
Til: [redacted]@coop.dk ([redacted]@coop.dk)
Fra: Rikke Donchil Holmberg ([redacted]@mim.dk)
Titel: VS: PFAS - kommende EU forbud - indikatorværdi eller græseværdi
Sendt: 21-11-2022 08:20

Kære Malene

Shima har sendt din mail videre til mig.
Arbejdet med udformningen af det kommende EU restriktionsforslag for PFAS ligger i Miljøstyrelsen, så du skal have fat i Magnus Løfstedt ([redacted]@mst.dk).

Mvh Rikke

Rikke Donchil Holmberg
Teamleder | Kemikalier
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Miljøministeriet
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Fra: Blume, Malene Teller <[redacted]@coop.dk>
Sendt: 18. november 2022 13:58
Til: Shima Dobel <[redacted]@mim.dk>
Emne: PFAS - kommende EU forbud - indikatorværdi eller græseværdi

Kære Shima
Jeg håber alt er vel hos dig.
Jeg vil høre om du ved hvem som arbejder med PFAS og det kommende forbud i EU (endnu ikke vedtaget, men høring i foråret osv).
Så vil min kollega Sarah kaltoft kontakte vedkommende vedr. om der er viden nu forventning til indikator værdi eller grænseværdi i PFAS forbuddet.
Vi spørger fordi det er svært at vurdere niveau for baggrundskontaminering eller tilsigtet brug.
Så hvis der er én med viden om dette vil det være en hjælp.
Mange tak og god weekend
Malene

Med venlig hilsen / Kind Regards

Malene Teller Blume
Kvalitetschef/Quality Manager
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Til: Mathias Sjöberg Pedersen ([redacted]@SUM.DK), [redacted]@dkma.dk ([redacted]@dkma.dk)
Cc: Martin Alex Bjørnholst ([redacted]@mim.dk), Rikke Donchil Holmberg ([redacted]@mim.dk), Peter Juhl Nielsen ([redacted]@mst.dk), Sehbar Khalaf ([redacted]@mst.dk), Grete Lottrup Lotus ([redacted]@mst.dk), Henrik Søren Larsen ([redacted]@mim.dk)
Fra: Dorte Bjerregaard Lerche ([redacted]@mim.dk)
Titel: SV: Proposed restriction on Per- and Polyflour Alkyl Substances (PFAS)
Sendt: 15-06-2023 14:42

Kære Mathias og Stine

Tak for jeres henvendelse til Martin Bjørnholst, som han har videresendt til mig.

Der har ikke været noget regeringsproces om et EU begrænsningsforslag for PFAS. Ud over det der står i regeringsgrundlaget (Regeringen vil arbejde for et forbud mod PFAS-stoffer på EU-plan og tage initiativer til begrænsning af brugen i Danmark, regeringsgrundlag-2022 (1).pdf), er der ikke taget politisk stilling til et forslag om at forbyde PFAS i EU.

På teknisk niveau er der ved at blive udarbejdet et forslag. Tilbage i 2019 og 2020 begyndte Miljøstyrelsen sammen med myndighederne i Tyskland, Holland, Norge og Sverige at indsamle og udarbejde det tekniske baggrundsmateriale, der kan lægges til grund for et EU-forbud mod PFAS under REACH-forordningen. Bekymringen går på, at PFAS stort set ikke nedbrydes og derfor akkumulerer i naturen eller i mennesker, og at i takt med at forskerne undersøger de forskellige PFAS, finder de ud af, at de undersøgte PFAS har skadelige egenskaber. Derfor valgte myndighederne en gruppetilgang frem for at forbyde stofferne en af gangen. I januar 2023 var rapporten færdig og blev sendt til det Europæiske Kemikalieagentur (ECHA) til fagligt check. Ud over miljø- og sundhedseffekter beskriver rapporten også mulige alternativer og økonomiske konsekvenser. Rapporten kan tilgås via linket: Registry of restriction intentions until outcome - ECHA (europa.eu)

I jeres dialog med industrien kan I opfordre dem til at indsende tekniske høringssvar. Under udarbejdelsen af rapporten var der flere høringsrunder, hvor virksomheder blev opfordret til at indsende teknisk dokumentation, og hvor mange virksomheder benyttede sig af muligheden. Den sidste blev faciliteret af ECHA og løb i periode fra d. 19. juli 2021 til 17. okt. 2021. Efter at rapporten blev sendt til ECHA, er der igen mulighed for at virksomheder kan indsende kommentarer i periode fra d. 22. marts 2023 til d. 25. september 2023.

I rapporten, der beskriver hvordan et forbud kunne se ud, er der undtaget 4 produktgrupper, fordi de har deres egen godkendelsesordning, der potentielt kan tage højde for problematikken omkring PFAS. Det er lægemidler, veterinære lægemidler, biocider og pesticider.

