

All you need to know about the new legislation on the use of Animal by-products in laboratories, classrooms and arts exhibitions



A. Coppens¹, D. Beeckman², R. Custers³, A. De Vleeschauwer⁴, S. Loret⁵, L. Mostin⁴, I. Sledsens⁶, K. van der Meulen⁷
¹ Ablynx, ² Bayer, ³ VIB, ⁴ CODA-CERVA, ⁵ University of Namur, ⁶ IDEWE, ⁷ Perseus
 in the framework of the Belgian Biosafety Professionals

Definition of Animal By-Products (ABP)

Entire bodies or parts of animals, products of animal origin obtained from animals, which are **not intended for human consumption**.

ABP includes e.g.

Carcasses of vertebrate animals used in experiments from contained use facilities

Blood and its components, such as **serum** and **polyclonal antibodies**

ABP-derived products obtained from one or more treatments, transformations or steps of processing of ABP

ABP excludes e.g.

ABP-derived **cell cultures** (lineage or primo), as they are living organisms (able to proliferate)

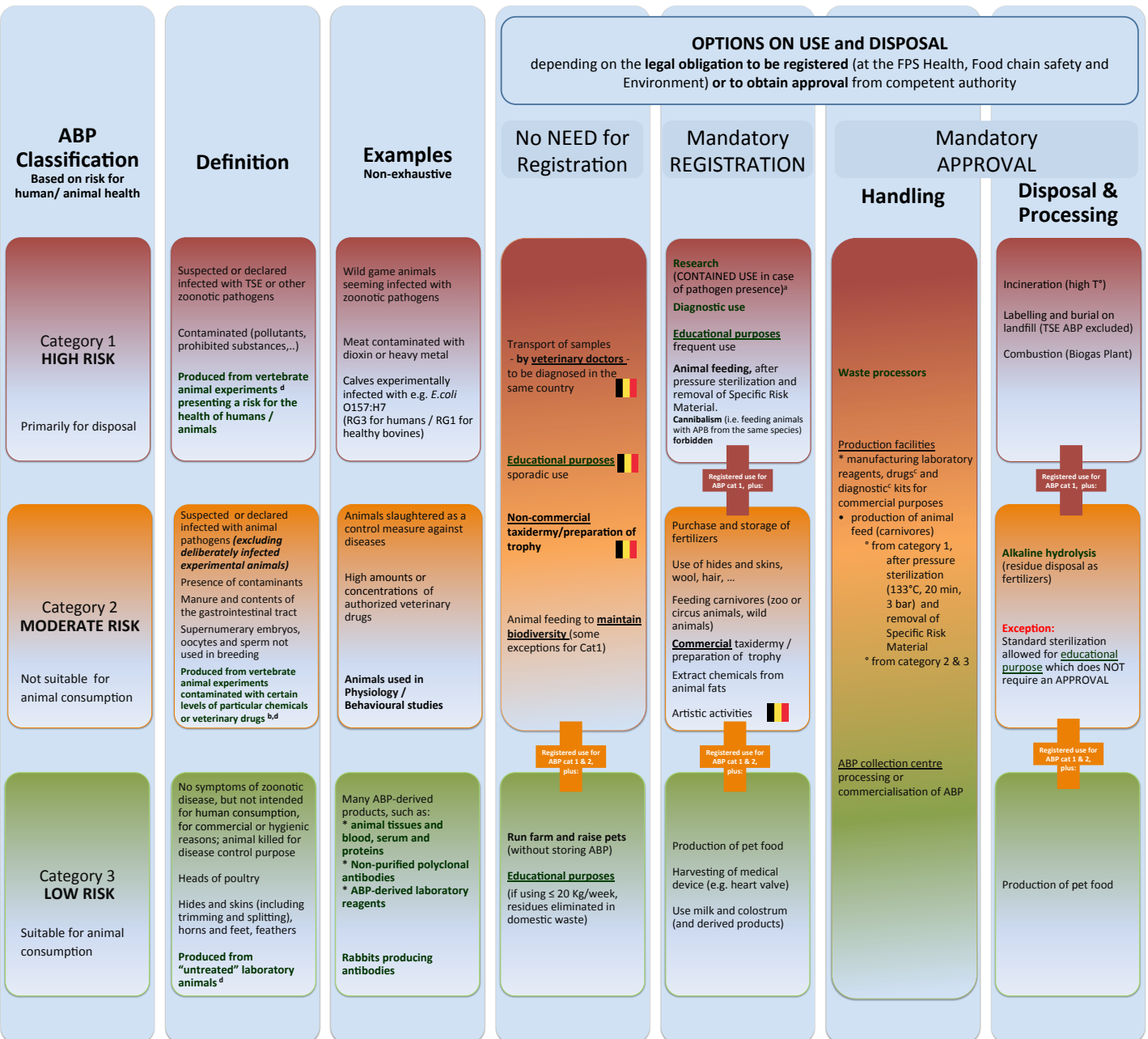
Cell culture-derived **monoclonal antibodies** and **purified antibodies** (unless stabilizers containing ABP are present)

