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Case No: 88475
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Decision No: 073/23/COL

Icelandic Ministry of Food, Agriculture and Fisheries
Borgartúni 26, 4. hæð
105 Reykjavík
Iceland

Dear Sir or Madam,

Subject: Letter of formal notice to Iceland concerning the collection of blood from pregnant mares for the production of PMSG/eCG hormone

1 Introduction

By letter dated 7 April 2022,¹ the EFTA Surveillance Authority (“the Authority”) informed the Icelandic Government that it had received a complaint against Iceland regarding the compliance of the production of PMSG/eCG² hormone in Iceland with Directive 2010/63/EU on the protection of animals used for scientific purpose (“Directive 2010/63” or “the Directive”).³

According to the complainants, which are 17 different NGOs based in Belgium, Canada, Denmark, Germany, Iceland, Italy, Netherlands, Poland, Switzerland and the United States, the high-volume collection of blood from pregnant mares carried out in Iceland for the production of the hormone PMSG/ eCG, is contrary to Directive 2010/63, in particular its Articles 4, 13, 20, 36 and 38.

Having assessed the case, the Authority has come to the conclusion in this letter of formal notice that the procedure of collecting blood from pregnant mares for the production of PMSG/eCG hormone in Iceland constitutes a procedure that falls under Directive 2010/63.

Consequently, Iceland has failed to fulfil its obligations under the Directive and in particular its Articles 1(2), 4, 13(1), 20, 21, 36, 37 and 38 and its Annex VI by not following the processes and assessments provided for in Directive 2010/63.

In addition, in breach of its obligation arising from Article 3 of the Agreement on the European Economic Area (“the EEA Agreement” or “EEA”), the Icelandic Government has by the adoption of Regulation No 900/2022 on blood collection from pregnant mares (“Regulation No 900/2022”), in August 2022, further enhanced the legal uncertainty governing the blood collection from pregnant mares and failed to ensure the effectiveness of Directive 2010/63.

¹ Doc No 1280932

² Pregnant Mare Serum Gonadotropin/equine chorionic gonadotropin

³ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 *on the protection of animals used for scientific purposes* (OJ L 276, 20.10.2010, p. 33). The Directive was incorporated into the Agreement on the European Economic Area at point 7 of Chapter XIII of Annex II by Decision of the EEA Joint Committee No 256/2014 of 12 December 2014.

2 Correspondence

By letter dated 5 May 2022,⁴ the Authority requested information from the Icelandic Government regarding the national rules applicable to the blood collection from pregnant mares for the production of the hormone PMSG/eCG and the procedure as such.

The case was discussed at the package meeting in Iceland on 9 June 2022.

By letter dated 15 June 2022,⁵ the Icelandic Government replied to the Authority's request for information. In the letter, the Icelandic Government informed the Authority that at that time on the basis of Article 4 of Regulation No 910/2014 on the welfare of horses ("Regulation 910/2014"), a person in charge of horse keeping or the representative of an activity covered by Annex I of the regulation was under the obligation to notify the Icelandic Food and Veterinary Authority ("MAST") of the planned activity no later than 30 days before the start of the planned activity. Blood collection from horses for the production of a product was listed as one of those activities in section No 6. The Icelandic Government also stated that MAST had issued guidelines on the conditions for blood collection from pregnant mares. The Authority was also informed that the Icelandic Government planned to enact a regulation on the issue during the summer of 2022.

As regards the Authority's question whether blood collection from pregnant mares is subject to assessment under Regulation No 460/2017 on the protection of animals used for scientific purposes ("Regulation No 460/2017"), the Icelandic Government stated that the procedure is not subject to an assessment under the regulation. The reason for this is that in the Icelandic Government's view the procedure does not fall under the scope of the regulation as further outlined in the sections below.

In addition, the Icelandic Government provided the Authority with information as regards the procedure for the collection of blood from pregnant mares, including information on the general duration of the individual blood extraction and the quantity of blood collected from each mare on a weekly basis.

Lastly, the Icelandic Government informed that there has not been an assessment of any other alternative scientifically satisfying method in this context.

The Authority notes that since the receipt of the Icelandic Government's letter of 15 June 2022 the forthcoming amendments to the Icelandic legal environment provided for in the letter have materialised as will be further elaborated below.

3 Relevant national law

Article 12(1) of Act No 55/2013 on Animal Welfare⁶ ("Act No 55/2013") provides as follows:

Extensive and technologically sophisticated animal facilities must be notified to the Food and Veterinary Authority prior to commencing operations. No such operations may begin unless the conditions relating to premises, equipment and knowledge, see Articles 10 and 29 to 32, have been fulfilled and an inspection has been carried out by the Food and Veterinary Authority.

⁴ Doc No 1286612.

⁵ Doc No 1296229; your reference MAR22040057/12.03.

⁶ The English translation of the Act is provided on the web page of the Icelandic Government and can be accessed under the following hyperlink: https://www.government.is/library/04-Legislation/Act%20no%2055_2013-on%20animal%20welfare--mai-2015.pdf. The translation is not fully updated as regards later amendments to the Act but that does not affect the provisions relevant for this case.

Article 20(1) of Act No 55/2013 provides as follows:

Live animals may not be used for educational or experimental purposes, research, the production or testing of chemicals or drugs, or medical diagnosis, except with the express authorisation of the Food and Veterinary Authority, in those cases where such use causes the animals to experience distress or pain. However, this shall not apply to activities subject to licencing, provided that the issued licence authorises the use of live animals for the abovementioned purposes.

Article 35 of Act No 55/2013 provides as follows:

The Food and Veterinary Authority may limit or halt operations for serious or repeated offences or when the parties concerned fail to comply with its directions within the specified time limit. The assistance of the police may be sought to halt operations.

Article 36(2) of Act No 55/2013 provides as follows:

The Food and Veterinary Authority may require remedies to be implemented. Where a keeper of animals refuses to comply with the directions of the Food and Veterinary Authority, the latter may order the situation to be remedied at the expense of the keeper.

Article 44 of Act No 55/2013 provides as follows:

Where a party is guilty of a significant or repeated infringement of this Act or any Regulations issued pursuant to it, that party may be stripped of its licence to keep animals, to be involved in animal trading or dealing with animals in other ways. The same shall apply where there is evidence that the party does not have the ability to care for animals within the meaning of Article 10. The revocation of a licence may either concern animals in general or individual species, and be temporary or permanent. The prosecuting authorities may seek the revocation of a licence in a criminal case irrespective of whether a punishment of the defendant is sought. A person who has been deprived of a licence pursuant to this paragraph and who disregards a court ruling to that effect shall be liable to fines.

Article 4 of Regulation 910/2014⁷ provides as follows:

The person in charge of horse keeping or the representative of an activity that falls under Annex I must notify the Food and Veterinary Authority of the planned activity no later than 30 days before the planned activity begins.

Annex I of Regulation 910/2014 provides as follows:

Notifiable and auditable activities are the following:

[...]

6. Horse farming where blood is drawn from horses for the production of products.

[...]

As noted above, the Directive was implemented in Iceland by Regulation No 460/2017. The regulation reflects the provisions of the Directive and seems not to call for concern as

⁷ The translations of the provisions of the regulation are unofficial translations by the Authority. The Icelandic version of the regulation can be accessed at the following hyperlink: <https://island.is/reglugerdir/nr/0910-2014>.

regards the implementation as such. However, for the context of the case it is appropriate to mention a few of its provisions.⁸

Article 2 of Regulation No 460/2017 provides as follows:

1. *This regulation applies to animals under the following circumstances:*
 - a. *when they are used or intended to be used in experiments, or*
 - b. *when they are bred specifically so that their organs or tissues may be used for scientific purposes*

[...]

4. *The provisions of this regulation also apply when sedatives, painkillers, anaesthetics or other methods are used that aim to ensure that the animal does not experience pain, distress, lasting harm or other types of stress. The regulation applies until the animals have been killed, rehomed or returned to a suitable habitat or husbandry system.*
5. *The regulation does not apply to the following:*
 - a. *non-experimental agricultural and aquacultural practices,*
 - b. *non-experimental clinical veterinary practices,*
 - c. *veterinary clinical trials required for the issuance or the maintaining of marketing authorisation of a veterinary medicinal product,*
 - d. *practices undertaken for the purposes of recognised animal husbandry,*
 - e. *practices related to a simple identification of an animal,*
 - f. *practices not likely to cause 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.*

Article 3(a) of Regulation No 460/2017 provides as follows:

Experiment: any use of an animal for experimental or other scientific purposes 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 good veterinary practice. This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, but excludes the killing of animals solely for the use of their organs or tissues;

Article 2(1) of Regulation No 900/2022⁹ provides as follows:

Blood collection: To extract blood from pregnant mares for the collection of the eCG (equine chorionic gonadotropin) hormone.

⁸ The translations of the provisions of the regulation are unofficial translations by the Authority. The Icelandic version of the regulation can be accessed at the following hyperlink: <https://island.is/reglugerdir/nr/0460-2017>.