I forhold til medicinsk udstyr ligger rapporten op til at undtage
- alle PFAS i:
-diagnostic laboratory testing until 13.5 years after entry into force
-PFAS-polymerer i:
-implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after entry into force
-tubes and catheters in medical devices until 13.5 years after entry into force
-coatings of Metered Dose Inhalers (MDIs) until 13.5 years after entry into force

Rapporten lægger desuden op til, at der skal tages stilling til om følgende skal undtages
- alle PFAS i:
-cleaning and heat transfer: engineered fluids for medical devices until 13.5 years after entry into force
-membranes used for venting of medical devices until 13.5 years after entry into force
-PFAS-polymerer i:
-hernia meshes until 13.5 years after entry into force;
-wound treatment products until 13.5 years after entry into force
-coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after entry into force
-Rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after entry into force
-PCTFE-based packaging for medicinal preparations, medical devices and medical molecular

diagnostics until 13.5 years after entry into force
-PTFE in ophthalmic solutions packaging until 13.5 years after entry into force
-packaging of terminally sterilised medical devices until 13.5 years after entry into force

Hvis I ønsker yderligere forklaring af de tekniske detaljer i forslaget, vil vi foreslå, at I henvender jer til Miljøstyrelsen.

Jeg håber, jeg har besvaret jeres spørgsmål, og ellers er I selvfølgelig velkommen til at skrive eller ringe.

Venlig hilsen

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

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Fra: Mathias Sjöberg Pedersen <[redacted]@SUM.DK>
Sendt: 11. juni 2023 13:25
Til: Martin Alex Bjørnholst <[redacted]@mim.dk>
Cc: Rikke Donchil Holmberg <[redacted]@mim.dk>; Henriette Benzon Bang <[redacted]@SUM.DK>; Stine Jønson ([redacted]@dkma.dk) <[redacted]@dkma.dk>
Emne: SV: Proposed restriction on Per- and Polyflour Alkyl Substances (PFAS)

Kære Martin

Jeg vil blot følge op på mailen fra Stine nedenfor.

Medicoindustrien begynder nu også så småt at rasle med sablen, og de vil meget gerne i dialog med os inden sommerferien om bl.a. PFAS – jeg går ud fra, at det handler om forslaget, som Stine henviser til nedenfor.

Har I mulighed for at give os en indflyvning i forslaget, dets baggrund, karakter og tilslutning blandt MS'erne samt særlig baggrunden for at foreslå lægemidler men ikke medicinsk udstyr undtaget? Som Stine skriver nedenfor har forslaget umiddelbart potentiale til at påvirke forsyningen at visse typer udstyr – og ikke mindst patientsikkerheden – på en uheldig måde.

Jeg har forsøgt at søge i vores sagsbehandlingssystem, og jeg kan ikke umiddelbart se, at der har været en regeringsproces, hvor ISM har været i loop ift. forslaget. Men det kan godt være mig, der har overset noget.

Mange hilsner
Mathias

Mathias Sjöberg Pedersen
Fuldmægtig, Center for Lægemidler og Internationale Forhold

M 2053 8523
@ [redacted]@sum.dk

INDENRIGS- OG SUNDHEDSMINISTERIET

Indenrigs- og Sundhedsministeriet
Tlf. 7226 9000

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Fra: Stine Jønson <[redacted]@dkma.dk>
Sendt: 7. juni 2023 10:52
Til: Martin Alex Bjørnholst <[redacted]@mim.dk>
Cc: Rikke Donchil Holmberg <[redacted]@mim.dk>; Mathias Sjöberg Pedersen <[redacted]@SUM.DK>
Emne: Proposed restriction on Per- and Polyflour Alkyl Substances (PFAS)

Kære Martin,

Vi er af vores tyske kollegaer blevet gjort opmærksom på, at der lige nu er fremsat et forslag om at udfase PFAS på tværs af sektorer, herunder medicinsk udstyr, og at der på nuværende tidspunkt er en høring i gang (22. marts – 23. september).
Det er første gang vi hører om forslaget, og vi har nogle bekymringer omkring hvorfor lægemidler er undtaget, men ikke medicinsk udstyr - og om man har tænkt over de konsekvenser, det kan have for patientsikkerheden, da konsekvensen kan være at flere produkter forsvinder fra markedet.
Vi hører lige nu fra den danske Optikerforening at de er voldsomt bekymrede over de konsekvenser, det må have for f.eks. kontaktlinser. Derudover er det særligt implantater og brok-mesh som er særligt udfordrede.

Da vi er helt på bar bund når det kommer til forslaget, vil jeg høre om nogen hos jer ved noget mere om det, og vil tage et møde med os for at give noget baggrund og forståelse, så vi er klædt på både i forhold til vores brancheforeninger men også de drøftelser der pågår i EU. EU Kommissionen har netop bedt os om at række ud til vores sundhedsattachéer, for at sikre at medicinsk udstyr bliver tænkt ind i forslaget f.eks. gennem nogen undtagelser.

Som vi forstår vores tyske kollegaer så er forslaget fremsat/underskrevet af bl.a. DK, NO, SE, NL og DE.

