

To: [REDACTED]
Cc: [REDACTED]
Subject: RE: PFAS - request for a meeting

Dear [REDACTED],

Thank you for your message and your interest in the development of the essential use concept. As you rightly point out, the European Commission is supported in its work on this topic by a contractor. The contractors are in the information gathering phase and are also preparing for a workshop which is preliminarily scheduled for March 2022.

Considering this, all input is currently directed through this channel. We would therefore respectfully decline your request for a meeting after the Christmas break and will forward your contact details to our contractor to keep you informed about the details of the upcoming workshop.

The preparation of a restriction proposal for a group of PFAS is an initiative of a group of Member States, we would therefore advise you to provide information on your specific uses in veterinary medicinal products to them. More information about this initiative can be found on the website of the European Chemicals Agency ([Registry of restriction intentions until outcome - ECHA \(europa.eu\)](https://echa.europa.eu/registry)).

Wishing you a nice holiday season, with best regards,

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This e-mail contains the personal opinions of the author and does not necessarily reflect the official opinion of the Commission. L'opinion exprimée ici est un avis personnel qui ne reflète pas nécessairement le point de vue officiel de la Commission.

From: [REDACTED]@animalhealtheurope.eu>
Sent: Tuesday, December 14, 2021 6:09 PM
To: [REDACTED] (ENV) [REDACTED]@ec.europa.eu>
Cc: [REDACTED]@animalhealtheurope.eu>; [REDACTED]
[REDACTED]@animalhealtheurope.eu>
Subject: PFAS - request for a meeting

Dear [REDACTED],

AnimalhealthEurope is the association representing manufacturers of animal medicines, vaccines and other animal health products in Europe. We are a Brussels-based not-for-profit body representing both corporate members and national animal health associations in Europe. It represents both innovators and generics alike, as well as large, medium-sized and small companies. AnimalhealthEurope's membership covers 90% of the European market for animal health products.

As you may know, some veterinary medicinal products (VMPs), after having been approved by the EMA contain PFAS.

However, as a result of the REACH Regulation (Reg 1907/2006) various initiatives are already impacting VMPs either during their manufacture or in their composition, and are in direct conflict with the rules in Reg 2019/6 (Veterinary Medicinal Products Regulation entry into force on 28 January 2022. For example the recently launched proposal for restriction of per- and polyfluoro alkyl substances (PFAS) which, given its broad definition of PFAS, threatens a ban on specific VMPs or renders their manufacture impossible as there are no alternatives. E.g. this could eliminate all inhalation anaesthetics currently used in both human and veterinary medicine, and it could cause significant treatment gaps in other areas with implications for animal health but also for public health as some of the conditions that are treated by these medicines (e.g. fleas and ticks, and the diseases they carry) can impact human health if the animals are left insufficiently treated, or even untreated.

As we are aware that you are responsible for this file in DG Envi, we would very much value to discuss with you the particularity of our sector and products, exchange on what the definition of “essential use “ could entail, be consulted by the consulting firm Wood you are working with and be informed/involved in relevant workshops on the topic.

I hope to have an opportunity to discuss these elements with you just after the Christmas break.

Best regards,



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