⁹ The English translations of the provisions of Regulation No 900/2022 are unofficial translations by the Authority. The Icelandic version of the regulation can be accessed on the following hyperlink: <https://island.is/reglugerdir/nr/0900-2022>.

Article 3 of Regulation No 900/2022 provides as follows:

Holding horses for blood collection is only permitted following a prior notification to the Icelandic Food and Veterinary Authority in accordance with Article 12 of Act No 55/2013, on animal welfare. Notification must be received by the Icelandic Food and Veterinary Authority no later than 60 days before the blood collection from the mares begins. The person responsible for keeping horses for blood collection shall be the registered keeper of all the mares he uses for that activity in the WorldFeng database.

Blood collection from pregnant mares is only permitted if a special permission from the Icelandic Food and Veterinary Authority has been obtained. The license is granted to the buyer of the blood on the basis of Article 20 of Act No 55/2013 on the welfare of animals and is valid for a maximum of three years from the date of publication. The permit is limited to establishments where the holding of horses for blood collection has been notified and inspected by the Icelandic Food and Veterinary Authority according to Paragraph 1.

According to Article 4 of Regulation 900/2022 the Icelandic Food and Veterinary Authority supervises the implementation of the regulation as well as its enforcement.

Article 5 of Regulation 900/2022 provides for the obligations of the license holder for blood collection. It provides as follows:

A licence holder under Article 3(2) is responsible for the following aspects:

- a. That records of mares in blood collection at each blood collection farm or establishment are available at the place where blood collection is performed.*
- b. To record all accidents, illnesses and deaths of mares and foals during the blood collection period.*
- c. To record any abnormalities that occur during blood collection (including instances of clear fear or stress in the mares during blood collection).*
- d. That those who are involved in the blood collection receive written instructions on the special reporting obligation of all those who deal with animals cf. Article 9 of Act No 55/2013 on animal welfare. The Icelandic Food and Veterinary Authority must be notified if: there is a suspicion of bad treatment, accommodation, feeding (physique) and if the marking of horses is not adequate (registration and micro-marking).*
- e. That the veterinarian is guaranteed sufficient assistance, so that there is always a person next to each mare during the blood collection.*
- f. Measurements are performed by a public laboratory of haemoglobin and/or haematocrit of a significant percentage of the mares each year ending in an odd number.*
- g. That a quality manual is kept which must be accessible to the Icelandic Food and Veterinary Authority. As a minimum, the quality manual shall contain:*
 - i. Procedures for registration and implementation according to a - f. It must be stated which party on behalf of the license holder is responsible for each aspect separately.*

- ii. *Procedures for reactions to abnormalities that may occur during blood collection, such as: accidents, illness, deaths and signs of fear or stress during blood collection.*
- h. *To send the Icelandic Food and Veterinary Authority an annual summary of the activities. The summary must be received by the Icelandic Food and Veterinary Authority no later than 31 December each year. As a minimum, the summary shall include:*
 - i. *The number of mares subject to blood collection divided into establishments (farms).*
 - ii. *Register of accidents, illnesses and deaths during the blood collection period.*
 - iii. *Register of other abnormalities during blood collection according to points c and e.*

Annually, a report must be submitted to the Icelandic Food and Veterinary Authority on the number of mares subject to blood collection divided by establishments, as well as loss of animals according to point d and measurements according to point e.¹⁰

Article 6 of Regulation No 900/2022 provides for the general requirements for the blood collection from pregnant mares. It provides as follows:

- a. *Only veterinarians with a valid license to practice in Iceland are allowed to perform blood collection from pregnant mares. However, the keeper of the mares is permitted to take samples from the mares to determine the start of blood collection with a special needle system following a veterinarian's recommendation.*
- b. *A veterinarian is responsible for the treatment he performs.*
- c. *Veterinarians are obliged to use local anaesthesia on the injection site and to record the use of local anaesthesia in the database Heilsa.*
- d. *It is never allowed to take more than 5 litres of blood per week from a mare and for a maximum of 8 weeks each year.*
- e. *Blood collection should normally be completed by 5 October each year.*
- f. *Blood may only be collected from mares that have reached the age of four years (turning 4 years old that year) and blood may not be collected from mares that are older than 24 years.*
- g. *The mares must be without visible signs of disease, in good physique (body condition score 3.5-4.5¹¹) and well cared for in all respects.*
- h. *Each veterinarian may not have more than 3 mares for blood collection at the same time (3 blood collection stalls).*

¹⁰ It is noted that the reference to points d and e in Article 5(2) does not seem to be accurate. In the draft regulation that was submitted to public consultation point d of Article 5(1) concerned the registration of accidents and deaths of mares and foals (now point b of Article 5(1) of Regulation No 900/2022) and point e referred to measurements performed by public laboratories (now point f of Article 5(1) of Regulation No 900/2022). Although the individual points have been changed since the public consultation the reference in Article 5(2) has not been updated.

¹¹ The Icelandic body condition score is made on the scale of 1-5, see Annex III to Regulation 910/2014.

- i. There shall be no more than 75 mares with foals in each blood collection group that is rounded up at any one time.*
- j. Facilities for blood collection must be such that there is no risk of mares and foals being injured.*
- k. It must be ensured that the mares have access to water and salt immediately after the blood collection.*
- l. The well-being of the mares shall be ensured during the herding to the corral as well as during the blood collection by careful handling and tying up.*
- m. If the blood collection causes suffering to the mare or threatens its well-being, the veterinarian must immediately stop blood collection from the mare in question.*
- n. If a mare is injured or falls ill, she should be treated without delay. If it is not possible to treat or improve the condition of the mare, she must be put down.*
- o. The mares must be kept on good pasture with access to good water and salt.*

Article 7 of Regulation 900/2022 provides as follows:

The keeper of horses is responsible for the welfare of his horses every year. During blood collection, he is responsible for the welfare of the mares during the herding and in the corral, until they are in a special blood collection stall. He is always responsible for the welfare of the foals accompanying the mares.

The licence holder, according to Article 3(2), is responsible for compliance with all the conditions of the license.

The veterinarian who takes care of the blood collection, on behalf of the buyer, is responsible for the welfare of the mares from the moment they arrive in the blood collection stall and that the procedures for blood collection are in accordance with animal welfare considerations. He must also look after the health and well-being of the mares and the foals accompanying them, after the blood collection.

4 Relevant EEA law

Article 3 of the EEA Agreement provides as follows:

The Contracting Parties shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Agreement.

They shall abstain from any measure which could jeopardize the attainment of the objectives of this Agreement.

Moreover, they shall facilitate cooperation within the framework of this Agreement.

Recital 4 of the Directive provides as follows:

The European Parliament in its resolution of 5 December 2002 on Directive 86/609/EEC called for the Commission to come forward with a proposal for a revision of that Directive with more stringent and transparent measures in the area of animal experimentation.

Recital 6 of the Directive provides as follows:

New scientific knowledge is available in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm. It is therefore necessary to improve the welfare of animals used in scientific procedures by raising the minimum standards for their protection in line with the latest scientific developments.

Recital 7 of the Directive provides as follows:

Attitudes towards animals also depend on national perceptions, and there is a demand in certain Member States to maintain more extensive animal-welfare rules than those agreed upon at the level of the Union. In the interests of the animals, and provided it does not affect the functioning of the internal market, it is appropriate to allow the Member States certain flexibility to maintain national rules aimed at more extensive protection of animals in so far as they are compatible with the TFEU.

Recital 10 of the Directive provides as follows:

While it is desirable to replace the use of live animals in procedures by other methods not entailing the use of live animals, the use of live animals continues to be necessary to protect human and animal health and the environment. However, this Directive represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so. To that end, it seeks to facilitate and promote the advancement of alternative approaches. It also seeks to ensure a high level of protection for animals that still need to be used in procedures. This Directive should be reviewed regularly in light of evolving science and animal-protection measures.

Recital 39 of the Directive provides as follows:

It is also essential, both on moral and scientific grounds, to ensure that each use of an animal is carefully evaluated as to the scientific or educational validity, usefulness and relevance of the expected result of that use. The likely harm to the animal should be balanced against the expected benefits of the project. Therefore, an impartial project evaluation independent of those involved in the study should be carried out as part of the authorisation process of projects involving the use of live animals. Effective implementation of a project evaluation should also allow for an appropriate assessment of the use of any new scientific experimental techniques as they emerge.

Article 1(2) of the Directive provides as follows:

This Directive shall apply where animals are used or intended to be used in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes.

[...]

The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods shall not exclude the use of an animal in procedures from the scope of this Directive.

Article 1(5) of the Directive provides as follows:

This Directive shall not apply to the following:

- (a) non-experimental agricultural practices;*
- (b) non-experimental clinical veterinary practices;*
- (c) veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;*
- (d) practices undertaken for the purposes of recognised animal husbandry;*
- (e) practices undertaken for the primary purpose of identification of an animal;*
- (f) practices not likely to cause 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.*

Article 3 of the Directive provides as follows:

- 1. 'procedure' means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known 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 good veterinary practice.*
- 2. 'project' means a programme of work having a defined scientific objective and involving one or more procedures;*

[...]
- 6. 'user' means any natural or legal person using animals in procedures, whether for profit or not;*

[...]