Mange hilsner
Stine

Med venlig hilsen/Kind Regards,

Stine Jønson
Sektionsleder, Eksternt Samarbejde og Koordinering
Head of Unit, External Collaboration & Coordination
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Lægemiddelstyrelsen
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LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Til: Carsten Bruun Skærbæk ([redacted]@SUM.DK)
Cc: Rikke Donchil Holmberg ([redacted]@mim.dk), Sandi Muncrief ([redacted]@mst.dk)
Fra: Dorte Bjerregaard Lerche ([redacted]@mim.dk)
Titel: SV: Spørgsmpl vedr. kommende EU-regulering om PFAS i lægemidler
Sendt: 11-07-2023 08:36

Kære Carsten
Det er Miljøstyrelsens kontor for Kemikalier, der har udarbejdet forslaget. Sandi Muncrief er chef:
https://mst.dk/service/om-miljoestyrelsen/organisation/miljoestyrelsens-enheder/kemikalier/

Venlig hilsen

Dorte Bjerregaard Lerche
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Fra: Carsten Bruun Skærbæk <[redacted]@SUM.DK>
Sendt: 31. maj 2023 10:53
Til: Dorte Bjerregaard Lerche <[redacted]@mim.dk>
Cc: Rikke Donchil Holmberg <[redacted]@mim.dk>
Emne: SV: Spørgsmpl vedr. kommende EU-regulering om PFAS i lægemidler

Kære Dorte

Tak for det fremsendte. Kan du sende mig kontaktinfo på de relevante medarbejdere og chefer i Miljøstyrelsen, som har siddet med denne opgave?

Vh.
Carsten

Fra: Dorte Bjerregaard Lerche <[redacted]@mim.dk>
Sendt: 30. maj 2023 10:28
Til: Carsten Bruun Skærbæk <[redacted]@SUM.DK>
Cc: Rikke Donchil Holmberg <[redacted]@mim.dk>
Emne: SV: Spørgsmpl vedr. kommende EU-regulering om PFAS i lægemidler

Kære Carsten

Miljøstyrelsen har sammen med myndighederne i fire andre lande udarbejdet et forslag til forbud/begrænsning af PFAS. Forslaget blev sendt til det Europæiske Kemikalieagentur (ECHA) d. 13. januar 2023, og kan ses på agenturets hjemmeside. Forslaget vil i 2023 blive gennemgået og vurderet af agenturets to videnskabelige komiteer, der vil komme med en udtalelse, inden forslaget sendes videre til Kommissionen, som ifølge REACH-forordningen skal fremsætte et forslag, hvis der er en uacceptabel risiko for mennesker sundhed og miljøet.

Link til forslaget:
https://echa.europa.eu/da/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b

Forslaget er ligeledes sendt i høring fra d. 22. marts til d. 25 september 2023 og alle kan indsende høringssvar:
https://echa.europa.eu/da/restrictions-under-consideration

I forslaget, som blev sendt ind, er lægemidler, veterinære lægemidler, biocider og pesticider undtaget, fordi de stoffer bliver vurderet inden for deres egen specifikke reguleringer.

Medicinsk udstyr er ikke undtaget, men der er foreslået specifikke undtagelser for noget medicinsk udstyr: PFAS-polymerer i astma inhalatorer, implanteret medicinsk udstyr samt rør og kateter.

Jeg håber, jeg har besvaret dine spørgsmål.

Venlig hilsen

Dorte Bjerregaard Lerche
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Til: Dorte Bjerregaard Lerche ([redacted]@mim.dk), Rikke Donchil Holmberg ([redacted]@mim.dk)
Fra: Henrik Søren Larsen ([redacted]@mim.dk)
Titel: VS: COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients
Sendt: 02-06-2023 16:04
Bilag: 2023-06-02_COCIR.draft.Letter.on.PFAS.RAC&SEAC.Opinion - Denmark.pdf; COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients.eml; 2023-06-02_COCIR.draft.Letter.on.PFAS.RAC&SEAC.Opinion - Denmark.pdf; SV: COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients.eml;

Kære Dorte
Vil du være venlig vedhæftde mail i at lægge i F2?
På forhånd tak
Henrik

Fra: Riccardo Corridori <[redacted]@cocir.org>
Sendt: 2. juni 2023 14:50
Til: Henrik Søren Larsen <[redacted]@mim.dk>
Emne: COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients

Dear Mr. Larsen,

Please find attached a letter, on behalf of the COCIR Secretary General, Annabel Seebohm, following up our previous communication, about the proposal for a restriction of PFAS that will be discussed next week during RAC and SEAC meetings.

Today COCIR submitted its first report to the public consultation on the Annex XV report. Our assessment shows that, without a proper derogation, critical medical devices will not be available anymore for EU hospitals and clinics with the entry into force of the restriction, significantly impacting healthcare in EU.

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

Best regards,

Riccardo Corridori
Senior Manager
Environmental, Health and Safety Affairs
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Tel.: +32 (0) 2 706 89 66 - Fax: +32 (0) 2 706 89 69
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COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Mr. **Henrik Søren Larsen**
Ministry of Environment and Food
Head of Department, Chemicals

Brussels, 2 June 2023

PFAS Restriction Proposal

Dear Mr. Larsen

Following my previous letter in March this year, I am re-contacting you about the published PFAS restriction proposal. As anticipated, the restriction does not include any exemption for medical imaging and radiotherapy devices, including medical devices that are an integral part of a modern imaging or radiotherapy suite.

