



Stjórnarráð Íslands
Matvælaráðuneytið

mar@mar.is
545 9700

Borgartúni 26
105 Reykjavík

stjornarradid.is

EFTA Surveillance Authority
Case handler: Gudlaug Jonasdottir
Avenue des Arts 19H, EFTA House
1000 Bruxelles, Belgium

Reykjavík 15. september 2023
Tilv.: MAR22040057/12.03

Efni: Regarding a letter of formal notice to Iceland concerning the production of PMSG/eCG hormone (Case nr. 88475).

Dear Madam,

Reference is made to the EFTA Surveillance Authority's letter of formal notice dated 10 May 2023 (Document No: 1330625) concerning the production of PMSG/eCG hormone (Case nr. 88475).

In the Authority's letter it is concluded that by not subjecting blood collection from pregnant mares for the production of PMSG/eCG hormone under the processes and assessments under Regulation No 460/2017 which implements Directive 2010/63/EU on the protection of animals used for scientific purposes, Iceland has failed to fulfil its obligation arising from the Directive, as adapted to the EEA Agreement by Protocol 1 thereto, in particular its Articles 1(2), 4, 13(1), 20, 21, 36, 37 and 38 as well as its Annex VI. In addition, by its adoption of Regulation No 900/2022, and by failing to ensure the effectiveness of Directive 2010/63/EU the Icelandic Government has failed to fulfil its obligation arising from Article 3 of the EEA Agreement.

In these circumstances and acting under Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, the Authority requested that the Icelandic Government submitted its observations on the content of this letter.

In previous communication between the Authority and the Icelandic Government, the latter stated that the procedure was not subject to an assessment under the regulation that implements Directive 2010/63/EU into national law in Iceland. This conclusion was based on the analysis of a working group on the matter, which found that the procedure fell outside the scope of the regulation. Subsequently, the Icelandic Government made further amendments to its national legal order, by adopting Regulation No. 900/2022 on blood collection from pregnant mares.


The Icelandic Government is of the opinion that some of the arguments stated in its letter from 15 June 2022, are still valid. However, having thoroughly assessed the Authority's letter of formal notice from 10 May 2023, the Ministry has come to the conclusion, that the procedure of collecting blood from pregnant mares for the production of PMSG/eCG hormone should fall under Directive 2010/63/EU. As regards to the previously mentioned findings the Icelandic Government would like to

inform the Authority of the following actions:


1. Regulation No. 900/2022 on blood collection from pregnant mares will be revoked by 1 November 2023.
2. The Ministry will send a formal letter to the relevant competent authority by 20 September 2023 on the matter, i.e., the Icelandic Food and Veterinary Authority (MAST), to inform the authority that necessary preparations must begin as soon as possible. MAST will also be instructed to inform the relevant parties of these actions.
3. The blood collection season for 2023 is in progress and is foreseen to terminate no later than 5 October. Any collection after 1 November will be subject to Regulation No. 460/2017 and the requirements it lays down.

The Icelandic Government will provide further information on the progress of the above steps in due course and as relevant.

Respectfully,



Ása Þórhildur Þórðardóttir
Director General



Elísabet Anna Jónsdóttir
Senior Adviser; Deputy Director