From:
To: (ENV)
Cc:
Subject: RE: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices
Date: 09 April 2020 13:24:53
Attachments: image016.png
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Dear , dear .
On behalf of , our members and myself, I would like to thank you for our meeting last Friday.
In the meantime, we have seen the updated draft delegated act from the Commission which addresses some of our concerns.
However, the new draft also raises some questions:

- The new derogation under point 9 allows use of PFOA in medical device articles but not use of PFOA for manufacturing of these article. Hence, the derogation does not seem to cover components which our sector supplies, meaning that the last date for supplying the components (i.e. use in the supply chain) would still be 4 July 2020?
- The derogation says 'medical devices other than implantable ones' – should this be 'other than implantable and invasive ones'?
- Point 9 refers to medical devices covered by the Medical Device Regulation, but there will be devices which will still be placed on the market and sold under the Medical Device Directive 93/42/EEC during the so-called 'grace period' until 26 May 2025. Can a reference to the Medical Device Directive 93/42/EEC still be added?
- Is the relevant date for medical device articles already in use in the Union 4 July 2020 or 3 December 2020? My reading of the draft is that it would be 4 July 2020 for all products, hence to make use of this clause the medical devices would still need to be produced before 4 July 2020?

Could you kindly give us your views on the above?
Thank you for your support.
With kind regards,

Mob.
www.medtecheurope.org
MedTech Europe

From: @ec.europa.e
Sent: Wednesday, April 1, 2020 10:13 AM
To: @medtecheurope.org>
Cc:
Subject: RE: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear
Thanks for sending the list of participants. Please share the connection details with them.
Regards

> **From:** @medtecheurope.org>
> **Sent:** Wednesday, April 1, 2020 10:00 AM
> **To:** @ec.europa.eu>
> **Cc:**
> **Subject:** RE: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices
>
> Dear ,
> Thanks again for the opportunity of having this call.

From our side, the following people would like to participate:

- [redacted] Regulations & Industrial Policy, MedTech Europe
- [redacted] Regulations & Industrial policy, MedTech Europe
- [redacted] Regulatory Affairs CoE IV-Systems, B Braun
- [redacted] Global Environmental Compliance, Baxter
- [redacted], BD

I will forward them your meeting invite if that is OK.
We will send you a short slide deck before the meeting.
With kind regards,

[redacted] Regulations and Industrial Policy
Mob. [redacted]
www.medtecheurope.org

MedTech Europe

From: [redacted]@medtecheurope.org>
Sent: Tuesday, March 31, 2020 2:12 PM
To: [redacted]@ec.europa.eu
Cc: [redacted]@medtecheurope.org>
Subject: RE: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Thank you very much.
[redacted] (in Cc) will send you the names from our delegation

From: [redacted]@ec.europa.eu [redacted]
Sent: Tuesday, March 31, 2020 2:04 PM
To: [redacted]@medtecheurope.org>
Cc: [redacted]@medtecheurope.org>
Subject: RE: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

OK, then let's use our teleconferencing system (BT). Here are the connection details:

Dial-in numbers:

Belgium International direct: +32 [redacted]

Participant passcode: [redacted] then #

For a complete list of Global Access Numbers, please visit:
http://www.btconferencing.com/ecwacs/globalaccess/

No problem for companies' experts participating. Please send me the list of names before the call. If you want to use slides, please send them in advance.
Regards
[redacted]

From: [redacted]@medtecheurope.org>
Sent: Tuesday, March 31, 2020 11:56 AM
To: [redacted] (ENV) [redacted]
Cc: [redacted]
Subject: RE: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear [redacted],
We are sorry to hear that. Yes Friday 3 April at 11am works for us. Since Skype for Business is our standard platform, perhaps we should instead use your WebEx system? Finally, please kindly advise whether we may invite a small number of company experts to join the remote meeting.
Thank you,
[redacted]

From: [redacted]@ec.europa.eu [redacted]
Sent: Tuesday, March 31, 2020 11:26 AM
To: [redacted]@medtecheurope.org>
Cc: [redacted]@medtecheurope.org>
Subject: RE: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical

Devices

Dear [redacted]

Unfortunately [redacted], is on sick leave. We can schedule the meeting for Friday from 11.00 to 12.00 and then we see if she can join. If she can't, it will be me and my colleague [redacted].

On technicalities, please let me know if you want to set up the call or if I should do it. Please notice that for us in the Commission skype for business does not work with external participants.

Regards

[redacted]

From: [redacted]@medtecheurope.org>
Sent: Tuesday, March 31, 2020 9:47 AM
To: [redacted] (ENV) [redacted]
Cc: [redacted]@medtecheurope.org>
Subject: RE: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear [redacted],

Since 1 April is tomorrow, may I ask if you have had the time to consider my below email?

If you need us to propose alternative dates, please let us know.

