Fullgild rafræn undirskrift
IÐUNN GUÐJÓNSDÓTTIR
2022-06-15 14:24:02 GMT
Ástæða: Undirskrift

Fullgild rafræn undirskrift
ELÍSABET ANNA JÓNSDÓTTIR
2022-06-15 14:28:58 GMT
Ástæða: Undirskrift

Government of Iceland
Ministry of Food,
Agriculture and Fisheries

mar@mar.is
(+354) 545 9700

Skúlagata 4,
101 Reykjavík

government.is

EFTA Surveillance Authority

Reykjavík June 15, 2022
Reference: MAR22040057/12.03

Subject: Complaint against Iceland concerning the production of PMSG/eCG hormone (Case No. 88475)

Dear Sir/Madam,

Reference is made to the EFTA Surveillance Authority´s ("the Authority") letter dated 5 May 2022 (Case No. 88475) where the Authority informs that it had received a complaint against Iceland concerning the compliance of the production of PMGS/eCG hormone in Iceland with Directive 2010/63/EU on the protection of animals used for scientific purpose.

In order for the Authority to examine and assess the complaint, the Authority invited the Icelandic Government to provide information on the following:

1. Description on the national rules applicable to the blood extraction from pregnant mares for the production of the hormone PMSG/ecG and if such procedures are subject to assessment under Regulation No. 460/2017 in Iceland.

Current status of applicable national rules on blood extraction is that on the basis of Article 4 of Regulation No. 910/2014 on the welfare of horses, a person in charge of horse keeping or the representative of an activity covered by Annex I must notify the Icelandic Food and Veterinary Authority (MAST) of the planned activity no later than 30 days before the start of the planned activity. Annex I, lists activities subject to MAST´s audit and horse keeping where blood is drawn from horses for the production of product is listed in section No. 6.

MAST has issued guidelines on the condition for blood extraction from pregnant mares and the guidelines are available on MAST´s website https://www.mast.is/static/files/leidbeiningar/Hross/skilyrdi-fyrir-blodtoku-ur-fylfullum-hryssum.pdf. The conditions are the following:

1. Extraction of blood is only permitted in establishments/farms that meet the following conditions:

a) Horse keeping for the purpose of blood extraction has been notified to MAST.

b) There have been no serious deviations due to animal welfare when keeping horses at the establishment in the past year.

2. A list of farms intended for extraction of blood must be sent to MAST before 1 May each year.

3. General requirements for extraction of blood from pregnant mares are:

    a) Only veterinarians with a valid operating license in Iceland can extract blood from pregnant mares. Possessor may take samples from the mares to determine the start of blood extraction with a special needle system following instruction of a veterinarian.

    b) Veterinarians are obliged to use local anaesthesia on the mares where the blood is extracted from and they shall register the use of it in the health database Heilsa.

    c) The maximum of blood that can be extracted from each mare per week is 5 litres and for maximum of 8 weeks.

    d) Blood extractions must be completed for 5 October each year.

    e) Blood can only be extracted from mares that have reached the age of four years (they may turn 4 in that year).

    f) The mares must be without any visible symptoms, in good physical condition (flesh grade 3,5-4,5) and they must be well groomed.

    g) Each veterinarian may not have more than 4 mares for extraction at a time. (4 booths).

    h) There shall not be more than 100 mares with foals in each collection group.

    i) The facilities must be such that there is no risk of mares and foals being injured.

    j) The mares must be ensured access to water immediately after the blood extraction.

    k) The welfare of the mares must be taken care of when collected and put into the booth, tied up and during the extraction with careful handling.

    l) If the blood extraction causes the mare to suffer or threatens her well-being, the veterinarian must immediately stop extracting the mare´s blood.

    m) If a mare is injured or ill, she should be treated immediately. If the mare cannot be treated or her well-being cannot be improved, she must be killed.

    n) The mares must be kept on good pasture with access to good water and salt.

4. Active internal control shall be accompanied by the following items and documents relating to the official control of MAST:

    a) Records of blood transfusions of mares at each blood collection site shall be available at the place of blood extraction.

    b) All mares must be registered in WorldFeng and micro tagged.

    c) The person responsible for keeping the horses shall be the registered keeper of the mares in WorldFeng.

    d) Records of all accidents and deaths of mares that are used for blood extraction and foals.

    e) Measurements of hemoglobin or hematocrit in significant proportion of mares every other year.

    f) Those involved in blood extraction shall receive written instructions on the special notification obligation of all those who interfere with animals cf. Article 9 of Act No. 55/2013 on Animal Welfare.

5. A report shall be submitted annually to MAST on the number of mares divided by establishments as well as mortality according to section 4, point d) and measurements according to section 4, point e).

