

From: [REDACTED]
To: [REDACTED] (GROW); GROW.D1; [REDACTED] (ENV); ENV POP
Cc: [REDACTED]; [REDACTED]; [REDACTED]
Subject: PFOA exemption - DIAsource Immunoassays (Belgium)
Date: jeudi 2 avril 2020 13:13:04
Attachments: [PFOA exemption - Letter to the EU commission - Signed.pdf](#)
[PFOA exemption - Letter to the EU commission - Unsigned.pdf](#)
Importance: High

Dear [REDACTED],
Dear [REDACTED],

On behalf of DIAsource Immunoassays, I'm writing to you in your capacity as [REDACTED] in charge of the REACH Regulation and the POP Regulation respectively, for the following reason.

One of our products portfolio uses PFOA as a critical component to perform the diagnosis of vitamin D deficiency, which is a major public health concern.
The current REACH regulation, and the upcoming amendment to the EU POPs Regulation, both plan to restrict the use of PFOA to certain exemptions.

In view of our attached analysis, our company would like confirmation from your part, stating that:

- With regard to the REACH Regulation:
 - our products benefit from the exemption provided for SR&D activities;
 - in any case, our products are medical devices covered by the exemption referred to in point 3 (c) of entry 68 of Annex XVII;
- With regard to the POPs Regulation:
 - our products benefit from the exemption provided for substances used for laboratory-scale research.

We would be grateful if you could get back to us on these points as soon as possible.

This being said, we understand the decision to restrict the manufacture, the placing on the market and the use of a product such as PFOA.

Although we consider that our products are exempt from the REACH and POPs Regulations, our company is committed to removing PFOA from our products as quickly as possible, and is making every possible effort to find a credible alternative to PFOA in the short and/or medium term.

We sincerely thank you for your attention to this letter. We are of course at your disposal for any further information you may require.

A copy of this letter is addressed to the European Chemicals Agency (Mr. Hansen, Executive Director).

Furthermore, we are available to meet you if you wish, if necessary by conference call.

PS: I have attached an unsigned copy of the letter, which is more readable than the scanned signed version.

Sincerely yours,

[REDACTED]
[REDACTED]

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