Kind regards,

[redacted]

From: [redacted]
Sent: Friday, March 27, 2020 3:38 PM
To: [redacted]@ec.europa.eu' [redacted]
Cc: [redacted]
Subject: RE: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear [redacted]

Thank you for the rapid reply.

We would indeed still welcome a phone exchange regarding this matter.

Suggested slots from our side:

- Wednesday 1 April: Before 1pm
- Friday 3 April :Between 11am and 2pm

Please kindly also confirm if we can invite company experts to the call, as was foreseen for the 16 March meeting that had to be cancelled.

Kind regards,

[redacted]

From: [redacted]@ec.europa.eu [redacted]
Sent: Friday, March 27, 2020 3:22 PM
To: [redacted]@medtecheurope.org>
Cc: [redacted]
Subject: Fw: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices
Importance: High

Dear [redacted]

many thanks for this document.

I would like to inform you that in the latest draft of the Commission delegated act on the inclusion of PFOA in Annex I of the POP Regulation (currently in the adoption procedure) we have granted 6 additional months for the derogations that were included in the REACH restriction but not in the decision of the Stockholm Convention. This includes also non-invasive and non-implantable medical devices. Please also notice the provisions of Art. 4(2) of the POPs Regulation on articles already produced at the entry into application of the amendment.

If you believe you still need a discussion with us, please propose me a date and time for a telephone discussion towards the end of next week.

Regards

[redacted]

From: [redacted]@medtecheurope.org>
Sent: Friday, March 27, 2020 12:10 PM
To: [redacted] (ENV) [redacted]
Cc: [redacted]
Subject: Remote Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices
Importance: High

Dear [redacted]

MedTech Europe kindly requests a remote meeting to replace the meeting on PFOA which was originally planned for 16 March (see below email chain).

We are aware that the Commission has had to cancelled all non-urgent meetings, but considering that the amendment to the POPs Regulation is in the final stages before adoption and could have a significant negative impact on the supply of medical devices, including certain technologies needed in intensive care units – e.g., devices for infusion therapy – we kindly request that the meeting be reconsidered, in form of a conference call or webinar.

Attached you will find more information about medical devices which would be impacted by the PFOA ban. We look forward to discussing with you if any solutions for our sector could be considered. The concentrations of PFOA reported by our member companies are far below the REACH restriction limit (0.1%) but above the new limit of 25 parts per billion proposed under the POPs Regulation. We would be asking for a short additional grace/implementation period for non-invasive and non-implantable medical devices which contain PFOA only as a trace contaminant.

We thank you for your attention and look forward to your reply.

With kind regards,

[redacted]

[redacted] Regulations & Industrial Policy
Dir. [redacted] | Mob. [redacted]
www.medtecheurope.org
MedTech Europe

From: [redacted]@ec.europa.eu

Are you a MedTech Europe member? If so, click the below for our Regulatory Guidance, Positions, Q&A, Training Tools, etc.
MedTech Europe

[redacted]@ec.europa.eu>
Sent: Wednesday, March 11, 2020 11:01 AM
To: [redacted]@medtecheurope.org>
Cc: [redacted]
Subject: RE: Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear [redacted],

Thank you for your email.

We are in the situation that unfortunately as you mentioned below, we have to cancel the meeting on 16/03.

It was foreseen to send you the cancellation today as I received this morning the confirmation to cancel it.

Thank you for understanding

Best regards,

[redacted]

From: [redacted]@medtecheurope.org>
Sent: Tuesday, March 10, 2020 6:11 PM
To: [redacted] (ENV) [redacted]
Subject: RE: Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear [redacted],

I just wanted to check whether the meeting will be maintained given the situation with the Corona virus.

We are still very committed to have the meeting; the reason I ask is because one person is coming from the US and of course we would like to avoid that he has to travel in vain.

Thanks and best regards,

[redacted]

From: [redacted]@ec.europa.eu [redacted]
Sent: Monday, March 9, 2020 10:12 AM
To: [redacted]@medtecheurope.org>
Subject: RE: Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear [redacted],

Thank you for the excel sheet. I have just did the request for your access.

Looking forward to see you next week.

Best regards,

[redacted]

From: [redacted]@medtecheurope.org>
Sent: Monday, March 9, 2020 6:53 AM
To [redacted] (ENV) [redacted]
Cc [redacted]
Subject: RE: Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear [redacted],

I'm sending you back the completed visitor template for our meeting with Ms. [redacted] on 16 March.

The participants from MedTech Europe will be:

- [redacted] Regulations & Industrial Policy
- [redacted] Regulations & Industrial policy
- [redacted] Regulatory Affairs CoE IV-Systems, B Braun

• [redacted] Global Environmental Compliance, Baxter

We look forward to the meeting.