Please be informed that COCIR has submitted today its first contribution to the public consultation for the RAC and SEAC opinions with our estimation for the socio-economic impacts of the proposed restriction and a technical assessment of the time required for substituting the many applications of PFAS, mostly fluoropolymers. A second submission will include all our collected knowledge about applications, alternatives, and plans for substitution.

Our key concern is that the current proposed restriction will result in a complete halt to sales of critical medical devices in Europe in just a few years. This would have a direct impact on not just the sector, but mostly on hospitals and patients in the EU. Medical imaging and radiotherapy equipment fall under Regulation (EU) 2017/745 (MDR). Substitution under MDR is a lengthy process due to the complexity of devices and the extensive testing and certification requirements.

Our simulations show that with a proper derogation for at least 13,5 years and the possibility to extend it for specific applications in the future where alternatives may not be available, the number of patients affected may be reduced. Please see the summary of our analysis and recommendations below.

Given the urgency of the matter, and the upcoming RAC and SEAC meetings in the beginning of June 2023 we kindly ask for your support in ensuring the concerns above are recognised so that medical imaging and radiotherapy technologies remain available to the health care sector in the EU/EEA countries.

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

Yours sincerely,

Annabel Seebohm
COCIR Secretary General

ANNEX:
SUMMARY OF ANALYSIS AND RECOMMENDATIONS

COCIR members use PFASs in a wide variety of electrical and non-electrical applications in the EU. These materials cannot be easily substituted as they form an integral part of the medical device. Any alternative with inferior performance could degrade the clinical performance of the devices and may directly and significantly impact the health of millions of patients in the EU.
The COCIR assessment of PFAS uses suggests that substitution of PFASs could be possible in 13,5 years for medical imaging and radiotherapy equipment and associated accessories and medical devices that are an integral part of imaging and radiotherapy procedures.

COCIR estimates around 10 tonnes per year are used in Europe in medical imaging and radiotherapy devices, almost all in fluoropolymers. 0,0012% of the estimated total usage of PFAS in Eu and 0,02% of the total usage estimated for the medical devices sector in the restriction proposal.

The following elements support the request for the derogation duration for 13,5 years:

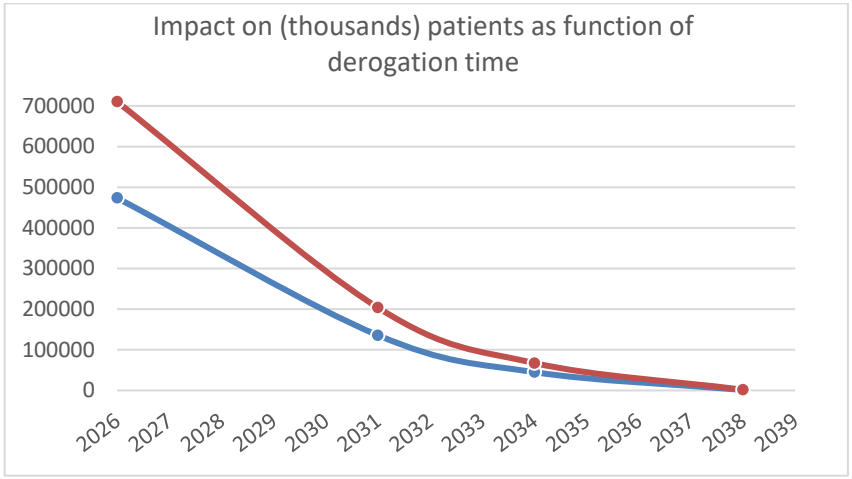
Technical aspects (Chapter 3 of COCIR 1st submission)

1. Identifying all PFAS applications within a global supply chain of 5.000 to 11.000 suppliers per company and assessing possible alternatives will require years.
2. PFAS-free components can only be tested and integrated into new designs once available. Most of the components will become available just before the expire of their derogations. The design time of medical imaging devices is 5 to 7 years while for radiotherapy equipment is 9 to 11.
3. Companies have limited specialized technicians and engineers while having a wide portfolio of applications. As already proven under RoHS redesign takes time and resources.
4. For certain applications there may not be alternatives providing the same clinical performances even in the expected timeframe, and therefore extension of derogations may be required.
5. Despite using some of the best substance tracking tools, there are still likely to be unidentified uses which will not be found by companies until late in the substitution process.

