



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Biotechnology

Brussels
SANTE.DDG2.E.3 [redacted] (2021)5138939

Dear [redacted]

Thank you for your question relating to the applicability of Regulation (EC) No 1829/2003 to a certain type of layer hens and their eggs, with the aim of clarifying whether they need an authorisation under Regulation (EC) No 1829/2003. According to the explanation and the material provided, the technology in question is based on the integration of a transgene (inducible lethal gene) into the male sex chromosome Z, which conveys that transgene to all male embryos of the following generation of chickens. As a result, the male embryos will cease developing soon after fertilisation, while the female embryos will develop normally into layer hens.

In accordance with Articles 3(1) and 15(1) of Regulation (EC) No 1829/2003, the latter applies to genetically modified organisms (GMOs) for food or feed use, to food and feed containing or consisting of GMOs, and to food, food ingredients and feed produced from GMOs. Accordingly, in order to determine whether the layer hens in question and their eggs are subject to that Regulation, it needs to be ascertained whether they consist of GMOs, and, if that is not the case, whether they are produced from GMOs.

As regards the first point, the definition of GMO in Article 2(2) of Directive 2001/18/EC refers to organisms '*in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*'. This does not seem to be the case of the layer hens in question, based on the provided information, according to which the transgene is only conveyed to the male embryos, not to the female embryos that develop into these layer hens.

With regard to the second point, which refers to food and feed produced from a GMO, that category would not apply to the eggs produced by the layer hens in question, if the latter are not GMOs.

As a result, the layer hens in question and their eggs would not need an authorisation under Regulation (EC) No 1829/2003.

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In addition, we would like to recall that all parental and higher generations that contain a genetic modification that does not occur naturally by mating and/or natural recombination as well as food or feed containing, consisting of or produced from such organisms are subject to the existing EU GMO legislation. To be placed on the EU market (raised, marketed, slaughtered...), these products require a GMO authorisation pursuant to Regulation (EC) No 1829/2003.

Please note that this letter expresses the view of the Commission services based on the information provided and does not commit the European Commission. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

Yours sincerely,

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