

Paris, le 28 février 2021

Madam President of the European Commission
Ursula VON DER LEYEN
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B-1049 BRUSSELS - BELGIUM

<u>Object</u>: Consideration of the potential of Gene-Edition in production animals (mammals) for the prophylaxis of significant panzootic infectious diseases.

Madam President,

As detailed by formal Notice dated June 20, 2019, the Académie Vétérinaire de France confirms that Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms has become obsolete due to the considerable progress in scientific knowledge and recent technical advances in New Breeding Technologies (NBT) such as those involving the use of programmable endonucleases (CRISPR-Cas9 for example). It urges the Commission to review and adjust the European regulation in its current draft and to take into account not only crop production but also animal production in order to facilitate critical research in the European Union on Gene Editing of production animals (Mammals).

Such research will contribute to improving animal health, or public health in the case of zoonoses, in particular by increasing the resistance of these animals to infectious diseases with significant overall economic impact. In this way, they will offer new ways of controlling the prevention of these major panzootic animal diseases in the long term.

The development of the CRISPR-Cas9 method (2012) is a technological revolution that facilitates genome editing, with many potential applications in animal medicine, as in human medicine or agronomy.

The Académie Vétérinaire de France affirms the validity of using these techniques for fundamental cognitive research objectives as is already the case in human health, and under development in animal health. The Académie is convinced that some applications can be part of the solution to help address urgent global challenges, such as campaigns against panzootic zoonotic or non-zoonotic diseases.

Indeed, through genetic engineering, it is now possible to modify the susceptibility of certain animal species to infectious diseases and thereby create whole herds resistant to certain diseases.

Gene Editing is one of the medium-term solutions to remove the permanent threat of highly contagious pathogens, some of which are transmissible to humans.

The applications of Gene Edition in the areas of animal health and the increase of disease resistance in production animals (mammals) has already been successfully implemented in several countries outside the European Union: in North America, the People's Republic of China and the United Kingdom. In 2017, pigs that are immune to the PRRS virus, a global disease causing annual losses estimated at \$2.5 billion in Europe and the United States of America, have already been produced. Similarly, in 2018, Chinese researchers developed pigs insensitive to classical swine fever virus.

It should be pointed out that Gene Edition does not introduce DNA sequences that are foreign to the species, but produces very precise sequence changes that could also occur naturally. These changes are, in fact, most often indistinguishable from natural genetic variants.

Genome Editing experiments for domestic production animals (mammals) are always carried out under containment since the majority of such animals are identified individually and followed from birth to death as well as products from them (milk and meat in particular) according to the current regulations. All breeding is carefully controlled, and can therefore be interrupted if necessary.

Despite their expertise, EU researchers have seen their work in this field severely hampered and discouraged by regulatory constraints, placing European genomics research in a precarious situation. More than 80% of the patents filed on CRISPR-Cas9 applications are American or Chinese and less than 10% are European. This situation is of concern for the Union's agri-food and health competitiveness and independence. Note that an adjustment of the regulation on Gene Editing in Europe would be completely in line with the strategy of the Green Pact of the European Union and meet its objectives of making the EU economy sustainable, investing in environmentally friendly technologies and supporting innovation.

The French Veterinary Academy urges the European Union to establish new rules to give public institutions and European companies the tools of innovation necessary to enable research on Gene Editing on production animals. This research will help reduce the potential health and economic impact of pathogens that cause potentially devastating animal disease panzootics.

Please accept, Madam President, our most respectful regards.

Jean-Pierre JÉGOU

Président de l'Académie Vétérinaire de France

Copies to:

- Mr Julien DENORMANDIE, Minister for Agriculture and Food (France)
- Mrs Stella KYRIAKIDES, Health and Food Safety Commissionner
- Mr. Thierry BRETON, Internal Market Commissionner
- Mr Jamusz WOJCIECHOWSKI, Agriculture Commissionner
- Mrs Mariya GABRIEL, Innovation, Research, Culture, Education and Youth Ministry Commissionner.