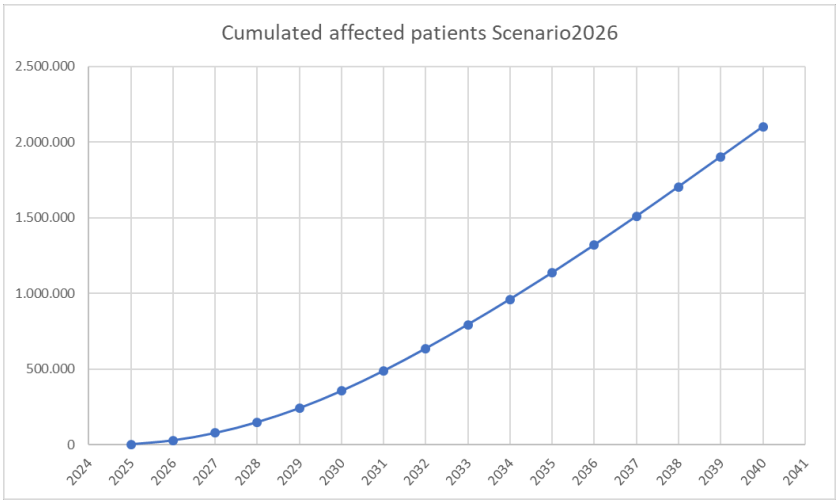
Socio-economic impacts (Chapter 4 of COCIR 1st submission)

Without a derogation for enough years the restriction will cause serious impacts on the availability of medical devices with the following consequences:

6. Devices being discontinued with a potential **reduction in access to healthcare for millions of patients** for a long period (from EIF to 2040). It may take far after 2040 before sales would recover but the decrease in the installed base (density) will not. See chapter 4.4.
7. The reduction in density can possibly cause **millions of cancer patients** to not receive optimal healthcare and maybe reduce their chances for better outcome (see chapter 4.5) at least until (and beyond) 2040. A 13,5 year derogation can lower such numbers to probably a few thousand.
8. The impact on cancer patients is compounded by the recent surge in cancer cases, up to 40%, that will require an even increased availability of radiotherapy centres.
9. The problem with waiting times in the EU will be exacerbated and add to the negative impact so far examined.



The simulation shows that with a 13,5-year derogation the impact on patients access to healthcare will drop from hundreds of millions to a few millions.



Several million cancer patients at risk of less-than-optimal care (mortality in EU)

A derogation is therefore required for at least 13,5 years. In addition, the wording must allow for the reuse of spare parts for refurbishment and repair of devices placed on the market before the entry into force of the restriction for the sector:

10. The “repair as produced principle” is essential to allow continued servicing and repair of medical imaging and radiotherapy equipment in use at hospitals and clinics in EU.
11. Refurbishment of medical devices requires spare parts to be available to refurbish used devices. As such the restriction wording must allow for this practice to continue delivering affordable healthcare and benefits to suitability.
12. It has been already proven under RoHS, for exemption 31a and 47 that the reuse of spare parts is always better from an environmental perspective than generating waste and manufacturing a new one (which may use critical raw materials or other SoCs).

At the end of the derogation period, it may be possible that some uses could be identified for which alternatives will not be available, or where the alternatives would be regrettable substitutions. In these cases, a mechanism to renew the derogation with clear deadlines and obbligations would be essential.

COCIR recommends derogating medical imaging and radiotherapy devices for 13,5 years. A review clause is included in our proposal, supposing 3 years for the evaluation of derogations are sufficient.

1. *By way of derogation, paragraphs 1 and 2 shall not apply to PFAS for the use in medical imaging and radiotherapy devices their accessories and other medical devices within the scope of Article 2(1) of Regulation (EU) 2017/745, required in a modern imaging suite or radiotherapy procedures and designed to work in such environments such as contrast injectors, patient monitoring, etc. until EIF+ 13,5 years.*

2. *Paragraph 1 and 2 shall not apply to PFAS for the use in new and recovered spare parts to repair, service, updating of functionalities or upgrading of capacity or refurbishment of medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging or radiotherapy suite, placed on the market before EIF+13,5.*

3. *Paragraph 1 and 2 shall not apply to medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging or radiotherapy suite, placed on the market for the first time before EIF+13,5*

4. *Paragraph 1 ad 2 shall not apply to PFAS in spare parts recovered from and used for the repair, reuse, updating of functionalities or upgrading of capacity or the refurbishment of medical imaging devices, radiotherapy devices and other me, provided that the reuse takes place in auditable closed-loop business-to-business return system and that each reuse of parts is notified to the customer.*

5. *The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector, their accessories and other medical devices required in a modern imaging or radiotherapy suite, by EIF+10 years to assess the need to maintain the derogation for specific applications for which no alternatives are yet available. The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector by [10 years after EIF] to assess the need to maintain the derogation for specific applications for which no alternatives are yet available and to publish proposed amendments to the Regulation.*

This wording proposal ensures, point by point:

1. Enough time for substitution without impacting innovation and availability of medical devices and therefore patients access to healthcare
2. Installed medical devices owned by hospitals will be maintained functional until the end of their lives instead of being prematurely discarded with a reduction in accessibility to healthcare affecting patients.
3. Medical imaging and radiotherapy equipment (capital investment equipment for healthcare providers) can continue to be sold, transfereed donate between hospitals, taken back and refurbished to increase safety and performances.
4. Circular economy activities such as refurbishment and reuse of recovered spare parts can continue benefitting EU hospitals, ensuring fast and cheaper repairs and shorter downtimes.
5. Certain timelines and obligations would ensure that industry can get the required extension, when needed, without the risk of having to stop orders and sales due to the delays in the evaluation process.

