry out the work to redesign and assess compliant versions of complex medical devices. The pool of engineers available globally is limited and so the medical industry cannot shorten the timescale by employing more engineers, instead other engineering projects and the development of new products will be postponed.

Development cycles: Without a limitation in scope, the proposed restriction would apply to small medical devices, complex imaging medical devices such as magnetic resonance, computed tomography, x-ray, nuclear imaging, but also to large scale installations like linear accelerators or particle therapy installations.
For imaging devices the development cycle is typically 5-7 years, while for bigger therapy systems the development cycles can reach 11 years. Substances can be substituted successfully with reasonable costs during a development cycle. The cost of substitution for already existing models is going to be extremely high and normally is not a viable option. Devices providing good clinical results will therefore be discontinued before their intended phase out, leaving EU hospitals with a lower quality at higher costs. Depending on the stage of the development cycle individual companies have for their product portfolio, this might also result in that certain companies will not be able to continue certain business lines due to the uneven playing field.

EXEMPTIONS

We believe that the classic approach of restricting substances with specific exemptions would not work for PFAs and the medical sectors. The number of known applications where substitution of PFAs may not be possible is high but many more can be expected to be discovered in the coming years, as usual, some critical ones at the very last minute. For 10 substances under the RoHS Directive more than 40 exemptions had been needed for the medical sector. This becomes even more critical when considering that the medical sector does only make up 1% of the whole electric and electronic industry, while approx. 30% of all exemptions had been needed and granted specifically for this sector. In addition, it was proven that the inclusion of the medical sector in RoHS did not provide a meaningful reduction of critical substances as more than 90% of the EEE industry was already regulated under RoHS and did not anymore use the substances (except in applications exempted by the EU).
We therefore believe the only workable option is to ensure that medical technology is given ample time after the entry into force of the restriction for other sectors, at last 5 to 7 years. Such a period of time is required to adopt solutions developed by other sectors with a far larger market impact, test them extensively and substitute PFAs where possible. In addition it would provide the time to check for which applications exemptions are needed and if, after the inclusion of other sectors, there is still a need to restrict those substances in the medical sector in specific. Experimenting not well-known alternatives on devices that

are critical for the life of patients and that are supposed to be in service for 10-15 years is not an option.

Even more, such a solution would avoid to discourage manufacturers of components using PFAs to just discontinue production leaving manufacturers of medical devices unable to continue the production of critical devices. This is not hypothetical as it is already happening for the restriction on PFOA introduced in the POP Regulation recently.

IMPACT ON INNOVATION

Medical devices are used to cure illness and save lives and so manufacturers are constantly carrying out research into products with better performance that will improve patients' chances of being diagnosed correctly and of being cured. The engineers who develop new products would be the same engineers that have the necessary expertise to design and develop compliant versions by replacing substances. These would need to be diverted to compliance in order to shorten the time needed to comply with substance restrictions as far as is feasible. This can be achieved however only at the expense of developing fewer new products and so having to comply with PFAs restriction could harm human health in the longer term due to diverting resources and this may also indirectly result in increased healthcare costs.

CONCLUSIONS

1. At least 3 years are needed for our sector (after the publication of the restriction for other sectors) to collect information on uses and applications.
2. At least 5 years are needed for our sector (from the time the restriction is entered into force for most of the other industries) to understand and qualify already developed and tested alternatives that can be adopted for our uses- for critical applications this can take up to 10 years.
3. The minimum time required to decide on alternatives and/or exemptions for the medical sector (imaging and radiotherapy) is therefore considered to be 8 years as a minimum (after the publication of the restriction for other sectors)
4. Considering the ban of PFAs may refer to several thousand substances, the above-mentioned timeline has to be considered with caution and do reflect the lower end.

COCIR underlines that any sunset date for medical devices shorter than 8 years (after the publication of the restriction for other sectors) risks to have a negative impact on the medical sector and on healthcare providers, while not providing a significant measurable positive effect on human health and the environment.

We therefore recommend a general exemption for our sector as "essential use", but as a minimum a derogation for 8 years, after the entry into force for other sectors, for further and more detailed evaluation.

COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Mr **Soren Hesla**
Ministry of Environment
Denmark

Brussels, 20 March 2023

Dear All,

I am contacting you on behalf of COCIR, the EU Association of the Radiological, Radiotherapy and Healthcare IT Industry, regarding the recently published proposal for a restriction of PFAS under the REACH Regulation.

We are reaching out to the respective Health and REACH authorities in Denmark, to bring to your attention a matter of great concern. In the PFAS restriction proposal published on February 7, 2023, **no derogations have been proposed for** medical imaging and radiotherapy technologies. Derogations are however much needed to ensure availability of such devices for hospitals and clinics.

Following our initial assessment of the PFAS restriction proposal, a letter was sent to Rijksinstituut voor Volksgezondheid en Milieu (RIVM) and the European Chemicals Agency (ECHA) on March 3, 2023, to alert these authorities of this omission and to urge them to address this situation before the public consultation on March 23, 2023. Please find the original letter below.

Given the urgency of the matter, we would like to request your support in ensuring this omission is correctly addressed so that medical imaging and radiotherapy technologies remain available for the health care sector.

Please do not hesitate to contact us for any question you might have.

Yours sincerely,

Annabel Seebohm
COCIR Secretary General

ANNEX – Letter sent by COCIR on 3 March 2023

European Chemicals Agency

(ECHA)

National Institute for Public Health and the Environment - Neatherlands (RIVM)

Brussels, 3 March, 2023

COCIR concerns for the lack of a proper derogation for medical devices from the draft proposal for restriction of PFASs

We are writing you this letter as we believe there was an omission in the Annex XV report on the proposal to restrict most uses of around 10 000 per- and polyfluoroalkyl substances (PFAS) that ECHA published and explained to journalists on February 7, 2023.
The medical technologies covered by COCIR (the European Association of the Radiological, Electromedical and Healthcare IT Industry) were not proposed to be derogated whereas we had argued in writing during the public call for evidence and in workshops that PFAS used in the devices cannot be substituted within the standard transitional period. **We therefore urge you to include in the final publication of the restriction proposal a derogation of a minimum of 12 years for radiotherapy and imaging devices and their legacy spare parts.**
Below a non-exhaustive list of imaging and radiotherapy devices[1]:

Imaging	Radiotherapy
• Magnetic resonance (MRI) • Computed tomography (CT) • x-ray (radiology, fluoroscopy, mammography, interventional, etc) • Nuclear imaging (PET, SPECT, PET/MRI, PET/CT, SPECT/CT) • Ultrasound • Magnetoencephalography	• Linear Accelerators (LINAC) • Brachytherapy • Stereotactic Radiosurgery • Proton Therapy • Particle therapy

COCIR participated in the public call for evidence organized by RVIM on PFAS with our contribution dated July 20, 2022 (attached) which explained the complexities and challenges in substituting PFAS in complex medical equipment. The contribution concluded that 'we therefore recommend a general exemption for our sector as "essential use", but as a minimum a derogation for 8 years, after the entry into force for other sectors, for further and more detailed evaluation'. COCIR also participated in the industry workshop that RIVM organised on Essential Use in February 2021. In these opportunities, RIVM and

[1] *COCIR can provide a full list if requested by RIVM or ECHA representatives.*

ECHA were both recipients of the presentation slides from COCIR, along with reports. COCIR also presented our views on PFAS restrictions amongst others in the workshop organised by FIPRA in October 28, 2021 where RIVM also made a presentation. Once again on December 6, 2022, in an event titled "PFAS: The challenge for highly regulated and essential sectors" RIVM and ECHA representatives received the presentation slides and a summary report after the event and we had hoped that all information provided would sufficiently describe the challenges we face.