ABP are controlled to ensure:

- Human and animal health is protected and pathogens are not inadvertently spread
- They are safely and suitably handled, transported and disposed

Legal Framework:

- Europe: EC 1069/2009 and 142/2011 (implementing EC 1069/2009) 2010/63/EU (protection of animals for scientific purposes)
- Belgium: RD of 27 April 2007 and RD of 4 May 2015



All you need to know about the new legislation on the use of Animal by-products in laboratories, classrooms and arts exhibitions

A. Coppens¹, D. Beeckman², R. Custers³, A. De Vleeschauwer⁴, S. Loret⁵, L. Mostin⁴, I. Sledsens⁶, K. van der Meulen⁷

¹Ablynx ²Bayer, ³VIB, ⁴CODA-CERVA, ⁵University of Namur, ⁶IDEWE, ⁷Perseus
in the framework of the Belgian Biosafety Professionals

The Belgian federal legislation “animal by-products intended for research, education, the feeding of non-food producing animals and the manufacturing and marketing of derivative products” (RD of 27 April 2007 and RD of 4 May 2015) was installed in response to the dioxin crisis. Animal by-products derived from animals unfit for human consumption, must not enter the feed chain. However, those animal by-products may be recovered under specific health conditions and used for the production of technical industrial products.

Animal by-products are used daily in scientific research. The legislation, however, made a distinction between the use of ABP for educational purposes and the use for research and diagnostics. For educational purposes, this law is quite simple but for persons or organizations carrying out scientific research, it is a complex matter, with some exceptions which are difficult to comprehend.

Depending on the degree of risk to human and animal health, an animal by-product is classified in one of three categories.

Each activity that falls under the ABP legislation must meet the following conditions:

- 1) The activity must be (a) registered or (b) approved. The difference in registration or approval depends on whether the activity respectively (a) produces or uses ABP as a reagent or diagnostic tool in the research environment, or (b) is an ABP waste destructor or a producer and/or collection center of ABP for commercial purposes. Each method of waste disposal which is not included in the legislation must be approved by the competent authorities. Educational institutions should not be registered in case of sporadic use of ABP (cat 1 & 2) or when using small amounts (cat 3 <20 kg/week). There is no difference in registration process for the different categories.

The “mandatory registration box” lists which activity may be performed with a specific class of ABP. E.g. research is allowed to handle ABP category 1, 2 and 3 ABP, while e.g. the production of pet feed is allowed only with a category 3 ABP.

- 2) Each activity must ensure that ABP are used safely to guarantee the health of humans and animals. This means that each ABP, present in the company or institute, must be labeled, registered and removed safely. Safe disposal may include that waste is picked up by an approved waste processor.

!!! To dispose euthanized animals used for experimentation, without the storage of ABP, the competent authority will have to decide whether a particular activity results in an ABP category (the determined category having an impact on the disposal method) or not.

- 3) The movement of ABP¹ within the European Union, intended for diagnostic, research and educational purposes, requires no import permit. However, for certain materials, a health certificate is needed.

To import ABP into the European Union, approval from the competent authorities is required and an import permit has to be applied for. For category 1 and 2 material, the import first needs to be notified in advance to the competent authorities via an official border inspection post (BIP) before entry into the European Union. Such notification is done via the online “TRAdE Control and Expert System” (TRACES) of the European Union, which allows tracking and tracing all movements of live animals and animal products imported into and traded within the European Union. In addition, a health certificate may be needed for import into the European Union, e.g. for unprocessed manure. In contrast to other ABP, research and diagnostic samples are not subject to veterinary checks at the border inspection post.

If you want to export ABP from the European Union, different rules may apply depending on the importing country.

Some examples of ABP within the scope of the ABP legislation:

- Animal **carcasses** of large and medium sizes (e.g. cow and goat) **from contained use facilities**
- Blood and its components, such as **serum** and **polyclonal antibodies**
- **ABP-derived products** obtained from one or more treatments, transformations or steps of processing of ABP

Some examples of ABP OUTSIDE the scope of the ABP legislation:

- Lab 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)

¹The “MOVEMENT TASK FORCE” of the BBP will deliver soon a manual for movements of biological material. A workshop about its use is scheduled on the 1st December 2016 in Ghent. For more details, contact Astrid.Coppens@ablynx.com