



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Crisis preparedness in food, animals and plants  
**The Director**

Brussels,  
SANTE G3/SDR/nc(2023) 5755782

**Subject: Current Status on Clones**

Dear Mr Buiting,

Thank you for your email of 13 April 2023 addressed to my colleague Ewa Camara concerning the following questions:

- Is cloning (the technique) allowed in the European Union;
- Is import of cloned live animals allowed;
- Is import of semen of cloned bulls allowed;
- Can you send me a link to the relevant regulation / documents on EURLEX?

The European Commission adopted in 2013 two proposals for Directives on cloning but they were withdrawn in July 2020.<sup>12</sup>

According to Council Directive 98/58/EC on the protection of animals kept for farming purposes, Member States are required to act at national level to avoid unnecessary pain, suffering or injury in the context of raising farm animals and mentions that such obligation also applies in the use of reproduction techniques. Therefore, any cloning techniques that would lead to such pain or suffering would not be in line with this Directive.

EFSA's scientific opinion on cloning from 2008<sup>3</sup>, concludes that "it is clear there are significant animal health and welfare issues for surrogate mothers and clones that can be

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<sup>1</sup> Proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes COM(2013) 892 final — 2013/0433 (COD)

<sup>2</sup> Proposal for a Council Directive on the placing on the market of food from animal clones COM(2013) 893 final — 2013/0434 (APP)

<sup>3</sup> Scientific Opinion of the Scientific Committee Food Safety, Animal Health and Welfare and Environmental Impact of Animals<sup>1</sup> derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and

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more frequent and severe than for conventionally bred animals. For cattle and pigs, food safety concerns are considered unlikely. No clear evidence has emerged to suggest any differences between food products from clones or their offspring, in terms of food safety, compared to products from conventionally bred animals. But we must acknowledge that the evidence base, while growing and showing consistent findings, is still small. That has been one of the challenges throughout this work.” This should therefore be taken into account by Member States when implementing Directive 98/58/EC.

Recital No 14 of the Novel Food Regulation<sup>4</sup> states that, until specific legislation on food from animal clones enters into force (which is not the case at the moment), food from animal clones should fall under the scope of this Regulation as food from animals obtained by non-traditional breeding practices and should be appropriately labelled for the final consumer in accordance with the Union legislation in force.

To date, no request for an authorisation of food from animal clones has been received by the Commission. In terms of labelling, any food should comply with Regulation (EU) No 1169/2011 on the provision of food information to consumers. In addition, in case of a potential future authorisation of food from animal clones, specific labelling requirements (e.g. denomination of the novel food) may be established under the Novel Food Regulation.

Animal products from the offspring from cloned animals are not considered as novel foods and do not fall under the Novel Food Regulation. They should however be subject to the relevant hygiene requirements (Regulations (EC) No 852/2004 and 853/2004).<sup>5,6</sup>

Regulation (EU) 2016/429 (Animal Health Law) and its delegated and implementing acts (Commission Delegated Regulation (EU) 2020/686, Commission Delegated Regulation (EU) 2020/692 and Commission Implementing Regulation (EU) 2020/999) provide rules on traceability of germinal products, movement of germinal products between Member States and entry into the Union of germinal products. However, the animal health legislation does not cover issues related to cloning and therefore does not address specifically the issue of entry into the Union of cloned animals and their germinal products (including semen).

Regulation (EU) 2016/1012 (the Animal Breeding Regulation) does not address issues relating to cloning.

To answer your questions about cloning technique and entry into the Union of cloned animals and semen from cloned bulls Member States can adopt measures in compliance with the relevant EU rules as explained above.

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their Offspring and Products Obtained from those Animals (Question No EFSA-Q-2007-092) Adopted on 15 July 2008.

<sup>4</sup> Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, OJ L 327, 11.12.2015.

<sup>5</sup> Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin

<sup>6</sup> Regulation (EC) No 852/2004 laying down hygiene rules for foodstuffs

Please note that this letter represents the views of the services of the Commission and has been prepared in order to assist you, based on the information that you provided the Commission services with. It does not commit the European Commission. Only the Court of Justice of the European Union is entitled to interpret Union law with final binding authority

Yours sincerely,

*[e-signed]*

Bernard Van Goethem