EU-Konsultation zum PFAS Verbot

Vorschlag zur Eingabe eines eigenen Beitrags im Rahmen des EU-Konsultationsverfahrens

1. Disclaimer

Die Teilnahme am EU-Konsultationsverfahren zum Verbot der PFAS unter Nutzung des anhängenden Textes erfolgt durch jeden im eigenen Namen und auf eigenes Risiko.

Eine Ausnahme für ihre Produkte oder das Erreichen einer verlängerten Übergangsfrist (derogation) unterliegt der Entscheidung im Rahmen eines politischen Prozesses und es wird explizit keine Erfolgsgarantie gegeben.

Teile der eingegebenen Informationen werden nach Eingang auf der EU-Website öffentlich gemacht. Wenn Sie damit nicht einverstanden sind, nutzen Sie das Verfahren nicht.

2. Argumentationslinie

Das Verfahren erfordert eigentlich eine Analyse, welche Produkte von einem PFAS-Bann betroffen sind, welche PFAS darin enthalten sind und welche Ersatzwerkstoffe oder Materialien evtl. zur Verfügung stünden.Über die langen und komplexen Lieferketten, in denen der eigentliche PFAS-Hersteller am weit entfernten Ursprung steht, lassen sich Informationen nur langwierig ermitteln. Dies ist umso schwieriger als die Medizinprodukte-Industrie aufgrund geringer Volumina innerhalb der Zuliefer-Industrie nicht höchste Priorität genießt.

So war es kleinen und mittleren Medizinprodukte-Herstellern nicht möglich die umfassende Analyse zu erstellen, weswegen eine Ausnahme oder ersatzweise die längst mögliche Übergangsfrist (12 Jahre) beantragt wird, da ein Wegfall der Produkte vom Markt die Versorgung von Patienten negativ beeinflusst.

3. Vorbereitung des Eintrags der eigenen Konsultation

Bereiten Sie eine Liste der von Ihrer Firma hergestellten Produkte in sehr generischer Form und auf Englisch vor (z.B.: endoscopes, accessories for sleep medicine, electro stimulation therapy). Diese muss an der gelb markierten Stelle eingefügt werden. Wenn möglich können Sie dahinter noch Verkaufsstückzahlen (z.B. der letzten drei Jahre) nennen, um den Impact der Regulierung zu verdeutlichen.

Passen Sie evtl. die blau unterlegten Texte des Fragenkataloges an Ihre Situation an, wenn Sie z.B. keine elektronischen Produkte herstellen.

4. Link zur Website des Konsultationsverfahrens

Rufen Sie folgende Website auf:

https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?RObjectId=0b0236e1885e69de

Auf der Website ist kein Login erforderlich, wohl aber die Angabe von Firmenname, Adresse und persönlichen Kontaktdaten. Diese können als vertraulich gekennzeichnet werden und werden dann nicht auf der EU-Website veröffentlicht.

5. Ausfüllanleitung

Der Fragenkatalog der Website und Texte, die die oben beschriebene Argumentationslinie darlegen, sind auf den folgenden Seiten wiedergegeben.

Folgen Sie der Anleitung Schritt für Schritt und haken Sie Check Boxen an, wie vorgegeben, bzw. kopieren Sie die blau unterlegten Texte in die entsprechenden Felder des Web-Formulars.

6. Praktische Unterstützung

Nehmen Sie am **20.9.2023 von 17:00 bis 18:30 Uhr** am **Online-Teams-Meeting** teil, an dem die Teilnehmer bei der Übermittlung einer eigenen Eingabe in das Konsultationsverfahren unterstützt werden. Das Meeting ist über folgenden Link zu erreichen:

Hier klicken, um an der Besprechung teilzunehmen

Besprechungs-ID: 344 551 949 028
Passcode: RK6Azx

7. Weitere Informationen

Auf unserer Website finden Sie weitere Informationen, die laufend aktualisiert werden:

https://www.keymkr.com/informieren-interagieren/drohendes-pfas-verbot-in-der-eu/

Fragen zu diesem Dokument bitte an:

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8. Fragenkatalog des Konsultationsverfahren

Frage auf der Website	Ausfüllanleitung
I have read the Consultation Guidance and Information Note	Read linked documents and Check box accordingly
Where did you learn about this consultation? (please select all that apply):	Check corresponding box. If you learned about the PFAS consultation via the KEYMKR or FFM e.V newsletter please check "industry organization".
SECTION I. Personal information	
First Name Family Name Email Country Phone (optional)	Fill in you information
SECTION II. Organisation	
I am submitting information: *	Check: "On behalf of an organisation or institution "
Type of organisation/institution:*	Select "Company"
Name of organisation / institution: *	Name your company
Select one of the following options : * • I agree to the disclosure of the name of my organisation/institution to the public • I want to keep the name of my organisation/institution confidential	Select one of the offered options. **Many companies choose to opt for confidentiality**.
SECTION III. Non-confidential comments	
	Check boxes: X Scope or restriction option analysis X Hazard or exposure X Information on benefits

