version 2, June 2018

EBSA Position Paper
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Consequences of the EU legislation on Animal By-Products for the scientific research sector

1. Introduction

Animal by-products (ABPs) are materials of animal origin that are not intended for human consumption. An EU regulatory framework exist for the handling of such ABPs. It consists of EU Regulations 1069/2009 and 142/2011. The EU legislation on ABPs and derived products has been set up after the BSE crisis that hit Europe at the turn of the millennium. As a measure to protect human and animal health, one of the most important measures taken was that it was no longer permitted to mix bone meal into animal feed. The legislation makes a distinction between three categories of ABPs:

Category 1: high risk material, primarily for disposal
Category 2: moderate risk material, not suitable for animal consumption and
Category 3: low risk material, suitable for animal consumption.

For each category, different collection, processing and destruction measures apply, in line with the risk they present.

2. Consequences of the EU legislation on Animal By-Products for the scientific research sector

The EU regulatory framework on ABPs was primarily set up from the perspective of the food sector. It has not fully taken into count the perspective of the scientific research sector, that also uses ABPs (e.g. experimental animals, serum, albumin) for different purposes, such as for diagnostics, biomedical and veterinary research. The scientific research sector is distinctly separate from the food production sector. In contrast to the food sector, ABPs are being used in a one-way direction. This means that the ABP materials are destroyed after use. They are inactivated to eliminate all (biological) risks and subsequently discarded in line with the contained use legislation. Re-introduction into the environment, including the food chain, is thus excluded. Still, the ABP legislation may require measures that either conflict or overlap with the contained use legislation. Representative examples are listed below.

Serum

Research organizations use bovine serum or calf serum routinely in cell culture media. As media that are removed during maintenance and cultivation of cells may still present certain biological risks (e.g. cells, pathogens), it is inactivated in a validated manner, for example using a chemical disinfectant, before being discarded. Consequently, serum components are destroyed. Unfortunately, such serum, including commercially manufactured serum

products, are regarded as ABP and therefore require an authorization to work with such serum and trigger the obligation to obtain import permits and keep track of the disposal of the serum after use. Even for the import of very small amounts of serum, as is the case with the import of a 1ml tube containing a frozen vertebrate cell line, such administrative obligations apply.

Cell cultures
Primary and established animal cell cultures are being used in the research sector extensively. Even though these cells stem from animals, they are not seen as ABPs because they are still living entities. After use they will either be killed or die off spontaneously. One would expect that these cells then *de-facto* become ABPs, however, this is not clear in the legislation. Consequently, it is not clear what requirements are triggered for disposal or whether they are in line with the risk of the cells (see above for serum).

Small rodents
Small rodents are frequently used to study basic molecular mechanisms and diseases. Such animals are housed in dedicated animal facilities. Housing systems include cages to contain the animals, their bedding and their food/water. All animal remainders and associated materials (e.g. bedding with feces and urine) are considered ABPs. However, as animals and related materials may still present certain biological risks (e.g. allergens, pathogens), they are inactivated in a validated manner, for example using a chemical disinfectant or autoclave, safely removed as 'hazardous medical waste' (in case of infectious material) for incineration or safely removed as industrial residual waste by incineration. Again, they never re-enter the environment such as manure from farm animals would do, and the cadavers also never re-enter the food chain. Despite the material being discarded in a controlled manner, completely preventing re-introduction into the food-chain, researchers are required to fulfill certain requirements of the ABP legislation that are, again, not proportional to the risk of the material.

Large (agricultural) animals
Large (agricultural) animals are also used in research. In most cases, such animals are euthanized at the end of the study. When pathogens are involved in the studies, the contained use legislation requires inactivation, that needs to be performed on site when using high risk pathogens. The mode of inactivation is not specified in the contained use legislation, but the method needs to be validated and the removal of the inactivated materials needs to be done by an approved destructor. The risk-based choice for a validated technique allows flexibility for the user, taking the material and location of the facilities into account.
In contrast, the ABP legislation permits only a limited number of techniques that can be used for destruction of ABPs from such animal experiments. The choice of techniques is largely driven by legislation and not by validation. For example, the recently introduced technique of alkaline hydrolysis, which has proven to be efficient and environmentally friendly, is allowed by the contained use legislation, but not by the ABP legislation, as it is only included as a processing but not as a final destruction technique. As alkaline hydrolysis is not included as a final destruction technique, the inactivated end products of alkaline hydrolysis still must be incinerated. This is a waste of resources as from a scientific point of view there is no need to inactivate a product that already has been inactivated.
Additionally, the final disposal techniques currently described in the ABP legislation are difficult to implement for most research organizations. For example, pressure sterilization is difficult to perform on large and heterogeneous volumes, such as animal carcasses. Incineration on the other hand triggers a tremendous number of administrative obligations and a dedicated environmental permit which is not possible at all locations.