Til: [redacted]@mim.dk (Henrik Søren Larsen)
Fra: Riccardo Corridori ([redacted]@cocir.org)
Titel: COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients
Sendt: 02-06-2023 14:50
Bilag: image003.png; image004.png; image005.png; image002.png; 2023-06-02_COCIR.draft.Letter.on.PFAS.RAC&SEAC.Opinion - Denmark.pdf;

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

Best regards,

Riccardo Corridori
Senior Manager
Environmental, Health and Safety Affairs
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Mr. **Henrik Søren Larsen**
Ministry of Environment and Food
Head of Department, Chemicals

Brussels, 2 June 2023

PFAS Restriction Proposal

Dear Mr. Larsen

Following my previous letter in March this year, I am re-contacting you about the published PFAS restriction proposal. As anticipated, the restriction does not include any exemption for medical imaging and radiotherapy devices, including medical devices that are an integral part of a modern imaging or radiotherapy suite.

Please be informed that COCIR has submitted today its first contribution to the public consultation for the RAC and SEAC opinions with our estimation for the socio-economic impacts of the proposed restriction and a technical assessment of the time required for substituting the many applications of PFAS, mostly fluoropolymers. A second submission will include all our collected knowledge about applications, alternatives, and plans for substitution.

Our key concern is that the current proposed restriction will result in a complete halt to sales of critical medical devices in Europe in just a few years. This would have a direct impact on not just the sector, but mostly on hospitals and patients in the EU. Medical imaging and radiotherapy equipment fall under Regulation (EU) 2017/745 (MDR). Substitution under MDR is a lengthy process due to the complexity of devices and the extensive testing and certification requirements.

Our simulations show that with a proper derogation for at least 13,5 years and the possibility to extend it for specific applications in the future where alternatives may not be available, the number of patients affected may be reduced. Please see the summary of our analysis and recommendations below.

Given the urgency of the matter, and the upcoming RAC and SEAC meetings in the beginning of June 2023 we kindly ask for your support in ensuring the concerns above are recognised so that medical imaging and radiotherapy technologies remain available to the health care sector in the EU/EEA countries.

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

Yours sincerely,

Annabel Seebohm
COCIR Secretary General

ANNEX:
SUMMARY OF ANALYSIS AND RECOMMENDATIONS

COCIR members use PFASs in a wide variety of electrical and non-electrical applications in the EU. These materials cannot be easily substituted as they form an integral part of the medical device. Any alternative with inferior performance could degrade the clinical performance of the devices and may directly and significantly impact the health of millions of patients in the EU.
The COCIR assessment of PFAS uses suggests that substitution of PFASs could be possible in 13,5 years for medical imaging and radiotherapy equipment and associated accessories and medical devices that are an integral part of imaging and radiotherapy procedures.

COCIR estimates around 10 tonnes per year are used in Europe in medical imaging and radiotherapy devices, almost all in fluoropolymers. 0,0012% of the estimated total usage of PFAS in Eu and 0,02% of the total usage estimated for the medical devices sector in the restriction proposal.

The following elements support the request for the derogation duration for 13,5 years:

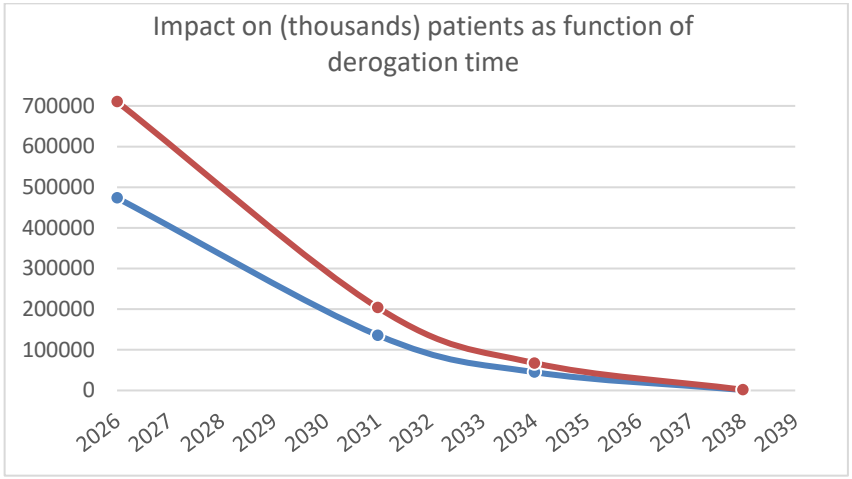
Technical aspects (Chapter 3 of COCIR 1st submission)

1. Identifying all PFAS applications within a global supply chain of 5.000 to 11.000 suppliers per company and assessing possible alternatives will require years.
2. PFAS-free components can only be tested and integrated into new designs once available. Most of the components will become available just before the expire of their derogations. The design time of medical imaging devices is 5 to 7 years while for radiotherapy equipment is 9 to 11.
3. Companies have limited specialized technicians and engineers while having a wide portfolio of applications. As already proven under RoHS redesign takes time and resources.
4. For certain applications there may not be alternatives providing the same clinical performances even in the expected timeframe, and therefore extension of derogations may be required.
5. Despite using some of the best substance tracking tools, there are still likely to be unidentified uses which will not be found by companies until late in the substitution process.

