EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Chemicals and Consumer Industries
REACH
ENVIRONMENT DIRECTORATE-GENERAL
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Subject: PFOA exemption - Request for derogation for IVD products

Dear [redacted],

Thank you for your letter of 2 April asking for a clarification on a possible exemption for the use of PFOA for the production of In Vitro Diagnosis (IVD) products by DIAsource Immunoassays.

Based on the information provided in your letter, we understand that the analysis of vitamin D in blood samples using these IVD products is routine analysis and therefore the products benefit from the exemption provided for scientific research and development activities according to Article 67.1 of the REACH Regulation. We also understand from the information provided in your letter that these products are medical devices other than implantable medical devices within the scope of Council Directive 93/42/EEC, and therefore covered by the exemption referred to in point 3(c) of entry 68 of Annex XVII to REACH.

Entry 68 will be superseded following the adoption of the draft Commission delegated act to amend Annex I to Regulation (EU) 2019/1021 (POPs Regulation) including PFOAs. The draft Commission delegated act amending the POPs Regulation has been adopted and notified to the European Parliament and the Council starting the two months period for possible objections[1]. Provided it is not objected by either of them, it is scheduled to apply from 4 July 2020 onwards.

According to Article 3 of the POPs Regulation, the production, placing on the market and use of substances listed in Annex I (including PFOA), whether on their own, in preparations or as constituents of articles, shall be prohibited. However, Article 4 states that Article 3 shall not apply in the case of a substance used for laboratory-scale research or as a reference standard. Although the concept of laboratory-scale research is not

[1] https://webgate.ec.europa.eu/regdel/#/dele gatedActs/1371

defined by the POPs Regulation, we consider that the production of the ELISA and RIA kits for the diagnosis of deficit of Vitamine D as described in your letter, are covered by the exemption in accordance with Article 4.

We nevertheless welcome your commitment and encourage you to proceed with the removal of the use of PFOA from your products as soon as possible.

Yours sincerely,

(e-sign)

[redacted]

DG Internal Market, Industry, Entrepreneurship and SMEs

(e-sign)

[redacted]

DG Environment