Our request falls in line with already published derogations for other restrictions. The DP+ restriction recognized the need to grant a 8 years derogation to medical imaging devices and 10 years to radiotherapy systems. The PFOA restriction granted 12 years to medical imaging and radiotherapy devices. The RoHS Directive granted initially 8 years for medical technologies and, when phthalates were included, 5 years were granted to our sector. RoHS exemptions are granted to our sector with a duration of 7 years that has almost always been extended to 14 years. Each decision has always been motivated by the same reasons and evidence of the technical difficulties of substitution, redesign and certification times, and high impacts on healthcare and patients caused by scarcity of medical devices. Considering the huge number of substances and the wide range of uses involved, we believe 8 years should be granted, since the entry into force of the restriction for other sectors is a minimum to ensure the continuity of supply of medical technologies to EU hospitals. COCIR considers 12 years is a safe assumption to reduce availability risks for all equipment to a minimum.
The scarcity of medical devices can have a highly severe impact on healthcare providers and patients in Europe.

The recent experience with MDR is emblematic. The too short deadlines provided in the MDR regulation have caused a critical situation with medical devices, to the point that doctors and hospitals have had to voice the need for urgent action by the European Commission to save the life of patients and in particular children with heart diseases.
Below some priority examples of public requests from the healthcare sector (links below):

- European cardiologists call for urgent action to prevent medical device shortages
- AEPC- Association for European pediatric and congenital cardiology: The implications of EU-MDR for the treatment of congenital heart disease
- CPME -European doctors are concerned about the availability of many medical devices on the European market. An internal survey showed that doctors are already struggling with shortages that could become much more serious in the near future.
- Biomed Alliance - Clinicians concerned about limited availability of medical devices.
- Report on orphan devices (for rare diseases) - there is a possibility that the MDR may result in products becoming unavailable, with the consequent risk of a loss of some interventions that rely upon those devices. Devices that are used for orphan or pediatric indications are in a particularly vulnerable situation.

European institutions are still struggling today **to fix the problem by extending the transition period of MDR to 8 years since the initial deadline.** Unfortunately, this late action would only partially solve the problem as many devices have already been discontinued.

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[2] *Links to articles and press releases referenced above on MDR:*

- *https://www.escardio.org/The-ESC/Press-Office/Press-releases/european-cardiologists-call-for-urgent-action-to-prevent-medical-device-shortage*
- *https://www.aepc.org/news/the-implications-of-eu-mdr-for-the-treatment-of-congenital-heart-disease*
- *https://www.cpme.eu/api/documents/adopted/2022/11/cpme.2022-159.Letter.EC.Medical.Devices.Regulation.18112022-1669286574.pdf*
- *https://www.biomedeurope.org/images/news/2023/Report_survey_results_v3.pdf*
- *https://europepmc.org/article/MED/36258097*

The PFAS restriction, if not amended, has the potential to a similar or even worse impact than the MDR regulation. Once medical imaging and radiotherapy devices become scarce, it would be too late to fix the problem. Companies are already struggling with scarcity in the supply of critical raw materials and semiconductors.
It would be appropriate to note that Europe is currently facing a cancer epidemic that is already producing a higher mortality rate than before. Medical imaging and radiotherapy devices are essential in cancer diagnosis and treatment and the role of radiation therapy is bound to grow due to the high cost-effectiveness of the technology. Unnecessarily curbing innovation and increasing scarcity is going to have irreversible impacts on the health of millions of cancer patients.
Media outlets addressing the cancer public health crisis:

- Politico: Europe's coming cancer wave[3]
- The Guardian: Europe faces 'cancer epidemic' after estimated 1m cases missed during Covid[4]
- CNN: A global epidemic of cancer among people younger than 50 could be emerging[5]

As may be observed from the records above, a priority for the sector is to ensure public health, which determines the need for specific and complex processes, to note:

- **Demanding Legal framework**: medical technologies are subject to strict sectoral regulations (IVDR, MDR) [6] which require thorough quality, performance, and substance validations with stringent environmental and health standards. These complex regulations imply that our products require considerably longer innovation cycles than most any other sectors with equal complexity. The sectoral regulations cover the entire life cycle of the products, from manufacturing to end-of-life management. That legislation makes substitution lengthy and costly as re-designing and testing must be accompanied with individual renewals of authorisations in every market the product is available (in most cases, over one hundred countries).

- **Complexity of the devices**: The average lifetime of medical technology spans 10 - 25 years, owing to the specificity of the design, testing, validation, approval and release phases for new generation products, and the regular updating of older product generations. A typical MRI unit weighs about 10 tons, has 3,600 assemblies, 27,000 sub-assemblies, 120,000 component parts and more than 1,000,000 articles.

