

Paris, January 30th, 2017

**Proposed Regulation on *In Vitro* Diagnostic medical devices
Request for introduction of an amendment for veterinary *In Vitro* Diagnostic
devices.**

Members of the European Parliament, Your Excellences, Vice-Presidents and Commissioners,

Please consider our request to incorporate one important modification in the political agreement reached on the Proposed Regulation on In Vitro Diagnostic (“IVD”) medical devices for humans¹. We are taking the exceptional measure of contacting you because it has only very recently become apparent that certain EU laws have an inadvertent negative impact on the veterinary sector. These laws unwittingly undermine key European control programs for veterinary diseases² and the free movement of veterinary IVDs.

Our organisation represents European Manufacturers of Veterinary Diagnostics, which represents 90% of the global animal health diagnostic market. Veterinary only IVDs, such as those used in national control programs, are formulated to be sterile for maximum effectiveness in detecting diseases to protect humans from zoonotic diseases, to safeguard the food supply, to support trade, to improve animal health, welfare and productivity, and to contain livestock disease outbreaks - and therefore must have secure access to necessary biocides.

However, the use of a large number of biocidal products in the EU is currently prohibited by the Biocidal Products Regulation (“BPR”)³. This is because the active substances in the biocidal products have not been included in the EU review program⁴, which is one condition of EU market access. The same problem does not exist for In Vitro Diagnostic medical devices for humans, as explained below.

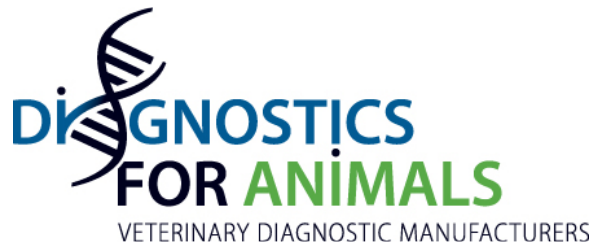
In contrast, human in Vitro Diagnostic medical devices are expressly excluded from the scope of the BPR by its Article 2(2)(b) but veterinary IVDs have been overlooked. We ask for your urgent support for the introduction of an amendment to *the Proposal for a Regulation of the*

¹ Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices: Interinstitutional File: 2012/0267 (CtOD).

² See, for example: https://ec.europa.eu/food/animals_en.

³ [Regulation \(EU\) No 528/2012](#) concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market.

⁴ [Commission Delegated Regulation \(EU\) No 1062/2014](#) of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.



European Parliament and of the Council on in vitro diagnostic medical devices to also clearly exclude veterinary IVDs from the scope of the BPR.

This situation risks that currently available veterinary diagnostic kits may no longer be available to detect, diagnose and monitor diseases to protect food supplies and prevent disease outbreaks. Control programs for diseases such as, but not limited to, transmissible spongiform encephalopathy (TSE), Bovine Tuberculosis, Foot and Mouth Disease⁵, West Nile Fever, Blue Tongue, and Avian Influenza rely on diagnostic kits that contain biocides subject to the BPR.

Veterinary products are subject to strict regulations at a national level in Member States.⁶ The use of biocides in both human and veterinary IVDs is no different. Our proposed amendment simply corrects the accidental omission of an equivalent exclusion from scope of the BPR for veterinary IVDs. Indeed, many of the identical IVDs for humans are also used in the veterinary context.

Thus, we suggest that the *Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices* be amended as follows; Article 3(2) on “Regulatory status of products” could insert the following underlined bold text:

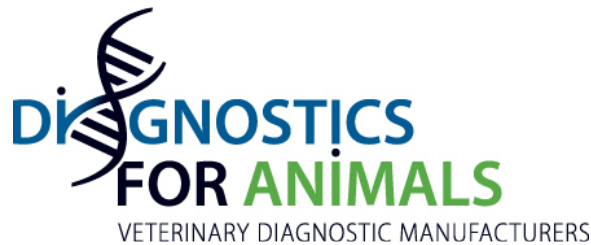
The Commission shall ensure the sharing of expertise between Member States, in the fields of in vitro diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.
Regulation (EC) No 528/2012 concerning the making available on the market and use of biocidal products shall not apply to biocidal products used in an in vitro diagnostic medical device, where the devices are lawfully marketed in the EU only or also for veterinary purposes (including for research and development).

