2023

DIAGNOSTICS FOR ANIMALS
VETERINARY DIAGNOSTIC MANUFACTURERS

Diagnostic For Animal Position on the Jan. 2023 proposed PFAS REACH Restriction

D4A PFAS RESTRICTION POSITION PAPER

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I. Executive Summary:

To ensure critical diagnostic products for Animal Health[1], Food Safety[2] and Quality, and Environmental Compliance[3] testing remain on the market to test for animal diseases, food borne pathogens and environmental compliance parameters, we recommend that the following proposals be introduced to avoid intended consequences from gaps in the proposed PFAS restriction.

1. Paragraph 5.n. derogation: we ask that the 'Diagnostic laboratory testing' concept under derogation 5.n. is defined more clearly to go beyond the narrow definition of a subset of human use medical devices, since there are other contexts in which essential diagnostic laboratory testing occurs:
   - include instrument, apparatus, appliance, implant, reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment or system, whether used alone or in combination, or other article intended by the manufacturer to be used, alone or in combination, for delivering diagnostic results; and
   - confirm expressly that its scope applies to (i) human, (ii) veterinary, (ii) food and (ii) environmental diagnostic laboratory testing. We suggest (by analogy with the approach taken in the Environmental Liability Directive 2004/35/EC) that environmental testing is defined as testing intended by the manufacturer to be used, alone or in combination, for delivering diagnostic results which is for diagnosis of the status, condition, quality, performance, and/or effects on or by one or more aspects of the environment, including in relation to species and habitats, water, land and air. We further suggest (by analogy with the approach taken in the General Food Law Regulation (EC) No 178/2002) that food testing is defined as testing which is intended by the manufacturer to be used, alone or in combination, for delivering diagnostic results which is for diagnosis of the status, condition, quality, performance, and/or effects on or by food, including with a view to protection of human life and health, protection of consumers' interests , the protection of animal health and welfare, plant health and the environment.

2. The proposed derogations account for a very limited number of narrow PFAS applications and do offer any option for complex situations not covered under the impact assessment. Longer transition periods may be justified where no available alternatives exist, for products with long validation and market approval cycles, for products with very long life cycles.

   We therefore recommend:
   - introducing a procedure to allow operators requesting a renewal or extended transition period for applications where no alternative is available or where longer transition is necessary to avoid availability risks for essential product categories.
   - introducing a grand-father clause with no time limit for parts contributing to servicing and refurbishing products placed on the market prior to the end of the applicable derogation timelines.

II. Introduction

DiagnosticsForAnimals (D4A) is the European trade association for the veterinary, food and environmental diagnostic and reagents industry. Our members are national, European, and multinational companies who research, develop, manufacture, distribute and supply diagnostic-related technologies and services.

III. General comments

D4A members manufacture *in vitro* diagnostic (IVD) assays (ELISA, PCR, Lateral Flow…), diagnostic analysers (chemistry and hematology analysers, rapid test readers…), laboratory equipment and reagents. Our industry develops, manufactures and distributes products and services primarily targeted to companion animals, breeders and food producers of livestock, poultry, dairy and environmental testing laboratories.

PFAS are found in the veterinary, food and environmental diagnostics industry due to their performance and characteristics in interactions with biological materials and for their electro-mechanical properties in equipment. Diagnostics and reagents may contain PFAS in finished products (diagnostic devices, packaging, analysers and other laboratory equipment and consumables) and manufacturing processes (manufacturing equipment, filtration membranes, tubing…).

These applications depend on the same technological ecosystems and on the same supply chains as the human IVD and Medical devices sectors.

Unlike the human IVD/MD sector, which is regulated at EU level, the regulatory framework for animal health diagnostics in the EU is mainly defined at country level with no product authorization harmonization (requirements and authorization procedures must be repeated separately for each national animal health program), with products requiring long design/validation/approval timelines. In addition to national requirements for marketing approval, an overlay of international and national norms, standards, and certifications (WOAH, ISO, AFNOR, GMP…) is also applying. Food safety and environmental testing is mainly reliant on validation against reference methods.