- **Complexity of the supply chain**: Most medical imaging devices manufacturers count up to 11000 suppliers in 5 to 7 tiers. Moreover, a large part of the supply chain is located outside the EU making the collection of information even more difficult and slower especially as many of the PFAS used were not considered to be hazardous to the extent that the suppliers would be required to inform about them.

- **Complexity in obtaining information from the supply chain:** Our experience with the RoHS Directive has shown that even with our sophisticated Bomcheck[7] tool,

[3] *https://www.politico.eu/article/europes-coming-cancer-wave/*
[4] *https://www.theguardian.com/society/2022/nov/15/europe-faces-cancer-epidemic-after-estimated-1m-cases-missed-during-covid*
[5] *https://edition.cnn.com/2022/10/14/health/early-onset-cancer-increase/index.html*
[6] *The Medical Devices Regulation 2017/745 (MDR) and the in vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR)*
[7] *https://sphera.bomcheck.com*

identification of substances in applications may take a minimum of 18 months. This is particularly problematic in view of the 6-month consultation period foreseen in the PFAS restriction proposal. We will in all likelihood not be able to identify a large part of PFAS uses by end of the consultation period, thereby risking that these technologies will not be available in the future with dramatic impacts on public health across the EU. The complexity of the involved technology implies that some applications of the targeted substances may be discovered even at a later stage. Additionally, it would be worth noting that substitution might not to be possible in a short period of time without compromising clinical results and compliance with our sectoral regulation (MDR). Finally, we anticipate that most uses of PFAS in our sector concern fluoropolymers, which poses a much more limited risk if the use is derogated according to the requested timeframe.

- **Long development cycle**: for imaging devices, the development cycle is typically 5-7 years, while for bigger therapy systems the development cycles can reach 11 years. Substances can be substituted successfully with reasonable costs during a development cycle. The cost of substitution for already existing models is going to be extremely high, as it disrupts the innovation cycle and normally it does not represent a viable option. Devices providing good clinical results will therefore be discontinued before their intended phase out, leaving EU hospitals with a lower quality at higher costs. Depending on the stage of development cycle individual companies have for their product portfolio, this may determine that certain companies will not be able to continue certain business lines due to the uneven global playing field that will arise as a result.

- **Number of patients using our devices:** There are approximately 24000 hospitals in the EU where medical technologies are in use. 40 million MRI scans and more then 70 million CT scans are performed in Europe every year. The number of exams and treated patients with the full portfolio of imaging and RT devices can hardly be estimated.

COCIR had the intention to submit more data to the public consultation organised by RIVM in 2020 but it was simply not possible to get data of PFAS use at that stage. The data gathering process is still ongoing and with the restriction proposal now covering more than 10.000 substances, we will need at least several years to have a clear idea of where PFAS are used and even more to test and validate alternatives to establish if any are available for each application. While some applications would be easy to substitute, this is normally exceptional.
As already indicated, 5 years are needed for our sector (from the time the restriction enters into force for most of the other industries that supply to our sector) to understand and qualify already developed and tested alternatives that can be adopted **for the manufacturing of new models.** For critical applications this can take up to 10 years. We argued in July 2020 for 8 years as a minimum considering that the restriction would apply to 4700 substances. In line with some other medical devices we indeed wish to benefit from the maximum period of 12 years given the essentiality of the products for human health, the high standard for substitution in our sectoral legislation, the complexity of our supply chains and the strategic importance of our sector.
12 years is also required to ensure that already existing models that cannot be redesigned can all be substituted by new designed PFAS-free models. Any shorter deadline may force companies to discontinue products with a risk of creating an artificial scarcity of critical medical devices (MDR *docet*).

We hope that this letter helps to understand the dramatic and entirely unnecessary impacts the proposed PFAS restrictions would have on our sector, which we politely ask ECHA to correct. We are fully in line with the idea of phasing out PFAS from our products, but this must be done in a manner which is proportionate, i.e. in balance with real PFAS related concerns and impacts on the companies, innovation and public health.