Article 4(1) of the Directive provides as follows:

Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure.

Article 5 of the Directive provides as follows:

Procedures may be carried out for the following purposes only:

[...]

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

- (i) the avoidance, prevention, diagnosis or treatment of disease, ill-health 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 plants; or*
- (iii) the welfare of animals and the improvement of the production 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;

[...]

Article 13(1) of the Directive provides as follows:

Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union.

Article 14(1) of the Directive provides as follows:

Member States shall ensure that, unless it is inappropriate, procedures are carried out under general or local anaesthesia, and that analgesia or another appropriate method is used to ensure that pain, suffering and distress are kept to a minimum.

Procedures that involve serious injuries that may cause severe pain shall not be carried out without anaesthesia.

Article 20 of the Directive provides as follows:

1. Member States shall ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period.

Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the requirements of this Directive.

2. The authorisation shall specify the person responsible for ensuring compliance with the provisions of this Directive and the person or persons referred to in Article 24(1) and in Article 25.

3. Renewal of the authorisation shall be required for any significant change to the structure or the function of an establishment of a breeder, supplier or user that could negatively affect animal welfare.

4. Member States shall ensure that the competent authority is notified of any changes of the person or persons referred to in paragraph 2.

Article 21 of the Directive provides as follows:

1. Where a breeder, supplier or user no longer complies with the requirements set out in this Directive, the competent authority shall take appropriate remedial action, or require such action to be taken, or suspend or withdraw its authorisation.

2. Member States shall ensure that, where the authorisation is suspended or withdrawn, the welfare of the animals housed in the establishment is not adversely affected.

Article 36 of the Directive provides as follows:

1. Member States shall ensure, without prejudice to Article 42, that projects are not carried out without prior authorisation from the competent authority, and that projects are carried out in accordance with the authorisation or, in the cases referred

to in Article 42, in accordance with the application sent to the competent authority or any decision taken by the competent authority.

2. Member States shall ensure that no project is carried out unless a favourable project evaluation by the competent authority has been received in accordance with Article 38.

Article 37 of the Directive provides as follows:

1. Member States shall ensure that an application for project authorisation is submitted by the user or the person responsible for the project. The application shall include at least the following:

- (a) the project proposal;*
- (b) a non-technical project summary; and*
- (c) information on the elements set out in Annex VI.*

2. Member States may waive the requirement in paragraph 1(b) for projects referred to in Article 42(1).

Article 38 of the Directive provides as follows:

1. The project evaluation shall be performed with a degree of detail appropriate for the type of project and shall verify that the project meets the following criteria:

- (a) the project is justified from a scientific or educational point of view or required by law;*
- (b) the purposes of the project justify the use of animals; and*
- (c) the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.*

2. The project evaluation shall consist in particular of the following:

- (a) an evaluation of the objectives of the project, the predicted scientific benefits or educational value;*
- (b) an assessment of the compliance of the project with the requirement of replacement, reduction and refinement;*
- (c) an assessment and assignment of the classification of the severity of procedures;*
- (d) a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment;*
- (e) an assessment of any justification referred to in Articles 6 to 12, 14, 16 and 33; and*
- (f) a determination as to whether and when the project should be assessed retrospectively.*

3. *The competent authority carrying out the project evaluation shall consider expertise in particular in the following areas:*

- (a) the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas;*
- (b) experimental design, including statistics where appropriate;*
- (c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;*
- (d) animal husbandry and care, in relation to the species that are intended to be used.*

4. *The project evaluation process shall be transparent.*

Subject to safeguarding intellectual property and confidential information, the project evaluation shall be performed in an impartial manner and may integrate the opinion of independent parties.

Article 54(2) of the Directive provides as follows:

Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures.

Member States shall submit that statistical information to the Commission by 10 November 2015 and every year thereafter.

Annex VI to the Directive provides as follows:

LIST OF ELEMENTS REFERRED TO IN ARTICLE 37(1)(c)

1. *Relevance and justification of the following:*

- (a) use of animals including their origin, estimated numbers, species and life stages;*
- (b) procedures.*

2. *Application of methods to replace, reduce and refine the use of animals in procedures.*

3. *The planned use of anaesthesia, analgesia and other pain relieving methods.*

4. *Reduction, avoidance and alleviation of any form of animal suffering, from birth to death where appropriate.*

5. *Use of humane end-points.*

6. *Experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact where appropriate.*

7. *Reuse of animals and the accumulative effect thereof on the animals.*

8. *The proposed severity classification of procedures.*

9. *Avoidance of unjustified duplication of procedures where appropriate.*
10. *Housing, husbandry and care conditions for the animals.*
11. *Methods of killing.*
12. *Competence of persons involved in the project.*

Annex VIII to the Directive describes the severity classification of procedures. The Annex provides as follows:

The severity of a procedure shall be determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure.

Section I: Severity categories

Non-recovery:

Procedures which are performed entirely under general anaesthesia from which the animal shall not recover consciousness shall be classified as 'non-recovery'.

Mild:

Procedures on animals as a result of which the animals are likely to experience short-term mild pain, suffering or distress, as well as procedures with no significant impairment of the well-being or general condition of the animals shall be classified as 'mild'.

Moderate:

Procedures on animals as a result of which the animals are likely to experience short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that are likely to cause moderate impairment of the well-being or general condition of the animals shall be classified as 'moderate'.

Severe:

Procedures on animals as a result of which the animals are likely to experience severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress as well as procedures, that are likely to cause severe impairment of the well-being or general condition of the animals shall be classified as 'severe'.

Section II: Assignment criteria

The assignment of the severity category shall take into account any intervention or manipulation of an animal within a defined procedure. It shall be based on the most severe effects likely to be experienced by an individual animal after applying all appropriate refinement techniques.

When assigning a procedure to a particular category, the type of procedure and a number of other factors shall be taken into account. All these factors shall be considered on a case-by-case basis.

The factors related to the procedure shall include:

- *type of manipulation, handling,*

- *nature of pain, suffering, distress or lasting harm caused by (all elements of) the procedure, and its intensity, the duration, frequency and multiplicity of techniques employed,*
- *cumulative suffering within a procedure,*
- *prevention from expressing natural behaviour including restrictions on the housing, husbandry and care standards.*

Examples are given in Section III of procedures assigned to each of the severity categories on the basis of factors related to the type of the procedure alone. They shall provide the first indication as to what classification would be the most appropriate for a certain type of procedure.

However, for the purposes of the final severity classification of the procedure, the following additional factors, assessed on a case-by-case basis, shall also be taken into account:

- *type of species and genotype,*
- *maturity, age and gender of the animal,*
- *training experience of the animal with respect to the procedure,*
- *if the animal is to be reused, the actual severity of the previous procedures,*
- *the methods used to reduce or eliminate pain, suffering and distress, including refinement of housing, husbandry and care conditions,*
- *humane end-points.*

Section III:

Examples of different types of procedure assigned to each of the severity categories on the basis of factors related to the type of the procedure

1. Mild:

(a) administration of anaesthesia except for the sole purpose of killing;

[...]

2. Moderate:

[...]

(k) evoking escape and avoidance reactions where the animal is unable to escape or avoid the stimulus, and are expected to result in moderate distress.

[...]

The reporting obligation provided for in Article 54(2) of the Directive is further outlined by Part B of Implementing Decision (EU) 2020/569¹² ("Decision 2020/569").

¹² Commission Implementing Decision (EU) 2020/569 of 16 April 2020 establishing a common format and information content for the submission of the information to be reported by Member States pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for

Point 10 of Point B of Part B provides for the purposes of the procedures that fall under the reporting obligation. One of the purposes listed is “*Regulatory use and routine production*”.

Further Point 10.3.3. of Point B of Part B of Decision 2020/569 provides as follows:

‘Routine production’ includes animals used in the manufacturing process of products such as antibodies and blood based products, for example, animals used in the manufacturing of serum-based medicinal products shall be included within this category.

Lastly, Point 21 of Point B of Part B of Decision 2020/569 provides as follows:

Routine production by product type

Blood based products

Monoclonal antibodies by ascites method only

Monoclonal and polyclonal antibodies (excluding ascites method)

Other products

5 The Authority’s assessment

5.1 The applicability of Directive 2010/63

5.1.1 General

Directive 2010/63 replaced Directive 86/609/EEC¹³ (“Directive 86/609”). The aim of the revision of Directive 86/609 was to raise the bar when it comes to the minimum standards for the protection of animals¹⁴ with the objective of reducing their use in procedures as much as possible.

That objective is clearly reflected in recital 6 of the Directive which states that it was considered necessary to improve the welfare of animals used in scientific procedures by raising the minimum standards for their protection in line with the latest scientific developments and new knowledge on factors influencing animal welfare. At the same time, the Directive allows for flexibility for those EEA States that wish to maintain rules aimed at more extensive protection of animals, cf. recital 7 of the Directive.

In addition, recital 10 of the Directive provides that it represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so.

As noted above, Article 1(2) of Directive 2010/63 states that the Directive is applicable where animals are used or intended to be used in procedures.

