

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Gentle reminder: Amendment of the EU POPs Regulation re PFOA restriction
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)

Dear [REDACTED]

I'm sorry for the delay but we are very busy in this period.

Legally, on 3 December the derogation will end and the general rules for PFOA will apply. The products will still be covered by the exemptions in Article 4(2), if applicable. As soon as the new delegated act enters into force the medical devices will be covered by the new UTC and their manufacturing, placing on the market and use will be allowed even if PFOA is above the threshold of 25 ppb.

National authorities are responsible for enforcement and they are informed that non-invasive and non-implantable medical devices containing substances below UTC will be covered soon by the new delegated act.

We have included this point for discussion at the POP CAs meeting of next week.

Regards

[REDACTED]

From: [REDACTED] <[REDACTED]@medtecheurope.org>

Sent: Tuesday, November 17, 2020 11:57 AM

To: [REDACTED] (ENV)

Cc: [REDACTED]

Subject: Gentle reminder: Amendment of the EU POPs Regulation re PFOA restriction

Dear [REDACTED]

This is a kind reminder that we would very much appreciate a response to the message of below.

Our members are worried about the situation and we have to clarify it as soon as possible.

Many thanks for your efforts in dealing with this request.

Best wishes,

[REDACTED]

[REDACTED]

From: [REDACTED]

Sent: Friday, 13 November 2020 09:20

To: [REDACTED] <[REDACTED]@ec.europa.eu>

Cc: [REDACTED]

Subject: RE: Gentle reminder: Amendment of the EU POPs Regulation: Follow-up on PFOA restriction

Dear [REDACTED],

Many thanks for your responses.

Based on the latest developments, it means that Parliament and Council have until 23 January to object.

That would mean at a minimum several weeks of 'gap' between 3 December and the ultimate publication and entry into force of the amendment.

Could you perhaps clarify what happens during that gap period?

That would be most helpful!

Best wishes,

[REDACTED]

[REDACTED] Regulations and Industrial Policy

Dir. | Mob. [REDACTED]

www.medtecheurope.org

From:

MedTech Europe



[redacted]@ec.europa.eu [redacted]

Sent: Thursday, 12 November 2020 17:42

To: [redacted]@medtecheurope.org>

Cc: [redacted]
[redacted]

Subject: RE: Gentle reminder: Amendment of the EU POPs Regulation: Follow-up on PFOA restriction

Dear [redacted]

I just received the confirmation that the adoption of the amendment is scheduled for 23 November.

Regards
[redacted]

From: [redacted] (ENV)

Sent: Thursday, November 12, 2020 5:32 PM

To: [redacted]@medtecheurope.org>

Cc: [redacted]
[redacted]
[redacted]

Subject: RE: Gentle reminder: Amendment of the EU POPs Regulation: Follow-up on PFOA restriction

Dear [redacted]

The internal procedure for launching the adoption via written procedure is not concluded yet.

The adoption should be launched in the upcoming days, and then it takes normally less than one week for the adoption.

This amendment is a Commission delegated act: https://ec.europa.eu/info/law/law-making-process/adopting-eu-law/implementing-and-delegated-acts_en

After the Commission adoption, the Parliament and the Council will have 2 months for the right of objection. If they do not object, the amendment is published and it enters into force.

Then, the most likely situation is that on 3 December the act is adopted but not yet published.

We will most probably raise this in the upcoming POPs CAs meeting.

Regards
[redacted]

From: [redacted]@medtecheurope.org>

Sent: Monday, November 9, 2020 9:21 AM

To: [redacted] (ENV) [redacted]

Cc: [redacted]
[redacted]

Subject: RE: Gentle reminder: Amendment of the EU POPs Regulation: Follow-up on PFOA restriction

Dear [redacted],

Further to our exchanges of below, I am coming back to you to request some clarifications regarding the proposed amendment of the POP regulation for PFOA.

In particular, it would be very helpful to know if you see the possibility for the amendment to be published within the next weeks. The current derogation will be applicable until 3rd December and it would be important for us to know if the amendment will be in place until this time.

Unfortunately the timeline for the adoption procedure is not really clear to me. Does it mean that the Commission only have to get the internal approvals and then the adoption will be published immediately?

Or do the Parliament and the Council have two months to formulate any objections after the internal approval and then the amendment enters into force?

In case the publication depends only on the internal approval at Commission level, we would appreciate if you could highlight the urgency in your department since the current derogation will end on 3rd December.

It would be most useful if you can clarify the above as our members have started to ask questions and we may be getting more in the next period.

Looking forward to your feedback.

Best wishes,

Regulations and Industrial Policy

Dir. | Mob.  www.medtecheurope.org

From: 

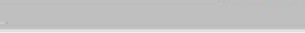
MedTech Europe



 [@ec.europa.eu](mailto:ec.europa.eu) 

Sent: Wednesday, 28 October 2020 12:19

To:  @medtecheurope.org

Cc: 

Subject: RE: Gentle reminder: Amendment of the EU POPs Regulation: Follow-up on PFOA restriction

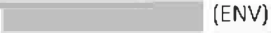
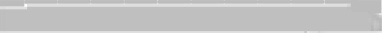
Dear 

We are still waiting for all internal approvals to launch the adoption procedure. We expect that the amendment should be adopted in the upcoming weeks. I will let you know when the procedure is launched and I will then be able to estimate the timeline more precisely.

Regards

From:  @medtecheurope.org

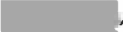
Sent: Wednesday, October 28, 2020 10:37 AM

To:  (ENV) 

Cc: 

Subject: Gentle reminder: Amendment of the EU POPs Regulation: Follow-up on PFOA restriction

Importance: High

Dear ,

I am writing to remind you that we would appreciate a response to the questions of below.

Our Chemicals WG meeting is today at 14h00 and it would be great to be able to provide the members with the latest updates.

In particular, we would be keen to know when the adoption of the delegated act might take place.

Thank you in advance.

Best wishes,

Regulations and Industrial Policy

Dir. | Mob.  www.medtecheurope.org

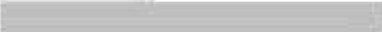
From: 

Sent: Wednesday, 14 October 2020 10:30

To:

MedTech Europe



 [@ec.europa.eu](mailto:ec.europa.eu) 

Cc: 

Subject: Amendment of the EU POPs Regulation: Follow-up on PFOA restriction

Importance: High

Dear [REDACTED],

I am the successor of [REDACTED] and I joined MedTech Europe recently.

I am now writing you to follow-up on [REDACTED] previous exchanges with you on PFOA and on the statement submitted by us in summer – attached.

Could you kindly let me know if there have been any developments at the Commission on this file and if our views have been considered? The next meeting of our Chemicals WG is coming soon and members are very keen to hear some updates on this issue.

Alternatively we can also have a direct discussion by phone if that is more convenient for you.

Looking forward to your feedback.

Best wishes,

[REDACTED]
[REDACTED] Regulations and Industrial Policy

Mob. [REDACTED]

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