The veterinary, food and environmental diagnostics industry is likely to be significantly impacted if the manufacturing and supply of certain parts were to be restricted within short timelines, thereby severely impacting the availability of important technology to animal health, food and feed and environmental monitoring professionals.

D4A members support the EU transition toward less hazardous chemicals and are actively mapping their product lines to identify PFAS sources, however the PFAS stakeholder consultation and public consultation timelines have not provided sufficient time to smaller stakeholders to complete thorough impact assessments. The risk of un-intended consequences to essential niche industries is real if necessary adjustments are not considered.

Our comments are meant to improve the proposed derogation for ‘Diagnostic laboratory testing’ (article 5.n.) and support a practical transition to PFAS alternatives, without compromising the availability of essential diagnostic solutions for animal health, food safety and environmental compliance.

IV. Comments to the ECHA public consultation on the Restriction of PFAS:

1. The definition of 'diagnostic laboratory testing' under derogation 5.n. and in notes under Annex A remains unclear:

1.1. No definition is proposed for 'diagnostic laboratory testing' (paragraph 5.n. derogation).

1.1.1. Annex A explanatory notes and other proposed derogations suggest that 'diagnostic laboratory testing' includes IVD reagents and tests but may exclude laboratory apparatus/ equipment and their accessories[4].

- Annex A describes 'Diagnostic laboratory testing' as a sub-category of 'Medical devices' according to EU Regulation 2017/745 and is separate from 'Electronic equipment'.
- The 'Electronic equipment' sub-category covers a very narrow range of apparatus specialized in high performance refrigeration/refrigerated equipment, and which are essentially 'accessories' in contrast to main laboratory analysers and other appliances used to prepare samples.

- All other essential laboratory equipment would otherwise default under the standard 18-month transition period.

However, in Annex E (Impact Assessment), the section on 'Diagnostic laboratory testing' mentions general use laboratory equipment namely and concludes that there is no good alternatives available[5].

1.1.2. Anchoring the 'Diagnostic laboratory testing' concept on existing definitions with a wider scope:

The introduction of a 'Diagnostic laboratory testing' concept goes in the right direction and should be based as far as possible on established concepts or categories while opening their use scope to the broad diagnostic eco-system which is essential for human and animal health, food safety, environmental monitoring…

Standard 'Diagnostic laboratory testing' environment includes 5 principal product groups:

1. Test devices and reagents (stand alone or in combination with dedicated or generic laboratory analysers): eg, ELISA, Agglutination, Lateral Flow, PCR, sequencing, magnetic bead-based assays, microfluidic devices, tests on a chip, sample extraction reagents…
2. Laboratory analysers for hematology, biochemistry, immuno-chemistry and other biomarkers, PCR amplification devices, chromatography systems…
3. Laboratory measuring devices: spectrophotometers, dispensing systems, cell counters, calibration devices…
4. Laboratory tools and accessories: centrifuges, vortexes and mixers, incubators & baths, cryostats, autoclaves, purification systems, filtration systems...
5. Calibration and reference materials (covered under derogation 5.t.)
6. <u>And their respective consumables</u>

These categories can be directly connected to existing definitions under the Medical Devices (EU 2017/745) and In vitro diagnostic Medical device (EU 2017/746) Regulation[6]. It is possible to include definitions in the restriction proposal, by analogy, covering the veterinary, food and environment contexts.

We propose to adopt and introduce these well-established definitions within a broader scope.

An appropriate scope should include the following applications:

- **Human health**
- **Animal health**
- **Food Safety and Quality**
- **Environmental Compliance testing**
- **R&D activities in the context of the above applications**

And ensures that all product categories necessary to deliver 'diagnostic laboratory testing' results are covered under this concept and remain subject to the same regulatory requirements and timelines.

2. Derogation timeline for 'Diagnostic laboratory testing'

2.1. The proposed paragraph 5 derogations lack a provision to allow asking for a renewal or extension of the transition periods.