Procedure is defined in Article 3(1) of the Directive as follows:

scientific purposes and repealing Commission Implementing Decision 2012/707/EU (OJ L 129, 24.4.2020, p. 16). The Decision was incorporated into the EEA Agreement at point 15zp of Chapter XIII of Annex II by Decision of the EEA Joint Committee No 135/2021 of 23 April 2021.

¹³ Council Directive 86/609/EEC of 24 November 1986 *on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes* (OJ L 358, 18.12.1986, p. 1). The Directive was incorporated into the EEA Agreement at point 7 of Chapter XIII of Annex II.

¹⁴ See also recital 4 of the Directive.

*“[...] any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known 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 good veterinary practice.
[...].”*

Thus, if the conditions of these two provisions are fulfilled, the Directive is applicable, unless one of the exceptions in Article 1(5) of the Directive apply to the procedure in question.

In its reply to the request for information the Icelandic Government maintained that the blood collection from pregnant mares does not have any experimental purpose. The blood is collected in order to isolate the PMSG hormone and the purpose of the collection is commercial. The collection does not have any educational purposes either. It is a collection of a product that is to be used in another product, that is for the purpose of producing a veterinary medicinal product.

However, in its reply the Icelandic Government does not elaborate on the concept of “other scientific purposes” which is one of the purposes which would, if fulfilled, lead to the procedure being considered to fall under the scope of the Directive. What constitutes a scientific purpose is further analysed in Section 5.1.2 below.

5.1.2 *The meaning of “other scientific purposes”*

The Directive does not define the concept of *other scientific purposes* and it has not been specifically addressed in the existing case law of the Court of Justice of the European Union (“CJEU”) in this context.

In the Authority’s view, the starting point for such definition would then usually be how it is generally defined.

The Concise Oxford English Dictionary¹⁵ defines science *inter alia* as “**1** *the intellectual and practical activity encompassing the systematic study of the structure and behaviour of the physical and natural world through observation and experiment.*”¹⁶

The word scientific is defined as “**1** *of, relating to, or based on science.*”¹⁷

The Oxford Encyclopaedic English Dictionary¹⁸ has a similar definition of the words with the word science being *inter alia* defined as “**1** *a branch of knowledge conducted on objective principles involving the systematized observation of and experiment with phenomena, esp. concerned with the material and functions of the physical universe [...]* **2** *a systematic and formulated knowledge, esp. of a specified type or on a specified subject [...]* **b** *the pursuit or principles of this.*”¹⁹

That dictionary defines scientific as “**2** *used in, engaged in, or relating to (esp. natural) science [...].*”²⁰

¹⁵ *The Concise Oxford English Dictionary*, Tenth edition revised Edited by Judy Pearsall, Oxford University Press, 2002.

¹⁶ *Ibid*, p. 1281.

¹⁷ *Ibid*.

¹⁸ *The Oxford Encyclopaedic English Dictionary*, edited by Joyce M. Hawkins and Robert Allen, Clarendon Press, 1991.

¹⁹ *Ibid*, p. 1299.

²⁰ *Ibid*.

The Webster's New Encyclopaedic Dictionary²¹ defines science as “**2** : *knowledge covering general truths or the operation of general laws especially as obtained and tested through the scientific method [...]*.”²²

The word scientific is defined as “*of, relating to or exhibiting the methods or principles of science.*”²³

It seems fair to deduct from the definitions above that blood collection from pregnant mares to produce a hormone that is used in a veterinary medicinal product, falls under the definition of *other scientific purposes* in the context of Directive 2010/63. That is particularly due to the fact that the development and production of medicinal products (veterinary as well as for human use) are based on principles of natural science such as biology, chemistry and physics. Indeed, the production of medicinal products and their placing on the market takes place following for example extensive scientific research and clinical trials. In addition, there are requirements in EEA law concerning pharmacovigilance once medicinal products have been placed on the market.

In that regard, it is also taken into account that according to Article 5(c), cf. Article 5(b)(ii) of Directive 2010/63 procedures can be carried out for the purpose of *inter alia* the manufacture of drugs for the aim of assessing, detecting, regulating or modifying physiological conditions in human beings, animals or plants, as will be further outlined below.

In addition, it is recalled that under the reporting obligation under Article 54(2) of the Directive, the EEA States shall provide information on the use of animals in procedures. Part B of Decision 2020/569 provides for what information shall be submitted in accordance with Article 54(2) of the Directive amongst the data input categories provided for in Point 10 of Part B are procedures for the purpose of routine production. According to Point 10.3.3. of Part B of Decision 2020/569 the term routine production includes animals used in the manufacturing process of products such as antibodies and blood based products, for example, animals used in the manufacturing of serum-based medicinal products.

Moreover, when classifying the routine production by product type in the input categories, point 21 of Part B of Decision 2020/569 provides that one of those categories is blood based products.

It should be noted that the European Commission has established a database, ALURES, which gives an overview of when and how animals in Europe are being used in science. In line with the instructions set out in Decision 2020/569, ALURES provides information on the number of animals used in the manufacturing process of products. One of the categories displayed is the number of animals used for the routine production of blood-based products.²⁴

5.1.3 *Level of pain, suffering, distress or lasting harm in the blood collection from pregnant mares*

Article 3(1) of Directive 2010/63 provides for the condition that in order to be considered a procedure within the scope of the Directive the condition that it causes a certain level of harm needs to be fulfilled.

²¹ Webster's New Encyclopedic Dictionary, second printing, Black Dog & Leventhal Publishers Inc., 1994.

²² *Ibid*, p. 912.

²³ *Ibid*.

²⁴ Further information on the ALURES database can be found here: https://ec.europa.eu/environment/chemicals/lab_animals/alures_en.htm. Information on the number of animals used for the routine production of blood-based products can be found in section 2 of the database which can be found here: https://webgate.ec.europa.eu/envdataportal/content/alures/section2_number-of-uses.html.

More precisely, the procedure must be of a nature that 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 good veterinary practice.

In its reply to the Authority's request for information the Icelandic Government maintained that the blood collection might cause the mares some discomfort, but that it did not exceed the level of pain prescribed in Article 3(1) of the Directive. No reasoning was provided as regards how the Icelandic Government came to that conclusion. However, at the package meeting in Iceland in June 2022 the representatives of the Authority were informed that the mares were subject to local anaesthesia before the extraction of blood.

In that regard, it should be noted that according to the third subparagraph of Article 1(2) of the Directive the elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods shall not exclude the use of an animal in procedures from the scope of the Directive.

Thus, the fact that local anaesthesia is applied does not exclude the application of the Directive to the procedure in question. In the case at hand, while local anaesthesia may help reducing the pain of the mares, it is likely to have limited effect on the distress from being handled, as further elaborated below.

According to Section II of Annex VIII of the Directive the assignment of the severity category shall take into account any intervention or manipulation of an animal within the procedure. It shall be based on the most severe effects likely to be experienced by an individual animal after applying all appropriate refinement techniques.

That instruction is further detailed in the National Competent Authorities' working document on a severity assessment framework²⁵ where it is stated that the recommended prospective severity classification assigned to procedures should be based on the highest severity anticipated for *any* animal.²⁶

It is also noted in that regard, that according to the National Competent Authorities' working document on a severity assessment framework the evaluation of the severity of a procedure is not a simple additive process where a number of mild procedures constitute a moderate procedure. To the contrary, the severity evaluation should be based on an overall assessment of the animal's experience from the start of the procedure to the end.²⁷

Further, according to point 1(a) of Section III of Annex VIII of the Directive administration of anaesthesia except for the sole purpose of killing is categorised as mild as regards the severity classification of procedures. According to Section I of Annex VIII on Severity categories the following procedures fall under the mild category:

Procedures on animals as a result of which the animals are likely to experience short-term mild pain, suffering or distress, as well as procedures with no significant impairment of the well-being or general condition of the animals shall be classified as 'mild'.

Point 1(a) of Section III of Annex VIII of the Directive does not differentiate between the administration of anaesthesia by injection or topically. It is the Authority's view that if the

²⁵ See https://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_Severity_Assessment.pdf (National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes. Working document on a severity assessment framework). The Document was endorsed by the National Competent Authorities for the implementation of Directive 2010/63 at their meeting of 11-12 July 2012.

²⁶ *Ibid*, p. 5.

²⁷ *Ibid*, p. 7.

anaesthesia is applied topically the level of pain from the administration of the anaesthesia itself is less than if it was administered by injection. Under such circumstances, given that the anaesthesia has been applied correctly and that its functions last for the duration of the blood extraction, the level of pain must be considered below the threshold of Article 3(1) of the Directive.

However, if the anaesthesia is administered by an injection, it must be concluded that the level of pain is at least equivalent to the pain caused by the introduction of a needle in accordance with good veterinary practice.