This will have the effect of permitting our industry to continue the uninterrupted supply of our current diagnostic kits (treated with biocidal products) used under control programs throughout Europe.

If there is no amendment to the law to prevent this unintended consequence Member States may be deprived of crucial tools for ensuring public health and food safety. Significant time and resources would be required to assess and comply with the BPR. This could result in the requirement for new formulations of existing products (which is not a short term solution), additional evaluation and approval of these modified products, and perhaps less effective reformulations of the existing products. We have reason to believe that upstream suppliers to

⁵ For example, the OIE-World Organisation for Animal Health, [describes Foot and Mouth disease as](#) “One of the most contagious animal diseases, with important economic losses”.

⁶ Member States with veterinary registration requirements and batch release testing include Germany, France, Netherlands, Belgium, Bulgaria, Czech Republic, Poland, Spain, Portugal, Romania and Slovakia.



the veterinary In Vitro Diagnostic devices sector will cease to support what is, for them, a niche market because of the significant additional costs potentially created by the uncertainties surrounding the BPR.

In the interest of transparency, I should inform you that our outreach to you and the content of the proposed amendment has been undertaken in full consultation with MedTech Europe - the European trade association representing the vitro diagnostic industry for human medical uses.

The attached appendix provides further explanation of the current regulatory situation facing veterinary IVDs. We would be happy to provide any further background which you might require and would welcome the opportunity to meet with you in the coming days to discuss these issues in person.

With the addition of one amendment, the Proposed Regulation provides an opportunity to remedy this accidental harm.

Thank you, in advance, for your time and consideration.

Jean-Louis HUNAUT

General Secretary



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Appendix:

THE SEVERE REGULATORY SITUATION FACING VETERINARY IVDs.

Veterinary In Vitro Diagnostic devices have been overlooked

1. In Vitro Diagnostic medical devices (for humans) and veterinary In Vitro Diagnostic devices (for animals) both contain biocidal products. In both cases, the biocidal products protect the IVD's reagents – these essential mixtures are used to produce a chemical reaction that allows researchers to detect the presence of other animal (or human) diseases.
2. Whilst In Vitro Diagnostic devices are not *“biocidal products”*⁷ in themselves, the BPR also regulates the placing on the market of *“treated articles that are not biocidal products”*⁸ i.e. the where the article which has been *“treated with, or intentionally incorporates, one or more biocidal products”*⁹ does not have a primary biocidal function - as is the case for IVDs.
3. Thus, treated articles may only be placed on the market if, *“...all active substances contained in the biocidal products that it was treated with or incorporates are included in the list”* of active substances (i) under the EU review programme for the systematic examination of all existing active substances contained in biocidal products (*“EU Review Programme”*)¹⁰ or (ii) already included in a Union list of approved active substances.

⁷ A biocidal product is defined in Article 3(1)(a) of the BPR as, inter alia, as: *“...any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action...”*

...

A treated article that has a primary biocidal function shall be considered a biocidal product.”

⁸ Article 58(1), BPR.

⁹ Article 3(1)(l), BPR.

¹⁰ [Commission Delegated Regulation \(EU\) No 1062/2014](#) of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council

4. The EU legislator identified the need to exempt In Vitro Diagnostic medical devices (for humans) from the abovementioned requirements of the BPR. This clear exemption is contained in Article 2(2)(b) of the BPR¹¹. However, the same cross-reference to veterinary In Vitro Diagnostic devices is missing. This means that veterinary IVDs which are treated articles fall within the scope of the BPR.
5. The amendment we are asking you to incorporate within the political agreement reached between the Council, Parliament and Commission would place veterinary and medical IVDs in the same position – ensuring both are exempt from the BPR. This makes sense since the use of biocides in both human and veterinary IVDs is no different and many of the identical IVDs for humans are also used in the veterinary context.