D4A welcomes the longer derogation period granted to Diagnostic Laboratory Testing, however the restriction report does not offer any substantiated scenario for this timeline and cannot capture all possible situation where longer timelines are necessary.

2.1.1. Although the dossier submitters have recognized that some applications have no available alternatives at this time, they did not recognize that the transition timelines necessarily need to be differentiated.

As noted in Annex E.2.9.4.8. Diagnostic laboratory testing, '*In the assessment of alternatives above we concluded that there is sufficiently strong evidence that alternatives to PFAS are not generally available in this field of applications'.*

2.1.2. Complex diagnostic platforms rely on the combination of multiple materials and sub-systems belonging to different manufacturing industries with incompatible transition periods.

The animal health, food safety and environmental compliance diagnostic sector has limited expertise on PFAS compound direct formulation or alternatives: direct formulation with PFAS compounds is limited to surface assay coating, with all other PFAS containing articles obtained from off the shelf third party manufacturers. It is therefore not in a position to drive independent complex substitution studies in the highly specialized electronic/electrical component or in the plastic manufacturing

domains for instance and will depend on timelines followed by larger industries or upstream sectors before it can move on along its own compliance path.

For other common articles and parts which are not known to be intentionally formulated with PFAS, but which may contain PFAS compound residues, systematic testing is not a viable solution due to the limited number of validated methods and of individual compounds which may be identified. Cost can run in the 1.000€+ per analysis depending on sample type and using an accredited laboratory: extrapolated to a simple in vitro analyser that may contains 500 hundred parts, full analysis may cost up to 0.5 Million €. For more complex platforms that may contains several thousand parts, cost would be economically non sustainable.

Sensible due diligence approach will target products considered at risk based on functionality and known material characteristics shared by suppliers[7]. For materials and products not suspected of containing PFAS compounds, operators may only react once PFAS verdicts are passed through supply chains, which may in turn delay substitution efforts.

Sectorial timelines will not follow parallel or straight routes but will cumulate and experience bottlenecks along complex supply chain compliance roadmaps.

2.1.3. Some diagnostic platforms have very long product cycles and will remain in service for up to 15/20 years: current transition timelines would drive early obsolescence and increase waste.

Enabling servicing and refurbishing capital equipment is essential to reduce waste and preserve resources and spare parts [or recovered parts] must remain available at least 20+ years after the transition period have ended.

It is therefore essential to consider introducing a mechanism to grant additional time beyond the 13.5 where necessary and to guarantee a grand-fathering clause with no time limit for spare parts to avoid causing early obsolescence and new waste.

V. Our recommendations:

- **Adding to paragraph 5 a provision to allow individual entities apply for a derogation renewal or an extended transition period**
- **Adding to paragraph 5 a derogation for spare parts and recovered parts used for the purpose of servicing or refurbishing electrical and electronic equipment (EEE definition) with no time limit.**

D4A supports the position published by the PFF4EU group in its paper dated April 2023. (https://www.fpp4eu.eu/library/position-paper-on-universal-pfas-restriction-proposal/)

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Transparency Register number: 113925414746-95

[1] REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products

[2] Commission Delegated Regulation (EU) 2022/1644 of 7 July 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific requirements for the performance of official controls on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof (Text with EEA relevance)

[3] https://environment.ec.europa.eu/law-and-governance/compliance-assurance_en

[4] Restriction report, Explanatory notes 5n)
The derogation for diagnostic laboratory testing includes precision refrigeration (blood bank refrigerator, vaccine storage), ultra-low temperature freezers or cryogenic storage, refrigerated centrifuges for sample separation, process chillers for precise temperature control and freeze-drying equipment. Use in in-vitro diagnostic devices is also covered. Additional information on uses of PFASs in the relevant applications can be found in Table A.103. in Appendix A.3.10.

Annex A, A.3.10. Medical devices :

Main medical devices containing PFAS are listed below. Each mentioned sub-use will be discussed in more detail in the section below.