Further, it cannot be overlooked that, to the Authority's knowledge, the mares in question are to a large extent not fully tamed and roam freely outside. Thus, the level of distress that prolonged fixation of the mares, which are not used to such procedures, has the potential of being considerable for at least some of the mares and could in its most severe form be classified as moderate under point 2(k) of Section III of Annex VIII of the Directive by "*evoking escape and avoidance reactions where the animal is unable to escape or avoid the stimulus, and are expected to result in moderate distress.*"

In this regard, it is noted that Section I of Annex VIII to the Directive classifies moderate procedures as:

Procedures on animals as a result of which the animals are likely to experience short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that are likely to cause moderate impairment of the well-being or general condition of the animals shall be classified as 'moderate'.

In the Authority's view, this assessment is reflected in a report by a working group appointed by the Icelandic Minister of Food, Agriculture and Fisheries, on the blood collection from pregnant mares²⁸ ("the report on blood collection from pregnant mares" or "the report"), which was published in May 2022. In the report it is stated that the blood collection itself is always stressful for the mares. However, it is noted that, as a result of the surveillance performed, usually the process goes well, and the mares recover in a relatively short time.²⁹

According to the report, there are three factors that need to be given a specific consideration during the process. First, when the mares are driven to the stalls for blood collection, they are gathered in a corral together with their foals where it can get crowded and where a lot of stress can be created. Second, when the mares are driven into the blood collection stall, where they are separated from their foals, tied up, their head raised, and a needle inserted to their jugular vein. Third, the conditions immediately after the blood collection are also of importance. That is whether the mares have access to water and salt and can be reunited with their foals and relax.³⁰

It is emphasized in the report that good handling of the mares is a prerequisite for the blood collection to be acceptable from an animal welfare point of view. It is stated that it is undisputed that the blood collection itself is a major intervention in the mares' lives and that things can go wrong if it is not done well. In the vast majority of cases, the mares seem to recover quickly from the blood collection and many even seem to get used to it quite well. However, it is noted that there are examples of mares that do not accept the intervention and that under such circumstances there is little else to do than to exclude them from the blood collection in general.³¹

²⁸ In Icelandic the title of the report is *Blóðtaka úr fylfullum hryssum. Starfsemi, regluverk og eftirlit* and it can be accessed at the following hyperlink: <https://www.stjornarradid.is/library/01--Frettatengt--myndir-og-skrar/MAR/Fylgiskjol/Skyrsla%20starfshops%20um%20blóðtöku%20úr%20fylfullum%20hryssum%20%20010622.pdf>.

²⁹ See the report on blood collection from pregnant mares, cited above, p. 38.

³⁰ *Ibid.*

³¹ *Ibid.*

Similar information is also given in a letter from MAST to the Icelandic Parliament dated 16 November 2022,³² where MAST presented its comments to a draft bill that proposes that blood collection from pregnant mares be banned. In the letter, MAST states that the local anaesthesia applied prevents pain but that the blood extraction causes discomfort and temporary distress (*vanlíðan*). MAST also notes that many things can go wrong, especially if the mares are not used to this role and/or if they are untamed or if the taming has failed. Those instances can lead to extreme stress and escape reactions.

Regarding the distress blood collection can cause to the pregnant mares, the Authority has also taken note of the scientific Article³³ referred to in the report on blood collection from pregnant mares as the only scientific Article available that deals directly with the blood collection from horses and its effect on their health and well-being.³⁴ The Article states that all the horses in the study developed moderate neck sweating, tachypnoea and tachycardia during the blood collection and that they also defecated and urinated at least once during the procedure.³⁵ While the amount of blood collected in the study was greater than in the Icelandic context, the information can serve as an indication on the level of stress experienced by horses when large amount of blood is collected. In the Article it is mentioned that all the horses participating in the study had undergone repeated blood collection in the past and therefore were accustomed to the procedure.³⁶

Lastly, the amount of blood collected and its frequency is also a factor that needs to be assessed in this context. If the amount of blood is more than the mares can tolerate then that in itself can cause them suffering that reaches the level provided for in Article 3(1) of the Directive.

According to the Icelandic Government blood collection takes place once per week for the maximum of eight weeks with the requirement that blood collection must be completed before 5 October each year. The maximum of blood that can be collected from each mare is five litres each time. This is also reflected in Article 6(d) and (e) of Regulation 900/2022 which sets out the same limits as regards the frequency of blood extractions and quantity of blood collected. The duration of the collection takes approximately five to ten minutes and the mare is then released into a pen where she gets access to water and salt and the foal is waiting for her.

In the report on blood collection from pregnant mares it is noted that there is not much scientific information available as regards the tolerance of mares to losing large amounts of blood. This applies both to their tolerance to the amount of blood that is collected each time as well as the quantity that is collected overall during the blood collection period.³⁷

Reference was made to the only scientific Article available that deals directly with the blood collection from horses and its effect on their health and well-being and it stated that the study was conducted to determine whether removal of approximately 25% of blood volume of horses (20 mL/kg of blood) resulted in adverse physiological effects. The report refers to the conclusion of the Article that the physiological effects of the blood collection on the main blood components were found to be temporary and within the reference range.³⁸

³² The letter can be accessed at the following hyperlink: <https://www.althingi.is/alttext/erindi/153/153-510.pdf>.

³³ See Malikides, N, J.L. Hodgson, J. L, R.J. Rose, R.J. and Hodgson, D.R. 2001, "Cardiovascular, Haematological and Biochemical Responses After Large Volume Blood Collection in Horses", The Veterinary Journal, volume 162, Issue 1, p. 44-55.

³⁴ See the report on blood collection from pregnant mares, cited above, p. 39.

³⁵ See Malikides N, J.L. Hodgson, J. L, R.J. Rose, R.J. and Hodgson, D.R., "Cardiovascular, Haematological and Biochemical Responses After Large Volume Blood Collection in Horses", cited above, p. 46.

³⁶ *Ibid*, p. 45.

³⁷ See the report on blood collection from pregnant mares, cited above, p. 39.

³⁸ *Ibid*.

In the Icelandic context, the report mentions that a blood sample of 20 mL/kg corresponds to 7.6 - 8.2 litres, which is a third more than is collected from the pregnant mares in Iceland. However, it is noted that the study did not include repeated collection of blood, but it is stated that most of the blood components were renewed in less than a week. It is also noted that the study was not performed on pregnant mares and that it is uncertain whether such circumstances have any effect.³⁹

Further, the report states that although there are no scientific studies available on the effects of extracting five litres of blood per week from pregnant mares, up to eight times in total, during the first half of pregnancy, the activity is based on decades of experience. The surveillance of the blood collection is manifold and has revealed that the health of the pregnant mares is good and production diseases almost unknown. There is full consistency between the internal control by the company responsible for the blood collection and MAST's surveillance of the pregnant mares. Measurements of haemoglobin in 2391 pregnant mares over a period of 11 years are also available, which give an overview of the mares' blood values one week after the blood collection. Those measurements indicate that the mares' blood loss is within limits that the mares can meet with their reserves (in the short term) and replenishment of new blood cells (in the long term). The concentration of haemoglobin remains within the reference range throughout the period of blood collection.⁴⁰

In MAST's letter to the Icelandic Parliament of 16 November 2022, the possible effects of the blood loss on the pregnant mares are listed. First, it mentions dehydration immediately following the blood extraction. In order to address the risk, there are conditions that the mares have access to water and salt immediately following the blood collection and that it is ensured that they have enough time to drink sufficiently before they are carefully driven to the pastures. It is noted that no symptoms of dehydration have been observed during MAST's monitoring of the blood collection.

Second, MAST mentions a drop in the concentration of calcium and other essential minerals in the blood. The result would be the metabolic disease Hypocalcemic Tetany, which is an acute and life-threatening disease. It is negligible that the pregnant mares develop that disease but according to information from the company responsible for the blood collection, the frequency has been approximately 2/5000 in recent years.

Third, MAST mentions a decrease in the concentration of haemoglobin in the blood. Among the conditions for the activities are the requirements that research is done every other year on the blood values in pregnant mares. According to the letter, the results of the research for 2021 is in line with the results of previous years. They show that the decrease in the average concentration of haemoglobin after the first two collections of blood was a total of 18% (from 13.3 g/dL to 10.9 g/dL), but after that no significant change in concentration was observed and haemoglobin levels remained stable throughout the period for blood collection. Haemoglobin reached its previous concentration two weeks after the termination of blood collection. In MAST's views this indicates that it takes the mares about two weeks to respond to the blood loss with increased blood production, as both water and grass are very rich in iron in Iceland. There is no indication that the drop in haemoglobin affects the mares' well-being or health, as the lowest average value during the blood collection period is within the reference limits given for horses in general and which have been observed in studies of the Icelandic horse. Nevertheless, great emphasis is placed on the mares not being subjected to strain when they are driven to and from the blood collection point.

The Authority has taken note of the information above but observes that there are some indications, according to the information available to the Authority, that the frequency of

³⁹ *Ibid*, p. 40.

⁴⁰ *Ibid*.

the collection of the blood is greater than generally recommended for horses.⁴¹ That information can serve as an indication that the total amount of blood extracted within the time frame of eight weeks exceeds the tolerable amount for the mares although data is not available in the Icelandic context as such.