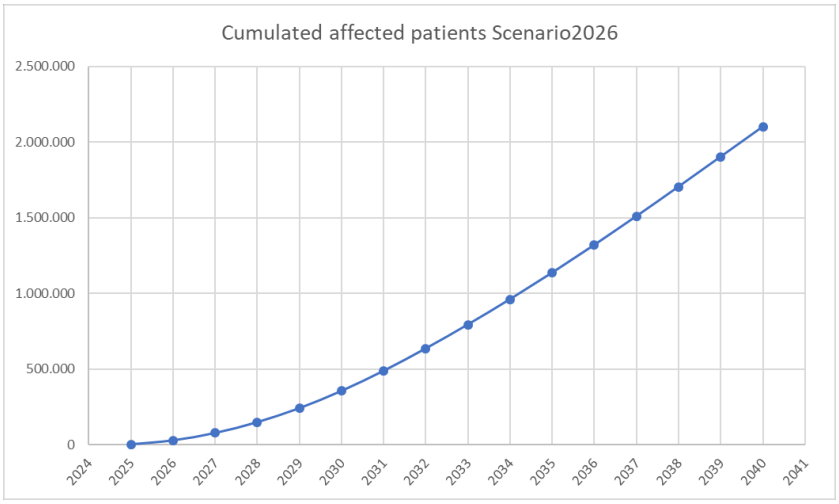
Socio-economic impacts (Chapter 4 of COCIR 1st submission)

Without a derogation for enough years the restriction will cause serious impacts on the availability of medical devices with the following consequences:

6. Devices being discontinued with a potential **reduction in access to healthcare for millions of patients** for a long period (from EIF to 2040). It may take far after 2040 before sales would recover but the decrease in the installed base (density) will not. See chapter 4.4.
7. The reduction in density can possibly cause **millions of cancer patients** to not receive optimal healthcare and maybe reduce their chances for better outcome (see chapter 4.5) at least until (and beyond) 2040. A 13,5 year derogation can lower such numbers to probably a few thousand.
8. The impact on cancer patients is compounded by the recent surge in cancer cases, up to 40%, that will require an even increased availability of radiotherapy centres.
9. The problem with waiting times in the EU will be exacerbated and add to the negative impact so far examined.



The simulation shows that with a 13,5-year derogation the impact on patients access to healthcare will drop from hundreds of millions to a few millions.



Several million cancer patients at risk of less-than-optimal care (mortality in EU)

A derogation is therefore required for at least 13,5 years. In addition, the wording must allow for the reuse of spare parts for refurbishment and repair of devices placed on the market before the entry into force of the restriction for the sector:

10. The “repair as produced principle” is essential to allow continued servicing and repair of medical imaging and radiotherapy equipment in use at hospitals and clinics in EU.
11. Refurbishment of medical devices requires spare parts to be available to refurbish used devices. As such the restriction wording must allow for this practice to continue delivering affordable healthcare and benefits to suitability.
12. It has been already proven under RoHS, for exemption 31a and 47 that the reuse of spare parts is always better from an environmental perspective than generating waste and manufacturing a new one (which may use critical raw materials or other SoCs).

At the end of the derogation period, it may be possible that some uses could be identified for which alternatives will not be available, or where the alternatives would be regrettable substitutions. In these cases, a mechanism to renew the derogation with clear deadlines and obbligations would be essential.

COCIR recommends derogating medical imaging and radiotherapy devices for 13,5 years. A review clause is included in our proposal, supposing 3 years for the evaluation of derogations are sufficient.

1. *By way of derogation, paragraphs 1 and 2 shall not apply to PFAS for the use in medical imaging and radiotherapy devices their accessories and other medical devices within the scope of Article 2(1) of Regulation (EU) 2017/745, required in a modern imaging suite or radiotherapy procedures and designed to work in such environments such as contrast injectors, patient monitoring, etc. until EIF+ 13,5 years.*

2. *Paragraph 1 and 2 shall not apply to PFAS for the use in new and recovered spare parts to repair, service, updating of functionalities or upgrading of capacity or refurbishment of medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging or radiotherapy suite, placed on the market before EIF+13,5.*

3. *Paragraph 1 and 2 shall not apply to medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging or radiotherapy suite, placed on the market for the first time before EIF+13,5*

4. *Paragraph 1 ad 2 shall not apply to PFAS in spare parts recovered from and used for the repair, reuse, updating of functionalities or upgrading of capacity or the refurbishment of medical imaging devices, radiotherapy devices and other me, provided that the reuse takes place in auditable closed-loop business-to-business return system and that each reuse of parts is notified to the customer.*