With kind regards,

[redacted]

[redacted] Regulations and Industrial Policy
Mob. [redacted]
www.medtecheurope.org

MedTech Europe

From: [redacted]@ec.europa.eu [redacted]
Sent: Monday, March 2, 2020 5:06 PM
To: [redacted]@medtecheurope.org>
Cc: [redacted]@medtecheurope.org>
Subject: RE: Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear [redacted],

Sorry for my belated reply as I was on leave last week.

Yes, we confirm that you can bring company experts to the meeting which will take place in DG ENVIRONMENT, Avenue du Beaulieu 5, 1160 - Auderghem / Oudergem, Brussels, **room BU 5 – 00/D.**

Please find enclosed an excel sheet that I kindly ask you to fill in with the personal details of all meeting attendees and send it back to me.

I need this information in order to make the building access request. You will receive an "e-pass visitor" by email that you will need to present at the entrance.

Thank you!

Best regards,

[redacted]

From: [redacted]@medtecheurope.org>
Sent: Friday, February 28, 2020 9:54 AM
To: [redacted] (ENV)
Cc: [redacted]
Subject: RE: Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear [redacted],

Could you kindly let us know if it is OK for MedTech Europe to bring company experts to the meeting, who would join [redacted] and myself?

Thank you very much, with kind regards,

[redacted]

[redacted] Regulations and Industrial Policy
Mob. [redacted]

www.medtecheurope.org

MedTech Europe

From:
Sent: Monday, February 24, 2020 9:59 AM
To: @ec.europa.eu'
Cc:

Subject: RE: Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear ,

On behalf of , I would like to confirm that both he and myself are available for a meeting on Monday, 16 March, from 10:00 – 11:00.

We thank you for this opportunity and look forward to the meeting.

Could you kindly confirm whether one or two subject-matter experts from our member companies may join this meeting too?

With kind regards,

Regulations and Industrial Policy
Mob.
www.medtecheurope.org

MedTech Europe

cid:image002.png@01D5F0B4.316E7640

From: @ec.europa.eu
Sent: Friday, February 21, 2020 6:32 PM
To @medtecheurope.org>
Cc:

Subject: Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear ,

On behalf of , I would like to thank you for your message regarding the meeting request below.

She gladly accept your invitation to meet for a discussion on PFOA at our premises.

We would like to propose you some time slots :

16 March - from 10:00 to 11:00

17 March - from 14:00 to 15:00 or from 15:00 to 16:00

Could you please confirm whether the proposed dates suit you.

PS. Sorry, my previous email went too quickly and I was waiting to be sure about 16 March.

Looking forward to hearing from you.

Best regards,

[redacted]

European Commission
DG Environment
Unit B2 – Sustainable chemicals

Office: [redacted]
B-1049 Brussels
[redacted]@ec.europa.eu

Website: http://ec.europa.eu/environment

Follow us on:

From: [redacted]@medtecheurope.org>
Sent: Wednesday, February 19, 2020 12:20 PM
To: [redacted] (ENV)
Cc: [redacted]
Subject: Meeting Request: Persistent Organic Pollutants Regulation and PFOA in Medical Devices

Dear [redacted]

MedTech Europe is kindly requesting a meeting with you regarding the planned restriction of Perfluorooctanoic acid (PFOA), which would ban medical devices (excluding invasive devices and implants) containing PFOA, as of 4 July 2020, as compared to 4 July 2032, which is the REACH deadline for which our members and their supply chains have been preparing.

Since the publication of the draft amendment to the POPs Regulation, and as indicated in MedTech Europe's feedback submitted on 5 December 2019, several medical technology companies have been informed by their suppliers that components which are used in medical devices contain PFOA above 25 ppm. PFOA is present in these applications as an unintentional trace contaminant below 0.1% and was therefore previously not reported according to REACH Article 33(1).

MedTech Europe participated in the meetings of the POP Review Committee when a restriction on PFOA was discussed. Already in 2018, we showed that PFOA may be present in various categories of medical devices, but in the end an exemption was only given to implantable and invasive medical devices.

Since that time, we have been able to compile additional, detailed information which confirms that hundreds of millions of medical device units would be impacted by the pending ban and would potentially no longer be available to European patients.

We would like to present this evidence to you and discuss how a disruption in the supply of medical devices could be averted, e.g. by exploring an additional derogation for PFOA present as an unintentional trace contaminant in medical devices which are not covered by any of the existing derogations.

I'm also copying our sectoral unit, SANTE.B6, plus the REACH unit GROW.D1.

Looking forward to your response and availability. Please also kindly confirm whether subject-matter experts from our membership might join this meeting.

Thank you and kind regards,

[redacted]

[redacted] Regulations & Industrial Policy
Dir. [redacted] | Mob. [redacted]
www.medtecheurope.org

MedTech Europe

Are you a MedTech Europe member? If so, click the below for our Regulatory Guidance, Positions, Q&A, Training Tools, etc.
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