Very short window before the BPR applies to veterinary IVDs

6. The BPR's rules on treated articles are new. They provide for a transition period which expires on 1 March 2017.¹² After that date, there is a risk that those veterinary IVDs which are treated articles containing active substances which are not included in the EU review programme, will no longer be able to be placed lawfully on the market.
7. We are very grateful that DG SANTE has recognised this imminent problem, and that its “pesticides and biocides” unit has helpfully sought a work around solution, as follows: The European Chemicals Agency (ECHA) would publishing an “open invitation”, which would allow interested companies to submit dossiers for the biocidal active substance/product type combinations which would need supporting for use in veterinary IVDs, because of the absence of an exemption from the BPR (in contrast with the situation for In Vitro Diagnostic medical devices for humans).

¹¹ Art. 2(2)(b) BPR, provides: “Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments:… (b) Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC;”

¹² Article 94(2), BPR.

8. This well established approach¹³ has been used in other situations where the person placing the product on the market has relied on guidance which gave reason to believe it did not need to participate in the EU review programme¹⁴. In this instance the guidance was first established in 2002 on “*preservation of biochemical reagents*”¹⁵.
9. However, this very welcome approach by DG SANTE to try to find a compliance solution has important limitations as regards timing: Companies which submit a “declaration of interest to notify”¹⁶ under the above-mentioned procedure are not automatically included in the EU review program. Time would be given for them (and potentially other interested companies) to submit a dossier – the completeness of which would have to be evaluated ¹⁷ Interested companies have twelve months to make a notification of essential data regarding the substance, starting only from repeal of the former guidance. Once a notification is declared compliant (i.e. valid) by ECHA, a participant has two years to submit an application. Our current understanding is that despite DG SANTE’s welcome efforts there is no clear way for companies manufacturing and marketing veterinary IVDs to be sure of their BPR compliance by 1 March 2017. These uncertainties act as a serious disincentive to participating in this market and therefore to providing essential animal health solutions. Indeed, it remains unclear whether upstream suppliers to the veterinary In Vitro Diagnostic devices sector, will invest in supporting what is, for them, a niche market because of the significant additional costs created by having to support biocidal active substances through the EU review programme. Moreover, reformulation is not a short term solution. Eliminating the use of certain biocides may require 3 to 5 years of redevelopment and successful performance of the reformulated products is not ensured nor is their acceptance by responsible authorities. Hence, the urgency of our request.

¹³ <https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance/notification-procedure>

¹⁴ Article 15(a) of Commission Delegated Regulation (EU) No 1062/2014 provides this procedure is applicable where: “*guidance published by, or written advice received from, the Commission or a competent authority...where that guidance or advice gave objectively justified reasons to believe that the product was excluded from the scope of Directive 98/8/EC or of Regulation (EU) No 528/2012, or that the relevant product-type was one for which the active substance had been notified and where that guidance or advice is subsequently reviewed in a decision adopted pursuant to Article 3(3) of Regulation (EU) No 528/2012 or in new, authoritative guidance published by the Commission*”.

¹⁵ [Doc-Biocides-2002/06-Rev2, 12.12.2005](#), “*Guidance document agreed between the Commission services and the competent authorities of Member States for the Biocidal Products Directive 98/8/EC*”, section 3.

¹⁶ Article 16, [Commission Delegated Regulation \(EU\) No 1062/2014](#) of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.

¹⁷ [Commission Delegated Regulation \(EU\) No 1062/2014](#) of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.

10. The absence of a full compliance solution by 1 March 2017 means that the use of identical biocides in human and veterinary IVDs, are treated differently. This results in unnecessary BPR requirements being applied, which is neither coherent nor proportionate. Indeed, that negative impact undermines the EU's ability to protect humans and to contain livestock disease outbreaks. There is no evidence to suggest that the use of biocides in veterinary IVD products poses any greater risk to human and animal health and the environment than human IVD products, yet the additional regulatory layer of BPR creates a significant and counter-productive impact on human and animal health and welfare.

Jean-Louis HUNAUULT

General Secretary