As regards the question whether blood extraction from pregnant mares is subject to assessment under Regulation No. 460/2017 in Iceland, the answer is that it is not subject to such assessment.

Regulation No. 460/2017 implements Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes. In the directive the word "procedure" is defined as: any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with know or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with veterinary practice.

The extracting of blood from pregnant mares does not have any experimental purpose. The blood is extracted in order to isolate the PMSG hormone and the purpose of the collection is commercial. The extraction does not have any educational purposes either. It is a collection of a product that is to be used in another product. The extraction of blood may cause the mares some discomfort, but it does not exceed what is said in the directive, i.e. it is not a level of pain, suffering, distress or lasting harm equivalent to, or higher than that caused by the introduction of a needle in accordance with good veterinary practice.

According to Article 5 of the directive, procedures may be carried out for the following purposes only:

a) basic research,

b) translational or applied research with any of the following aims:

i. the avoidance, prevention, diagnosis or treatment of disease, ill-ealth or other abnormality or their effects in human beings, animals or plants;

ii. the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plant; or

iii. the welfare of animals and the improvement of the production of conditions for animals reared for agricultural purposes;

c) for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products.

If the procedures of blood extraction are subject to the provisions of directive 2010/63/EU the procedure must comply with the purposes of procedures described above. However, according to the wording if the provision the extraction is neither done to develop, manufacture nor test any of the following: quality, effectiveness or safety of drugs, other substances or products. If the purpose of the blood extraction had the purpose of the aforesaid it would obviously fall under the scope of the directive and that is the fundamental point. The purpose is however commercial and this is a non-experimental agricultural practice that has been practiced in Iceland for over 40 years.

2. Description on the procedure for extracting blood from pregnant mares, including information on the general duration of the individual blood extraction from each mare and the quantity of blood collected from each mare on weekly basis.

The gestation period of mares is around 11 months. Mares intended for blood collection generally shed in May. According to information from MAST there is one stallion with 20 mares in a free-range area and they are all let in between 20 May and 10 June. All impregnations are natural.

About 40-45 days after the impregnation has taken place, a blood sample is taken to assess if the

mare is pregnant and to measure eCG/PMSG in her blood. Pregnant mares usually start producing the hormone from the 40th day of pregnancy and the level of the hormone reaches a maximum 55-70 days after impregnation but then it decreases after 100-140 days when the hormone disappears from the blood.

Blood extraction can generally start on day 50 and from that point blood is extracted once per week for the maximum of 8 weeks as was described above in MAST´s requirements and the maximum of blood that can be extracted from each mare is 5 liters.

The blood extraction is performed in special stalls that have been built close to roundups or paddocks. The mares and their foals are driven from the free-range area into the roundup and from there the mares are directed one by one into a funnel into the blood extraction stalls while the foals wait in the roundup. Once a mare has entered a stall, the stall is closed from behind.

In the stall the mare is tied in such a way that the head is tilted up and to the side so that the jugular vein fits to the stung. As mentioned above, the veterinarians are required to use local anaesthesia on the area where the blood is extracted from. Once the mare has been stung the blood flows into a special container and each extraction takes approx. 5-10 minutes. The mare is then released into a pen where she gets access to water and salt and the foal is waiting for her. After the extraction the group is driven back to the free-range area.

3. In the letter the Authority askes if blood extraction from pregnant mares I subject to authorisation by the Icelandic authorities, and if so, what is the criteria for the authorisation to be granted. The Authority also asked if is taken into consideration for the assessment if there is an alternative scientifically satisfying method available, not involving the use of live animals. Finally, the Authority asked if the procedure is not subject to authorisation if there is any specific reason for why that is not the case.

Since the blood extraction is not considered to be done for the purpose of science, experiments or education, there has not been an assessment of any other alternative scientifically satisfying method. In addition and according to the ministry´s knowledge there is no evidence that other substances or drugs replace those that are made from PMSG that is isolated from blood extracted from pregnant mares, or that they have the same activity.

As mentioned in the answer to the first question blood extraction from pregnant mares is not subject to authorisation by the Icelandic authorities. It is however and according to Article 4, cf. Annex I of Regulation 910/2014, on the welfare of horses subjected to a notification requirement to MAST.

However, this arrangement will be changed this summer as stated at the package meeting between the Authority and the Ministry of Food, Agriculture and Fisheries which was held on 9 June. A regulation on blood extraction from pregnant mares will be set. The regulation will take into account the condition that MAST has set for blood extraction so far, but it will also include new conditions such as a special authorisation granted by MAST for the purpose of blood extraction based on Articles 20 and 46 of Act No. 55/2013, on animal welfare.

This document is signed electronically. The parties have examined the content of the document and are fully authorized to confirm it with their signature.

Elísabet Anna Jónsdóttir Iðunn María Guðjónsdóttir