Object: Diagnostics and Biocides

Dear Madam, Sir,

We are contacting you today to draw your attention to the negative impact of the implementation of

the biocides regulation on the marketing of veterinary diagnostic tests and their availability. This

point will be discussed at the next CVO meeting on March 24th.

Veterinary diagnostic products contain biocides for their preservation and meet the definition of

"treated article" in European Regulation (UE) n° 528/2012 (RPB) (\* Article 3). This regulation requires

that the "treated articles" only use biocidal substances approved at European level.

Veterinary diagnostic products are not exempted from the BPR regulation (unlike animal feed,

human medicines, veterinary medicinal products, in vitro diagnostic medical devices IVDs.)

Veterinary diagnostic tests incorporating a biocide which has not been the subject of an application

for approval by 1 September 2016 may no longer be placed on the market. (\*\* Article 94 on

transitional measures). As a result, many diagnostic tests, which are now essential for monitoring the

health status of livestock, could disappear from the market in the short term if no action is taken.

At present, only one substance used in veterinary diagnostic products is approved (the exemption attributed to the largest part of the human IVD market is one of the causes of the lack of interest to have more substances submitted for approval). Some substances submitted are still under review, and their status is unknown for several months or even years.

We ask you to consider the complicated situation faced by veterinary diagnostic manufacturers. The BPR exempts products that are regulated under other EU Directives.  Because human pharmaceutical and diagnostic products and veterinary pharmaceutical and vaccine products are regulated under other EU Directives, products falling under these categories are exempt from the BPR. Biocides used in Veterinary Diagnostics are identical to those used in the Human IVDs and at similar concentrations.  They are safe for the animal or food consumer because it is an in vitro test and its use is limited to the laboratory.

The substitution of a biocidal product will lead to delays in the availability of the reagent and in some

cases the early withdrawal of certain products which are not in compliance, thus causing problems in

the availability of the diagnostic arsenal and the fight against animal diseases.

We are at your disposal to study all solutions to secure the marketing of our products.

Thank You,

The members of Diagnostics for Animals