	X Other socio economic analysis (SEA) issues X Transitional period X Request for exemption
I understand that it is my responsibility not to include confidential information in responses to general comments and in any responses to requests for specific information (e.g. company name, email addresses, phone numbers, signatures etc.). ECHA will not be held liable for any damages caused by making non confidential responses publicly available.	Read text and accept by checking the box.
Please provide your general comments in the box below	We are a manufacturer of medical devices and care for the wellbeing of our patients in every aspect. This covers our direct role as a provider of instruments and products to facilitate diagnostics and therapy. But also as part of the society and individual citizens we care for the environment and are concerned about chemicals accumulating in nature and humans. As medical device manufacturers we are part of an industry with long and complex supply chains. From what we know it is very likely that among the many parts we purchase from our direct suppliers there are parts that either contain PFAS or where PFAS are involved during the manufacturing process. During the consultation period it was not possible for us to perform a complete and thorough analysis, which of our parts and components would be affected by a potential ban of PFAS. We as a small and medium enterprise, order very low volumes of materials compared to consumer product companies or the automotive industry, but nevertheless require high quality products and many proofs for regulatory purposes. This results in a very low impact and priority with our suppliers. As a manufacturer we do not purchase PFAS directly. As the knowledge which parts, components or processes involve PFAS often is not available at our direct supplier but is only available further upstream in the supply chain, gathering information is a time consuming and sometimes futile endeavor. This absence of support is hard to show as supporting evidence. Publicly available information show that metal parts (e.g. with friction reduction surface treatment), certain polymer parts or electronics containing PTFE, PVDF, PFA or PFPE or using these polymers during manufacturing would be subject to the ban. This will result in major efforts to replace these materials, while even the major chemical companies do not provide or promise replacement materials in the foreseeable future. Even when those would be available at some point in the future the effort to introduce the replacement within engineering is calculated by us

	to be 2 to 3 years with further 3 years to validate their application in medical devices. The necessary change control and gathering of clinical data is strongly enforced by the notified bodies following EU regulation. As there are presently no replacement materials available the cost of engineering and validation cannot be calculated to be presented as supporting evidence. It is very likely that following a PFAS ban as planned many of the medical devices listed below under "1 Sectors and (sub-)uses" will be discontinued and be no longer available for patients benefit. Even with the maximum derogation time a timely replacement of PFAS and uninterrupted availability is far from sure. For us as an SME medical device manufacturer it is impossible to give detailed substantiated information on the alternatives and efforts needed after a complete ban of PFAS. However, the very likely consequence will be a discontinuation of medical devices that are in daily use all over Europe!
Specific Information Requests	
1: Sectors and (sub-)uses	Check box "I have information on this topic" And copy the following text into the web form:
	Sector: Medical devices (Annex E.2.9.) We request that <LISTE DER PRODUKTE EINFÜGEN z.B. in folgendem Format:> Product family / Sold items 2019..2021 Electrostimulation devices / 2343 Electrodes / ca. 120000 be newly added to derogation as missing uses.
2: Emissions in the end-of-life phase	Check box "I **don't** have information on this topic"
3: Emissions in the end-of-life phase:	Check box "I **don't** have information on this topic"
4: Impacts on the recycling industry:	Check box "I **don't** have information on this topic"
5: Proposed derogations – Tonnage and emissions	Check box "I **don't** have information on this topic"

6: Missing uses – Analysis of alternatives and socio-economic analysis	Check box “I have information on this topic” And copy the following text into the web form:
	As already stated in the general comments, the medical devices listed under 1. Sectors and (sub-)uses are very likely affected by a PFAS ban, as they consist of parts and materials listed in many other sectors covered in the Restriction Report e.g. electronics or coated metal parts. Missing these products will very likely lead to a discontinuation of the listed medical devices after a PFAS ban. Even when replacement materials for these parts and materials would be available at some point during a derogation period, we as a medical device manufacturer would have only the remaining time of said derogation period to engineer and validate the use within our medical devices. The current enforcement of the medical device regulation is very clear regarding the necessary proofs. We therefore request the exemption or at least the maximum derogation period of 12 years for the products listed under 1. Sectors and (sub-)uses on the basis of the negative impact on patient care if said medical devices would be no longer available due to the non- availability of necessary pre-products and the time-consuming revalidation after technical changes.
7: **Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis**	Check box “I **don't** have information on this topic”
8: Other identified uses – Analysis of alternatives and socio-economic analysis	Check box “I **don't** have information on this topic”
9: Degradation potential of specific PFAS sub-groups:	Check box “I **don't** have information on this topic”
10: Analytical methods	Check box “I **don't** have information on this topic”
SECTION IV. Non-confidential attachment	
	Nichts anhängen
SECTION V. Confidential Attachment	
Ich bin kein Roboter Captcha	Captcha bearbeiten
Submit to ECHA	Press Submit!