In addition, the Authority notes that while the scientific Article referred to by the report on blood collection from pregnant mares concluded that “volumes less than or equal to 20 mL/kg when collected appropriately from selected healthy donor horses appeared to result in no adverse effects on physiological measurements”, it is clearly noted that “some significant effects on cardiovascular, haematological and biochemical variables were found over time, most variation in measurements occurred within published reference ranges and did not constitute a significant biological or physiological change.” It was also noted that recovery of the variables measured to pre-collection levels was rapid. Some variables did not show any difference in values. Recovery of packed cell volume, red blood cell count and Haemoglobin to pre-collection values took only three to nine days, while plasma total protein took 31 days to recover to values just below time zero values.⁴²

Irrespective of the fact that the scientific evidence is not conclusive on the issue, the Authority is of the opinion that the information referred to above makes it safe to conclude that the collection of five litres of blood from pregnant mares has sufficient physiological effects on them for such collection to be considered above the threshold laid down by Article 3(1) of Directive 2010/63. From the information, it is clear that the pregnant mares need time to recover and for the blood components to be renewed. In the Authority's view, such effects could be considered to cause “*moderate impairment of the [...] general condition of the animals*” so that it would constitute a moderate procedure under Section I of Annex III to the Directive. In that regard, the frequency of the blood extraction is also taken into account, in particular due to the assertion by the Icelandic Government that most of the blood components have recovered within the time between the collection of blood and MAST's assertion that it takes the mares about two weeks to respond to the blood loss experienced. In any event, the effects should at least be considered to be mild as that category also includes procedures “*with no significant impairment of the well-being or general condition of the animals.*”

Taking into consideration all the above, it must be concluded that the level of pain suffering, distress or lasting harm goes above the threshold set out in Article 3(1) of the Directive and that in terms of severity blood collection from pregnant mares for the production of PMCG/eCG hormone constitutes at least a mild procedure and possibly even a moderate one.

5.1.4 Exceptions from the applicability of the Directive

In its reply to the Authority's request for information Iceland maintains that the purpose of the blood collection is commercial and that it is a non-experimental agricultural practice that has been practiced in Iceland for over 40 years. Hence Iceland refers to the exception stated in Article 1(5)(a) of the Directive.

The National Competent Authorities' Working document of specific articles in Directive 2010/63,⁴³ *inter alia* provides the following in terms of agricultural practices.

⁴¹ See for example:

https://www.bvl.bund.de/SharedDocs/Downloads/05_Tierarzneimittel/Leitlinien_blutprodukte.pdf?sessionid=EEAAA9BFFC2A70054AEA562C01A94F3BE.1_cid363?__blob=publicationFile&v=3 and <https://www.sussexequinehospital.co.uk/blood-transfusions/>.

⁴² See *Cardiovascular, Haematological and Biochemical Responses After Large Volume Blood Collection in Horses*, p. 53 to 54.

⁴³ See https://ec.europa.eu/environment/chemicals/lab_animals/pdf/Consensus_document.pdf. The document sets out the consensus on the understanding of the articles discussed at the meeting of the

Agriculture can be defined as the production of food, feed, fibre and other goods by the systematic raising of domesticated plants and animals. Agriculture covers all activities essential to food/feed/fibre production, including all techniques for raising and "processing" livestock. Agriculture includes agronomy, animal husbandry, and aquaculture. Agriculture practices are simply practices used in agriculture to facilitate farming.⁴⁴

As an example of agricultural practices the working document mentions *"disbudding/dehorning of cattle, castration of lambs, pigs and cattle, debeaking in poultry, nutritional manipulation of weight in broiler replacement breeders, rearing and weaning practices in dairy and veal calves, restraint around parturition e.g. pigs and advanced breeding techniques for agricultural purposes, such as embryo transfer and vasectomy to, for example, improve health or genetics of the flock or herd."*⁴⁵

Despite the Icelandic Government's contention that this is a general agricultural practice, it cannot be overlooked that the blood collection is for the purpose of producing medicinal products.

The Authority notes that from an agricultural perspective there is neither an independent need for the collection of blood from pregnant mares nor does it form an integral part of other agricultural practices. To the contrary, the blood collection forms an integral part of the production of a medicinal product which without the collection of blood would not be produced.

Therefore, it is the Authority's view, that the practice goes beyond what would be considered as non-experimental agricultural practices, taking also into consideration the general consensus on what is considered to fall under Article 1(5)(a) of the Directive and thus outside its scope.

It is also the Authority's view that the practice does not fall under any other exception provided for in Article 1(5) of the Directive.

5.1.5 Purposes of the procedure

As noted above, Article 1(2) of the Directive provides that the Directive shall apply where animals are used or intended to be used in procedures. The definition of procedure in Article 3(1) includes three types of purposes for a use of an animal to be considered a procedure: 1) experimental; 2) scientific; or 3) educational.

As noted above, the procedure in question has a scientific purpose and falls under the definition of a procedure set forth in Article 3(1) of the Directive.

In addition, Article 5 of the Directive, provides that procedures may only be carried out for the purposes set out therein. That includes the following:

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

[...]

(ii) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or

[...]

National Contact Points on 6-7 October 2011. It is intended to promote uniform implementation and application of the Directive.

⁴⁴ National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes Working document on specific articles in Directive 2010/63/EU, p. 2.

⁴⁵ *Ibid*, p. 3.

(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;

In its reply to the Authority's request for information, the Icelandic Government states the following (the Authority's emphasis):

*"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 of 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."*

It is the Authority's opinion, that the purposes set out in Article 5 of the Directive do not determine whether the procedure as such falls under its scope, but provide for further conditions that need to be fulfilled for the granting of an authorisation for the procedure in question. From the provision it can be inferred that if the procedure is not carried out for those purposes, it cannot be carried out at all.

One of those purposes, is set forth in Article 5(c) which provides that a procedure can be carried out for any of the aims in point (b)⁴⁶ in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products.

It can be inferred from the text referred to above (emphasised in bold) that the Icelandic Government does not consider that the manufacture of drugs as such is one of the purposes authorised by Article 5(c) of the Directive. That also takes into consideration the discussions at the package meeting in Iceland where this was debated.

It is the Authority's view, that it is not pertinent to interpret the provision as suggested by the Icelandic Government as that would entail a reading under which the collection of the blood would be done in order to manufacture the quality, effectiveness or the safety of drugs. Taking also into consideration that the reporting obligation of the EEA States foresees reporting on procedures for the purposes of routine production of blood based products, that argumentation is somewhat flawed.

Therefore, it seems more appropriate to read the provision differently and along the lines that a procedure can be carried out for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of *any of the following*: drugs, foodstuffs and feed-stuffs and other substances or products.

It follows, that the blood collection from pregnant mares for the production of PMSG/eCG hormones is in accordance with Article 5(c) of the Directive to be for the manufacture of drugs with the aim to regulate or modify physiological conditions in animals.

5.1.6 Conclusion on the applicability of Directive 2010/63

Taking into consideration all of the above, it must be concluded that the blood collection from pregnant mares for the production of PMSG/eCG hormone falls under the definition of a procedure as defined in Article 3(1) of the Directive as it entails the use of an animal for other scientific purposes which may cause the animal level of pain, suffering, distress or lasting harm at least equivalent to (and possibly higher than) that caused by the introduction of a needle in accordance with good veterinary practice.

⁴⁶ Considering point (ii) of point (b) being fulfilled in the instance of this case.

It follows, that the procedure falls under the scope of the Directive as its Article 1(2) provides that it shall apply where animals are used or intended to be used in procedures.

5.2 Obligations of the EEA States concerning procedures under Directive 2010/63

It follows from the conclusion in Section 5.1.6 above that Directive 2010/63 is applicable to the blood collection from pregnant mares, that the process prescribed therein must be followed for such procedures.

That entails that the procedure must be assessed and authorised in accordance with the requirements set out by the Directive.

The Directive requires not only that each project has been authorised, cf. its Article 36(1), but also that all breeders, suppliers and users are authorised and registered with the competent authority, cf. Article 20(1) of the Directive. Thus, there is a requirement that not only a project is assessed under the Directive but also those involved in the project.

In addition, where a breeder, supplier or user no longer complies with the requirements set out in the Directive, action needs to be taken in order to remedy the situation or to suspend or withdraw the authorisation granted, cf. Article 21(1) of the Directive.

Article 37(1) of the Directive provides that an application for a project includes at least the project proposal, a non-technical project summary and information on the elements that are set forth in Annex VI to the Directive:

From both Article 37(1) and the list of elements referred to in Annex VI, it can be seen that the application for a project authorisation needs to be quite detailed and e.g. relevance and justification provided for the reasons why the use of animals is necessary as well as how the welfare of the animals used is ensured.

In particular, point 2 of Annex VI provides that the application needs to include information how methods to replace, reduce and refine the use of animals in procedures will be applied. According to a working document⁴⁷ on the non-technical project summaries, the applicant needs to demonstrate that the potential alternatives to the use of live animals have been thoroughly explored, and that no suitable alternatives have been identified.⁴⁸

According to recital 39 to the Directive, the likely harm to the animal should be balanced against the expected benefits of the project. Therefore, an impartial project evaluation independent of those involved in the study should be carried out as part of the authorisation process of projects involving the use of live animals.