Insects

Because the ABP legislation applies to 'animals' in general, without any further delineation, it also applies to insects. Insects are e.g. used to study certain types of diseases or development of the nervous system (fruit flies (*Drosophila melanogaster*)). Based on a thorough risk analysis, it is difficult to see how research activities involving such insects would create a risk for the animal or human food chain. Moreover, insects used for research purposes are being killed after use and discarded as residual industrial waste, without any chance of re-entering the food chain.

3. The possibility to have derogations for research

Regulation 1069/2009 does provide the possibility for competent authorities to authorize, by way of derogation from articles 12, 13 and 14 of this regulation, the use of ABPs and derived products for research purposes under conditions which ensure the control of risks to public and animal health (article 17 of the Regulation). In practice, however, there are no competent authorities that truly make use of this derogation possibility for research activities. Even though there are good reasons to do so, because most of the requirements for ABPs, such as import permits, certain administrative requirements and the descriptive requirements for inactivation and disposal, can be lifted without compromising public and animal health. Other regulatory frameworks already ensure safety.

EBSA would welcome competent authorities to make use of the derogation possibility for research via article 17 of the Regulation. But because this is a derogation possibility that competent authorities can make use of freely, there is a genuine risk of creating differences between countries. Instead of individual competent authorities making use of this possibility, EBSA would therefore be in favor of introducing derogations for research in the Regulation itself.

4. A more proportionate approach

The ABP legislation is frequently conflicting or overlapping with other regulatory frameworks that ensure the protection of human and animal health and the environment, and on top of that the ABP legislation also has significant administrative consequences as well as consequences on the use and disposal of ABPs. As already illustrated in the examples above, research organizations using ABPs need to be registered with the national competent authorities, are required to have import/export permits for several materials, maintain logs, and are confronted with complex waste handling issues not proportional to the remaining risk of the materials. For many people in research organizations the consequences of the ABP legislation on their activities are difficult to fully grasp.

It is acknowledged that the overall aim of the ABP legislation is genuine and serves to protect human and animal health from the use of ABPs that are not intended for human consumption. This especially means that measures need to be in place to prevent that hazardous ABPs could (re-)enter the food and/or feed chain. However, such measures are provided for ABPs used in scientific research by other regulatory frameworks, such as the contained use legislation. Risk management measurements implemented and overseen by the biosafety professional, the health professional and the environmental coordinator, ensure safe handling of materials. Consequently, the measures imposed by the ABP legislation for such ABPs are frequently disproportional to the remaining risks. To work towards a risk-based approach in the ABP legislation, EBSA recommends to:

a. Recognize that in the scientific research sector there is a very low risk that hazardous ABPs would (re-)enter the environment, and especially the food and feed chain.
b. Acknowledge the biosafety measures, driven by other regulatory frameworks, that are already in place in the scientific research sector for all biological materials that they use.

c. Subsequently create a derogation in the Regulation for the use of ABPs for research purposes, thereby:
    1) simplifying the import and administrative requirements for the use of ABPs in research,
    2) broadening the allowed means of inactivation/disposal to include any type of physical, thermal, chemical or biological means on the condition that the method is fit for purpose and has been validated, and
    3) avoiding overlap in the different applicable legislations leading to situations where inactivated material must be inactivated again.

European Biosafety Association (EBSA) unites biosafety professionals from 24 countries in Europe, as well as other regions. EBSA establishes and communicates best biosafety and biosecurity practices amongst its members and encourages dialogue and discussions on developing issues. EBSA represents and defends the collective interests of its members in all areas relating to biosafety and biosecurity.

EBSA
Kerkstraat 108
9050 Gentbrugge, Belgium
T: +32 9 233 48 66
W: www.ebsaweb.eu
E: ebsa-office@ebsaweb.eu
VAT: BE 0475.189.538