- *Fluorinated meshes and wound treatment;*
- *Medical textiles;*
- *Medical implants;*
- *Tubes and catheters;*
- *Coatings;*
- *Cleaning and heat transfer: engineered fluids;*
- *Sterilization gases;*
- *Packaging;*
- ***Electronic equipment;***
- ***Diagnostic laboratory testing;***
- *Metered Dose Inhalers (MDI);*
- *Others.*

A.3.10.1.8. Electronic equipment
Although electronics is a separate use section, it should be noted that numerous electric medical devices such as scanners, screens etc. qualify as electronic devices. In electronics, PFAS is mainly applied in cables and wires, printed circuit boards and in (LCD) screens. See for more details the Electronics and Energy section A.3.12.

A.3.10.1.9. Diagnostic laboratory testing
Examples where PFASs are used in laboratory equipment include precision refrigeration (blood bank refrigerator, vaccine storage), ultra-low temperature freezers or cryogenic storage, refrigerated centrifuges for sample separation, process chillers for precise temperature control and freeze-drying equipment. PFASs are

also used in in vitro diagnostic devices. See Table A.101 in the appendix for additional information on main applications in this area.

[5] ***Annex E.2.9.4.8. Diagnostic laboratory testing***

> *In the assessment of alternatives above we concluded that there is sufficiently strong evidence that alternatives to PFAS are not generally available in this field of applications. The Dossier Submitters note that a ban on PFAS could have substantial impacts on the feasibility of diagnostic laboratory testing, which in turn would have severe implications on public health. The Dossier Submitters conclude that there is [sufficiently strong evidence] that a ban of the use of PFAS in diagnostic laboratory equipment is [likely] to have considerable impacts on public health and that it would lead to [high socioeconomic costs]. Furthermore, the Dossier Submitters note that the second stakeholder consultation indicated that the complete process from identification of alternative to approved product takes at least 5-10 years in this sector. This indicates that a relatively long derogation period is required to avoid these costs.*

[6] Medical Devices (EU 2017/745) and In vitro diagnostic Medical device (EU 2017/746) Regulation definitions:

- Medical device:
  - *Article 2* **Definitions** For the purposes of this Regulation, the following definitions apply:
    (1) 'medical device' means any **instrument, apparatus, appliance**, implant, **reagent, material or other article intended by the manufacturer to be used, alone or in combination**, for human beings for one or more of the following specific medical purposes:
    — **diagnosis**, prevention, monitoring, prediction, prognosis, treatment or alleviation **of disease**,
    — **diagnosis, monitoring,** treatment, alleviation of, or **compensation for, an injury or disability**,
    — investigation, replacement or modification **of the anatomy or of a physiological or pathological process or state,**
    — **providing information by means of *in vitro* examination of specimens** derived from the human body, including organ, blood and tissue donations

- In vitro diagnostic medical device
  - *Article 2* **Definitions** For the purposes of this Regulation, the following definitions apply:
    2) '*in vitro* diagnostic medical device' means any medical device which **is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment**, or system, **whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations**, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:
    (a) concerning a physiological or pathological process or state;
    (b) concerning congenital physical or mental impairments;
    (c) concerning the predisposition to a medical condition or a disease;
    (d) to determine the safety and compatibility with potential recipients;
    (e) to predict treatment response or reactions;
    (f) to define or monitoring therapeutic measures.
    Specimen receptacles shall also be deemed to be *in vitro* diagnostic medical devices;

- Accessory for an [in vitro diagnostic] medical device

- 2 (4) 'accessory for an *in vitro* diagnostic medical device' **means an article which, whilst not being itself an *in vitro* diagnostic medical device, is intended by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically enable the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the *in vitro* diagnostic medical device(s) in terms of its/their intended purpose(s)**;

[7] Check Your Tech, A guide to PFAS in electronics (https://chemsec.org/app/uploads/2023/04/Check-your-Tech_230420.pdf)