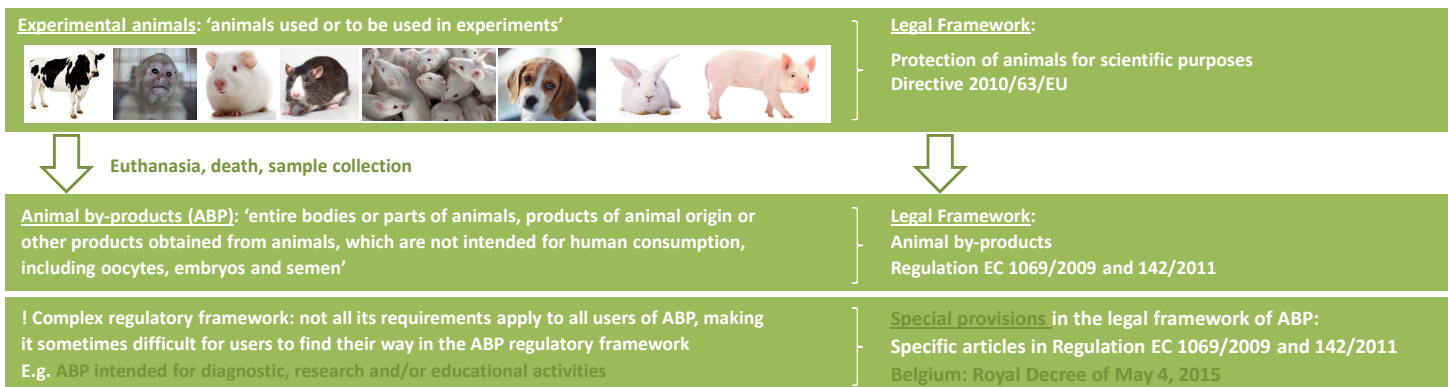


Animal by-products for diagnostic, research and educational purposes: a sparkle of light in a complex regulatory framework?

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ABP are controlled to protect human health, animal health and environment

<p>Goals include:</p> <ul style="list-style-type: none"> • Prevent inadvertent spread of pathogens • Ensure safe and suitable handling, transport and disposal • Prevent entry into the food-chain 	<p>Excluded from ABP are e.g.</p> <ul style="list-style-type: none"> • Animal-derived cell cultures (lineage or primo), as they are living organisms • Cell culture-derived monoclonal antibodies • Purified antibodies (unless stabilizers containing ABP are present)
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ABP are classified according to risk

Category	Category 1 High risk - For disposal only	Category 2 Moderate risk - Not for animal consumption	Category 3 Low risk - Not for human consumption
Includes	ABP produced from animal experiments ^a presenting a risk for the health of humans / animals	Produced from vertebrate animal experiments ^a contaminated with certain levels of particular chemicals or veterinary drugs	Produced from "untreated" experimental animals ^a
Examples	<ul style="list-style-type: none"> • Monkeys experimentally infected with HIV ^b • Animals that die during an experiment • Animals euthanized during an experiment 	<ul style="list-style-type: none"> • Animals used in physiology / behavioral studies • Non-contaminated farmed animals that survive experiment • Manure 	<ul style="list-style-type: none"> • Non-purified polyclonal antibodies • ABP-derived laboratory reagents • Rabbits to produce antibodies

Main consequences of the Royal Decree on ABP intended for diagnostic, research and educational purposes

Before using of ABP	<p>Notification of competent authorities (<i>Federal Public Service - Health, Food Chain Safety and Environment (FPS-HFCSE)</i>) → registration of user</p> <p>! No notification and registration when sporadic use of ABP cat. 1 and 2 or less than 20 kg/week of ABP cat. 3 for <u>educational</u> purposes</p> <p>! No notification and registration for veterinarians who are allowed to practice their profession</p>
Use of ABP	<p>Maintain a register noting e.g. receipt of ABP, type and origin of samples, disposal methods and dates</p> <p>! After their use, all ABP for diagnostic and research purposes must be destroyed, archived or returned to the place of origin</p>
Import of ABP from outside the European Union	<p>Notification of competent authorities (<i>Federal Agency for Food Chain Safety (FAVV-AFSCA)</i>) → apply for import permit and apply for health certificate depending on the risk/quantity of material</p> <p>Correct labeling ("For research and diagnostic purposes")</p> <p>Immediate transport to destination (no intermediate operators)</p> <p>! Entry via official border inspection post (BIP), but no veterinary border control</p>
'Dispatch' (export) of ABP	<p>Different rules may apply depending on the importing country: (http://www.favv-afsc.fgov.be/exportderdelanden/dierlijkeoorsprongnietgeschikt/ or http://www.favv-afsc.fgov.be/exportationpaystiers/origineanimaleimpropres/)</p>
Transactions within the European Union	<p>No notification or import permit</p> <p>Health certificate depending on the risk/quantity of material (<i>Federal Agency for Food Chain Safety</i>)</p> <p>! From the perspective of the ABP regulation, registered laboratories are allowed to transport ABP intended for diagnostic, research and educational purposes themselves within the European Union. However, also other regulatory frameworks have to be taken into account to determine final transport requirements (e.g. Dangerous Goods Regulatory framework)</p>
Processing of ABP (e.g. thermal treatment, chemical treatment, ...)	<p>Not mandatory from the perspective of the ABP regulation, but when processing ABP, authorization from the competent authorities is required</p> <p>! No authorization for processing is required when ABP are strictly used for educational purposes</p> <p>! In case infectious organisms have been used to deliberately infect animals, processing (e.g. waste treatment and inactivation) requirements of the contained use legislation have to be fulfilled ^{b, c}</p>
Final disposal of ABP	<p>Mandatory via an approved means of destruction (incineration, co-incineration or pressure sterilisation), unless kept for reference purposes</p> <p>! Depending on risk, quantity and frequency of ABP use, an educational institute can be allowed to dispose according to regional requirements</p> <p>! Some ABP that are part of cell cultures, laboratory kits or laboratory samples, can be treated by means that are at least equivalent to the validated method for pressurized steam autoclaves</p>