Belgian
Biosafety
Professionals

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Position of the Belgian Biosafety Professionals (BBP) on the draft royal decree (RD) on animal by-products (ABP)

Reply to the draft RD kindly transmitted by Quentin Dumont de Chassart to René Custers on April 10, 2015

The royal decree aims to regulate the use of ABP for diagnosis, research, education or artistic installations.

The modalities for the use of ABP for diagnosis, research and education purposes are described in Chapter III of the draft RD. Art. 19, §2 mentions that for educational institutions the use of certain ABP is authorized without prior notification to the DG, which is highly appreciated. However, we are wondering whether this exemption only applies to educational activities with ABP or whether it also targets research activities within the educational institutions (academic research). If so, why is the exemption only made for educational institutions and not for activities with ABP for research at non-educational institutions?

Moreover, it is less clear to us how ABP in industrial production, such as in biotechnological and biopharmaceutical companies, are to be interpreted within the scope of the draft RD. Indeed, the use of ABP in industrial production is not included in possible user(s') activities listed in the article 17 of the European regulation CE n° 1069/2009. More precisely, we wonder if ABP commonly used and/or produced by companies, such as animal sera and antibodies, are seen as "products commercialized for technical use" (article 36 in the European regulation CE n° 1069/2009)? In this case, can these companies be regarded as research laboratories? Given the fact that within these biotechnological and biopharmaceutical companies also considerable research activities are performed, and educational institutions also perform a lot of research, in our opinion, it would be more convenient to distinguish between activities for research and educational purposes vs. activities for commercial purposes. In this way, it would be clearer for the end-user to know what is applicable for that type of activity.

We would also appreciate your feedback on the status of and permit/notification requirements for (research) institutes working with, euthanizing and subsequently decontaminating experimental animals by sterilization under pressure or alkaline hydrolysis.
It is unclear to us whether these institutes just fall under the scope of the sections referring to the use of ABP for research without the need of an agreement, as described in the draft decree,

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or whether they are processors of ABP and subsequently need to be recognized as a processing plant.

Art. 11 of the draft RD describes that when receiving ABPs, each time a notification needs to be done to the DG with a copy of the invoice, acknowledging receipt of the material with a signature, and this within 2 working days following receipt of the material. This creates a high administrative burden for the users of ABPs and we are wondering what the grounds are for this requirement, especially in view of the time period before receiving invoices (generally superior to 2 working days). Would it not be sufficient to indicate to the DG which types of materials are going to be received when notifying to the DG in order to obtain the registration?

Art. 16 of the draft RD describes that the packaging of samples for research and diagnosis should be such that any risk for spreading of disease in humans or animals is avoided. In our opinion, this should also apply for any ABP for educational or artistic activities.

We also think that Art. 18 of the draft decree creates an ambiguity. Indeed, it specifies that veterinarians are allowed to send ABP samples to a diagnosis laboratory registered in Belgium. However, if we have well understood, diagnosis laboratories are exempt of official approval ("Agrément/Erkenningen") from the DG. Consequently, we wonder about the feasibility of this legal measure (how will it be possible to send samples to a non-registered institution?)

Finally, in Art. 19 § 2, regarding the sporadic use (only applicable for CAT1 & 2 material) of large quantities of ABP (> 20 Kg, only for CAT3), it is not clear whether the temporary permit should be asked every time, or if it will be delivered for a given period of time. We are also wondering about the meaning of 'sporadic' (a short period over a one year period with multiple uses or a few separate activities per year, such as once a month?). Moreover, the fact to consider sporadic use and large quantities of CAT3 material in the same sentence is a little bit confusing. Finally, this article is only about sporadic use in educational research and we wonder why it is not applicable to non-commercial research activities in any other facilities (including those of private companies). A distinction based on the activity would be clearer for the end-user than the current approach of the draft, which considers the finality of the user i.e. education *vs.* commercial production.