Echoing that principle, Article 36(2) provides that the EEA States shall ensure that no project is carried out unless a favourable project evaluation has been received.

⁴⁷ Following the adoption of Directive 2010/63 the National Contact Points of the Member States and the Commission agreed to discuss a number of articles contained in the Directive with the aim to finding a common approach. Some elements were referred to a specific Expert Working Group meetings. The outcome of those meetings were then submitted to the National Contact Points for endorsement. The consensus on the elements discussed under this procedure have been published in number of documents on the different elements. Where applicable, those documents will be referred to below in order to be able to further elaborate upon issues that fall under specific provisions of the Directive.

⁴⁸ See *National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes. A working document on Non-technical Project Summaries*, p. 16-17. The working document was revised and endorsed by the national competent authorities on 25 to 26 November 2021. The document can be accessed at the following hyperlink:
https://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed%20NTS.pdf .

Article 38(1) of the Directive provides that the project evaluation shall be performed with a degree of detail appropriate for the type of project and shall verify that the project is justified from a scientific or education point of view or required by law, its purpose justifies the use of animals, and that it is designed to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.

Article 38(2) sets out the requirements that the project evaluation shall consist of. They consist e.g. in the evaluation of the objectives of the project, the predicted scientific benefits or educational value; an assessment of the compliance of the project with the requirement of replacement, reduction and refinement; an assessment and assignment of the classification of the severity of the procedure and a harm-benefit analysis of the project.

Furthermore, Article 38(3) states that the competent authority carrying out the project evaluation shall consider expertise in certain areas, one of them being the areas of scientific use for which the animals will be used including replacement, reduction and refinement in the respective areas.

The Directive does not entail that a common format is used for project evaluations and the setup in this regard is left up to the individual EEA State. However, Articles 38(1) and (2) provide for a number of aspects that need to be assessed with the degree of detail appropriate for the type of project, implying that the degree of detail can vary depending on the project in question.

The main element of importance in the assessment in the context of this case follows from Article 4(1)⁴⁹ of the Directive which provides that it shall be ensured, wherever possible, that a scientifically satisfactory method or testing strategy, not entailing the use of live animals, is used instead of a procedure. This is further reflected in Article 13(1) of the Directive which provides that EEA States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under EEA law.

This entails that if it is the conclusion of the Icelandic authorities following an assessment in accordance with the Directive, that the same result can be achieved without using live animals then the blood collection from pregnant mares shall not be carried out (“necessity test”).

Neither the Directive nor the working documents on the project evaluation and retrospective assessment⁵⁰ mention specifically how detailed the assessment needs to be as regards this particular issue, but it seems safe to deduct from Articles 4(1) and 13(1) of the Directive, read in conjunction with the working document for the context of this case, that the assessment needs to reflect that consideration has been taken of the fact that other medicines are available.⁵¹ Taking also into consideration that the non-technical project summary needs to contain information that alternatives have been thoroughly explored and that no suitable alternatives have been found, it can be inferred that some sort of comparison of the alternative medicines needs to take place in the assessment.

⁴⁹ Article 4 of the Directive provides for the requirement of replacement, reduction and refinement, which is one of the elements to be assessed in the project evaluation, cf. Article 38(2)(h) of the Directive.

⁵⁰ See *National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes. Working document on Project Evaluation and Retrospective Assessment*. The document was endorsed by the national competent authorities on 18 to 19 September 2013. The document can be accessed at the following hyperlink: https://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_PE-RA.pdf.

⁵¹ See *National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes. Working document on Project Evaluation and Retrospective Assessment*, p. 19.

The complainants maintain that numerous alternatives are available to breeders for the induction and synchronisation of oestrus in farmed animals and their efficacy is very similar to PMSG according to studies and practical experience. It was noted that in Germany there are 36 synthetic hormones available for different animal species and indications.

In its reply to the request for information the Icelandic Government stated that to its 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.

Another aspect of importance for the assessment is the harm-benefit analysis that must be conducted in accordance with Article 38 of the Directive. Part of this is a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment.

5.3 The compliance of the Icelandic legal environment and administrative practice with Directive 2010/63

As noted in Section 2 above, the Icelandic Government expressed its view that Directive 2010/63 is not applicable to the procedure of blood collection from pregnant mares in Iceland. Due to this, the Icelandic Government maintained that blood collection from pregnant mares is not subject to assessment under Regulation No 460/2017 which implemented the Directive in Iceland.

It follows from the Icelandic Government's declaration and the provisions of Regulation No 900/2022 that administrative practice does not subject blood collection from pregnant mares to the procedures and assessments provided for by the Directive and in the Icelandic context Regulation No 460/2017. In that regard it is noted that the case law of the EFTA Court provides that declarations such as the one in the case at hand confirming administrative practice can serve as an evidence of its consistent and general nature.⁵²

In that regard, the Authority observes that there is nothing in Regulation No 460/2017 that prevents blood collection from pregnant mares being subjected to the assessment under the Regulation. To the contrary, in light of the Authority's conclusion set out above that blood collection from pregnant mares falls under the term procedure under Directive 2010/63 and thus its scope of application according to its Article 2(1), it is the Authority's view that the blood collection from pregnant mares should indeed be subject to the processes and assessments provided for in Regulation No 460/2017.

According to Article 2(2)(a) of Regulation No 460/2017, it applies to animals when they are used or intended to be used in experiments. While the Icelandic term for experiment is in general regarded to have a narrower scope than the term procedure, the Authority notes that the wording is in line with the wording of the Icelandic version of Article 1(2) of Directive 2010/63.

Further, the definition of experiment according to Article 3(a) Regulation No 460/2017 is in line with the definition of procedure in Directive 2010/63 stating that the term experiment means "*any use of an animal for experimental or other scientific purposes 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 good veterinary practice.*"

⁵² Case E-6/12 *EFTA Surveillance Authority v The Kingdom of Norway* [2013] EFTA Ct. Rep. 618, paragraphs 60-63.

Therefore, it seems to be safe to conclude that the meaning of the term experiment under Regulation No 460/2017, as well as the Icelandic version of the Directive, is broader than the general understanding of the word encompassing the same features as the term procedure.

It is also the Authority's view that the procedure does not fall within any of the exceptions set out in Article 2(5) of Regulation No 460/2017, which reflects Article 1(5) of the Directive.

As noted in Section 1 above, Regulation No 900/2022 on blood collection from pregnant mares was adopted in Iceland in August 2022. The regulation was adopted following a proposal from the working group which delivered the report on the blood collection from pregnant mares. In the report it is stated that the aim of the proposal was to address the lack of clarity in the Icelandic legal environment in terms of the blood collection as well as to make it clear that the procedures do not fall under the scope of Regulation No 460/2017.⁵³

Having assessed Act No 55/2013 and Regulation No 900/2022, the Authority must conclude that there are some shortcomings to the processes established by them as well as the assessment performed from the perspective of Directive 2010/63.

According to Article 2(1) of Regulation No 900/2022 the term blood collection in the context of the regulation only applies to the act of extracting blood from pregnant mares for the collection of the eCG hormone. Article 3(1) provides that a prior notification to MAST in accordance with Article 12 of Act No 55/2013, is required in order to be able to hold horses for blood collection. The notification must be received no later than 60 days before the blood collection begins.⁵⁴

Article 12(1) of Act No 55/2013 provides that extensive and technologically sophisticated animal facilities must be notified to MAST before they start their operations. For such operations to begin certain conditions relating to the premises, equipment and knowledge of those involved must be fulfilled and an inspection carried out by MAST.

Article 3(2) of Regulation No 900/2022 lays down the obligation to obtain a permit from MAST for the blood collection from pregnant mares which is granted to the buyer of the blood for the period of three months and is limited to establishments where the holding of horses for blood collection has been notified to MAST and inspected by them. The permit is granted on the basis of Article 20 of Act No 55/2013.

Article 20 of Act No 55/2013 deals with experimental, educational and medical activities. Article 20(1) provides that live animals may not be used for educational or experimental purposes, research, the production or testing of chemicals or drugs, or medical diagnosis, except with the express authorisation of MAST, in those cases where such use causes the animals to experience distress or pain.

While Article 3 of Regulation No 900/2022 and Articles 12(1) and 20(1) of Act No 55/2013 ensure that blood collection from pregnant mares is subject to authorisation from MAST and that those keeping horses for blood collection notify MAST of their activities, it is not clear that the authorisation obligation applies to all projects as required by Article 36(1) Directive and there is no authorisation requirement for breeders and suppliers as required by Article 20(1) of the Directive.

⁵³ See report on the blood collection from pregnant mares, cited above, p. 46.

⁵⁴ The Authority notes that Article 4 of Regulation No 910/2014, cf. point 6 of its Annex I, similarly provides that horse farming where blood is drawn from horses for the production of products is notifiable to MAST no later than 30 days before the planned activity begins. Thus, it appears that the Icelandic legal environment is not fully consistent in terms of the notification obligation. However, as Regulation 900/2022 is specifically aimed at the blood collection from pregnant mares the Authority bases its conclusion in this case on that regulation in this context.