5. *The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector, their accessories and other medical devices required in a modern imaging or radiotherapy suite, by EIF+10 years to assess the need to maintain the derogation for specific applications for which no alternatives are yet available. The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector by [10 years after EIF] to assess the need to maintain the derogation for specific applications for which no alternatives are yet available and to publish proposed amendments to the Regulation.*

This wording proposal ensures, point by point:

1. Enough time for substitution without impacting innovation and availability of medical devices and therefore patients access to healthcare
2. Installed medical devices owned by hospitals will be maintained functional until the end of their lives instead of being prematurely discarded with a reduction in accessibility to healthcare affecting patients.
3. Medical imaging and radiotherapy equipment (capital investment equipment for healthcare providers) can continue to be sold, transfereed donate between hospitals, taken back and refurbished to increase safety and performances.
4. Circular economy activities such as refurbishment and reuse of recovered spare parts can continue benefitting EU hospitals, ensuring fast and cheaper repairs and shorter downtimes.
5. Certain timelines and obligations would ensure that industry can get the required extension, when needed, without the risk of having to stop orders and sales due to the delays in the evaluation process.

Til: [redacted]@cocir.org (Riccardo Corridori)
Fra: Henrik Søren Larsen ([redacted]@mim.dk)
Titel: SV: COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients
Sendt: 02-06-2023 16:04
Bilag: image001.png; image002.png; image003.png; image004.png;

Dear Mr. Corridori,
Many thanks for informing us about your assessment about the use of PFAS in medical devices.
Best regards,
Henrik Søren Larsen

Kind regards,

Henrik Søren Larsen
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Ministry of Environment
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Fra: Riccardo Corridori <[redacted]@cocir.org>
Sendt: 2. juni 2023 14:50
Til: Henrik Søren Larsen <[redacted]@mim.dk>
Emne: COCIR Letter - PFAS restriction for medical imaging and radiotherapy devices - Derogation required to allow continued healthcare for EU patients

Dear Mr. Larsen,

Please find attached a letter, on behalf of the COCIR Secretary General, Annabel Seebohm, following up our previous communication, about the proposal for a restriction of PFAS that will be discussed next week during RAC and SEAC meetings.

Today COCIR submitted its first report to the public consultation on the Annex XV report. Our assessment shows that, without a proper derogation, critical medical devices will not be available anymore for EU hospitals and clinics with the entry into force of the restriction, significantly impacting healthcare in EU.

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

Best regards,

Riccardo Corridori
Senior Manager
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Til: Carsten Bruun Skærbæk ([redacted]@SUM.DK)
Cc: Rikke Donchil Holmberg ([redacted]@mim.dk)
Fra: Dorte Bjerregaard Lerche ([redacted]@mim.dk)
Titel: SV: Spørgsmpl vedr. kommende EU-regulering om PFAS i lægemidler
Sendt: 30-05-2023 10:28

Kære Carsten

Miljøstyrelsen har sammen med myndighederne i fire andre lande udarbejdet et forslag til forbud/begrænsning af PFAS. Forslaget blev sendt til det Europæiske Kemikalieagentur (ECHA) d. 13. januar 2023, og kan ses på agenturets hjemmeside. Forslaget vil i 2023 blive gennemgået og vurderet af agenturets to videnskabelige komiteer, der vil komme med en udtalelse, inden forslaget sendes videre til Kommissionen, som ifølge REACH-forordningen skal fremsætte et forslag, hvis der er en uacceptabel risiko for mennesker sundhed og miljøet.

Link til forslaget:
https://echa.europa.eu/da/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b

Forslaget er ligeledes sendt i høring fra d. 22. marts til d. 25 september 2023 og alle kan indsende høringssvar:
https://echa.europa.eu/da/restrictions-under-consideration

I forslaget, som blev sendt ind, er lægemidler, veterinære lægemidler, biocider og pesticider undtaget, fordi de stoffer bliver vurderet inden for deres egen specifikke reguleringer.

Medicinsk udstyr er ikke undtaget, men der er foreslået specifikke undtagelser for noget medicinsk udstyr: PFAS-polymerer i astma inhalatorer, implanteret medicinsk udstyr samt rør og kateter.

Jeg håber, jeg har besvaret dine spørgsmål.

Venlig hilsen

Dorte Bjerregaard Lerche
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Fra: Carsten Bruun Skærbæk <[redacted]@SUM.DK>
Sendt: 25. maj 2023 10:20
Til: Dorte Bjerregaard Lerche <[redacted]@mim.dk>
Emne: Spørgsmpl vedr. kommende EU-regulering om PFAS i lægemidler

Kære Dorte

Vil du give mig et kald hurtigst muligt, når du ser denne mail?

Jeg har lige nogle spørgsmål til noget kommende EU-regulering om PFAS i lægemidler, som vi i ISM har fået en henvendelse om.

Vh.
Carsten

Med venlig hilsen

Carsten Bruun Skærbæk
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Dansk køl&varme
Brancheforening for køle- og varmepumpevirksomheder.

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