The Animal By-Products legislation; complex legal requirements that sometimes collide with established contained use regimes

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The ABP legislation

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, it is for instance 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, for instance a tissue sample of a TSE affected animal
Category 2: moderate risk material, not suitable for animal consumption, for instance manure from mice from an experimental facility
Category 3: low risk material, suitable for animal consumption, for instance bovine serum for use in cell culture

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

The R&D sector presents a very low risk

A primary objective of the ABP legislation is to prevent hazardous animal-derived biological materials re-entering the food or feed chain. But the risks of such materials re-entering the food or feed chain from the R&D sector is extremely low, as this sector already applies appropriate procedures for the inactivation and disposal of animal-derived biological materials. At the end of the R&D proces animal-derived biological materials are treated as true waste, and not as material with additional use potential in food or feed.

Cell cultures and serum

Cell cultures themselves are not ABPs, as these cells are considered living material. But the medium of such cell cultures in most cases contains bovine serum which is an ABP. As a consequence it is necessary to have an authorization to work with such ABPs, 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.

Small rodents

Small rodents are frequently used in R&D to study basic molecular mechanisms and diseases. All animal remainders and associated materials (e.g. bedding with feces and urine) are considered ABPs. Despite the material being discarded in a controlled manner, thus preventing re-introduction into the food chain, researchers are required to fulfill certain requirements of the ABP legislation that are not proportional to the risk of the material.

The ABP and contained use legislation have sometimes differenct approaches for the same thing

ABP legislation	Contained use legislation
Registration required for use of ABPs in R&D	Authorization request or nofication procedure
Administrative requirements for keeping track of the material until disposal	Less strict traceability requirements
Import permits	No import permits
Very limited amount of accepted methods of inactivation	Inactivation by any validated physical, chemical or biological means
Waste handlers and disposal firms need to be registered	No specific requirements for waste handlers and disposal firms

"The R&D sector has not been very well considered when the ABP legislation was set up."

Recommendations to regulatory authorities

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 simplify the import and administrative requirements for commonly used ABPs in research that do not or no longer present a hazard for re-entering into the food or feed chain.
d. Broaden 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.
e. Avoid overlap in the different applicable legislations leading to situations where inactivated material must be inactivated again

An EBSA position paper on ABPs

The work presented is the result of efforts of the EBSA project team on ABPs which has developed an EBSA position paper on ABPs. This position paper is available on the EBSA website.

www.ebsaweb.eu/position-papers