Similarly, the Icelandic legal environment falls short when it comes to ensuring that when a breeder, supplier or user no longer complies with the requirements set out in the Directive, action is taken in order to remedy the situation or to suspend or withdraw the authorisation granted, cf. Article 21(1) of the Directive.

Article 35 of Act No 55/2013 provides that MAST may limit or halt operations for serious or repeated offences or when the parties concerned fail to comply with its directions within the specified time limit. Under Article 36(2) of Act No 55/2013 MAST can also require remedies to be implemented.

However, the threshold for revocation of a licence under Article 44 of Act No 55/2013 is higher than the threshold for such revocation under the Directive. Moreover, the Authority has some doubts as regards whether licences granted to users, as defined in Article 3(6) of the Directive, can be revoked under the provision as it only applies to licences to keep animals, to be involved in animal trading or dealing with animals in other ways.

Moreover, Article 36(2) of the Directive provides that the EEA States shall ensure that no project is carried out unless a favourable project evaluation has been received and Article 38 provides for further requirements as regards the performance of the project evaluation and its content.

Regulation No 900/2022 does not lay down any such requirements nor can they be inferred from the provisions of Act No 55/2013. This entails, in particular that it cannot be affirmed that the assessment provided for in Articles 4 and 13(1) of the Directive has been carried out during the evaluation of the project under Article 38.

As noted in Section 5.2 above, the Icelandic Government maintains that to its knowledge there is no evidence that there are equally effective alternative methods available in the case at hand, that do not involve the use of live animals.

However, the Authority has received no information from the Icelandic Government indicating that a project evaluation entailing the elements set out in Article 38 of the Directive, including an assessment as to whether a scientifically satisfactory method or testing strategy, not entailing the use of live animals can be used, is carried out.

It is the Authority's view that it is for the Icelandic Government to assess the scientific evidence available in order to evaluate whether there are in place equally effective alternative methods without the use of live animals and to base its conclusion as regards applications for authorisation of the procedures on that evidence.

The Authority's conclusion is thus that by not carrying out the aforementioned project evaluation based on the relevant assessments, Iceland is in breach of Articles 36 and 38 of the Directive. This conclusion is however without prejudice to the outcome of such evaluation.

Similarly, neither Regulation No 900/2022 nor Act No 55/2013 contain any requirements to the content of an application for a project authorisation as provided for in Article 37 of the Directive. In that regard, the Authority has also taken into consideration the conclusion above that it is not clear from the wording of Article 3(2) of Regulation No 900/2022, read in conjunction with Article 20 of Act 55/2013, that it is required that each project is authorised as is required by the Directive.

The Authority notes that Article 6 of Regulation No 900/2022 provides for the general requirements for the blood collection from pregnant mares. The provision lays down certain requirements related to their wellbeing, such as the obligatory use of local anaesthesia, the maximum amount of blood that can be collected from each mare, the

age of the mares used, physique, facilities and access to water and salt immediately after the blood collection. It is provided that the well-being of the mares shall be ensured during that process and that if the blood collection causes suffering to the mare or threatens its well-being, blood collection from the mare in question must be stopped immediately.

It can be inferred from the provision that it is intended to ensure the wellbeing of the mares during the blood collection and it touches upon certain aspects that would generally be assessed under the project evaluation or that are set out in general terms in the Directive. The provision is in line with Article 14 of the Directive which provides for the obligation of EEA States to ensure where appropriate that procedures are carried out under general or local anaesthesia, but otherwise it does not as such implement the requirements set out in Article 38 of the Directive or any other of its provisions.

Lastly, the Authority recalls that Article 3 EEA not only requires EEA States to take all measures necessary to guarantee the application and effectiveness of EEA law but also to abstain from any measure that could jeopardise the attainment of the objectives of the EEA Agreement.

It is established in the case law of the EFTA Court that:

*Article 3 EEA requires the EEA States to take all measures necessary, regardless of the form and method of implementation, to ensure that a directive which has been implemented [...] prevails over conflicting national law and to guarantee the application and effectiveness of the directive. [...] The Court recalls that the EEA States may not apply rules which are liable to jeopardise the achievement of the objectives pursued by a directive and, therefore, deprive it of its effectiveness [...]*⁵⁵

In that regard the Authority notes that instead of subjecting the blood collection from pregnant mares to the processes and assessments under Regulation No 460/2017 which in the Authority's opinion is the appropriate basis for such procedures, the Icelandic Government has by its adoption of Regulation No 900/2022 enhanced the situation of legal uncertainty that already had been identified in Iceland as regards the legal basis for the collection of blood from pregnant mares⁵⁶ and failed to ensure the effectiveness of Directive 2010/63. Subjecting the blood collection from pregnant mares to the provisions of a different legal act and regulation jeopardises the aim of the Directive to raise the minimum standards for the protection and wellbeing of animals as well as the attainment of the requirement of the Directive that no procedure is authorised unless it has been assessed in accordance with the Directive.

5.4 Summary of the Authority's assessment

As outlined above, the Authority is of the view that the blood collection from pregnant mares for the production of PMSG/eCG hormone falls under the definition of a procedure as defined in Article 3(1) of the Directive as it entails the use of an animal for other scientific purposes which may cause the animal level of pain, suffering, distress or lasting harm at least equivalent to (and possibly higher than) that caused by the introduction of a needle in accordance with good veterinary practice.

Accordingly, the procedure falls under the scope of the Directive as its Article 1(2) provides that it shall apply where animals are used or intended to be used in procedures.

⁵⁵ Case E-12/13 *EFTA Surveillance Authority v Iceland* [2014] EFTA Ct. Rep. 58, paragraph 73. See also Case E-15/12 *Jan Anfinn Wahl v the Icelandic State* [2013] EFTA Ct. Rep. 534, paragraph 54.

⁵⁶ See the report on the blood collection from pregnant mares, cited above, p. 46.

It follows from that conclusion that the process prescribed in the Directive must be followed for such procedures which entails that in practice the procedure must be assessed and authorised in accordance with the requirements set out by the Directive.

As the Icelandic legal environment and administrative practice currently stand blood collection from pregnant mares is not subject to the processes and the assessments provided for in Regulation No 460/2017 which implements the Directive.

While a special regulation – No 900/2022 – on the blood collection from pregnant mares has been adopted in Iceland, neither that Regulation nor Act No 55/2013 ensure compliance with the provisions of the Directive.

First, while blood collection from pregnant mares is in general subject to an authorisation from MAST, the Icelandic legal environment neither makes it certain that each project is subject to an authorisation in accordance with Article 36(1) of the Directive, nor does it include an authorisation requirement for breeders and suppliers as required by Article 20(1) of the Directive.

Second, it is not fully ensured that when a breeder, supplier or user no longer complies with the requirements set out in the Directive, action is taken in order to remedy the situation or to suspend or withdraw the authorisation granted, cf. Article 21(1) of the Directive.

Third, a project evaluation in line with Articles 36(2) and 38 of the Directive is not carried out before a project is authorised. That entails that it is not ensured that projects are only carried out when a favourable project evaluation has been received as required by Article 36(2) of the Directive. It follows that the requirements in Article 38 of the Directive as regards the performance of the project evaluation and its content cannot be considered to be fulfilled. That entails, that it cannot be considered ensured that the assessment provided for in Articles 4 and 13(1) of the Directive has been carried out during the evaluation of the project under Article 38.

Fourth, Article 3(2) of Regulation No 900/2022, read in conjunction with Article 20 of Act No 55/2013, does not set out any requirements for the content of an application for an authorisation for blood collection from pregnant mares. Taking also into consideration that it is not clear that every project should be subject to authorisation under Article 3(2) of Regulation No 900/2022, the requirements to the content of an application for a project authorisation set out in Article 37 of the Directive are not fulfilled, including as regards the request for information on the elements set out in Annex VI of the Directive.

Lastly, by its adoption of Regulation No 900/2022 the Icelandic Government has further enhanced the situation of legal uncertainty that already had been identified in Iceland as regards the legal basis for the collection of blood from pregnant mares.

The Authority recalls that Article 3 of the EEA Agreement required EEA States to take all measures necessary to guarantee the application and effectiveness of EEA law and also to abstain from any measure that could jeopardise the attainment of the objectives of the EEA Agreement.

By its adoption of Regulation No 900/2022 the Icelandic Government has enhanced the situation of legal uncertainty as regards the legal basis for the collection of blood from pregnant mares and failed to ensure the effectiveness of Directive 2010/63.

Consequently, it is the Authority's view that Iceland has failed to take the appropriate measures to ensure fulfilment of the obligations arising out of the EEA Agreement.

6 Conclusion

Accordingly, as the information presently stands, the Authority must conclude 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 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 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 requests that the Icelandic Government submits its observations on the content of this letter *within two months* of its receipt.

After the time limit has expired, the Authority will consider, in the light of any observations received from the Icelandic Government, whether to deliver a reasoned opinion in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice.

For the EFTA Surveillance Authority

For Arne Røksund
President

Stefan Barriga
College Member

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This document has been electronically authenticated by Stefan Barriga, Mel-po-Menie Josephides.