JUDGMENT OF THE COURT

16 September 2026*

(Directive 2010/63/EU – Animal welfare – Blood farming – Equine chorionic gonadotropin/Pregnant mare serum gonadotropin – Non-experimental agricultural practices – Practices undertaken for the purposes of recognised animal husbandry – Definition of 'procedure')

In Case E-24/25,

REQUEST to the Court under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by the District Court of South Iceland (*Héraðsdómur Suðurlands*), in the case between

Ísteka ehf.

and

Matvælastofnun (The Icelandic Food and Veterinary Authority),

THE COURT,

composed of: Páll Hreinsson, President, Bernd Hammermann (Judge-Rapporteur) and Michael Reiertsen, Judges,

Registrar: Ólafur Jóhannes Einarsson,

having considered the written observations submitted on behalf of:

– Ísteka ehf. ('the Plaintiff' or 'Ísteka'), represented by Peter Dalmay, advocate;

– Matvælastofnun (The Icelandic Food and Veterinary Authority) ('the Defendant'), represented by Þorvaldur Hauksson, acting as Agent;

* Language of the request: Icelandic. Translations of national provisions are unofficial and based on those contained in the documents of the case.

– the EFTA Surveillance Authority (‘ESA’), represented by María Escobar Gómez, Sigurbjörn Bernharð Edvardsson, Sigrún Ingibjörg Gísladóttir and Melpo-Menie Joséphidès, acting as Agents; and

– the European Commission (‘the Commission’), represented by Flor Castilla Contreras, Dorota Milanowska and Ken Mifsud Bonnici, acting as Agents,

having heard oral arguments of the Plaintiff, represented by Peter Dalmay; the Defendant, represented by Þorvaldur Hauksson; ESA, represented by María Escobar Gómez and Sigurbjörn Bernharð Edvardsson; and the Commission, represented by Dorota Milanowska and Flor Castilla Contreras, at the hearing on 11 March 2026,

gives the following

J U D G M E N T

I INTRODUCTION

1 This request for an advisory opinion from the District Court of South Iceland (*Héraðsdómur Suðurlands*) concerns the interpretation of Article 1(2), Article 3(1) and the provisions of Article 1(5)(a), (d) and (f) of 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 (‘the Directive’ or ‘Directive 2010/63/EU’). The questions referred concern firstly whether Article 1(2) must be interpreted as meaning that blood collection from pregnant mares for the production of the active pharmaceutical ingredient equine chorionic gonadotropin (‘eCG’), also known as pregnant mare serum gonadotropin (‘PMSG’), constitutes a ‘procedure’ using animals within the meaning of Article 3(1) and, if that is the case, whether the provisions of Article1(5)(a), (d) and (f) of the Directive must be interpreted in such a way that that directive does not apply to the blood collection practice in Iceland.

II LEGAL BACKGROUND

EEA law

2 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 2010 L 276, p. 33, and Icelandic EEA Supplement 2015 No 8, p. 167) was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 256/2014 of 12 December 2014 (OJ 2015 L 311, p. 4, and Icelandic EEA Supplement 2015 No 71, p. 4) (‘JCD No 256/2014’). JCD No 256/2014 inserted the Directive in point 9b of Part 7.1 of Chapter I of Annex I (Veterinary and phytosanitary matters) to the EEA Agreement and as point 7 of Chapter XIII of Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement. Pursuant to Article 4 of JCD No 256/2014, that ‘Decision shall enter into force on 13 December 2014, provided that all the notifications under Article

103(1) of the EEA Agreement have been made, or on the day of the entry into force of the Decision of the EEA Joint Committee No 197/2015 of 25 September 2015, whichever is the later'. Constitutional requirements were indicated by Norway. The requirements were fulfilled by 26 May 2015. Constitutional requirements were indicated by Iceland as regards Decision of the EEA Joint Committee No 197/2015 of 25 September 2015 (OJ 2017 L 85, p. 1, and Icelandic EEA Supplement 2017 No 19, p. 1) ('JCD No 197/2015'). The requirements were fulfilled by 10 June 2016. JCD No 197/2015 and JCD No 256/2014 entered into force on 1 August 2016.

3 Recitals 6, 10 to 12 and 31 of the Directive read:

> *(6) 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.*
>
> *(10) 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.*
>
> *(11) The care and use of live animals for scientific purposes is governed by internationally established principles of replacement, reduction and refinement. To ensure that the way in which animals are bred, cared for and used in procedures within the Union is in line with that of the other international and national standards applicable outside the Union, the principles of replacement, reduction and refinement should be considered systematically when implementing this Directive. When choosing methods, the principles of replacement, reduction and refinement should be implemented through a strict hierarchy of the requirement to use alternative methods. Where no alternative method is recognised by the legislation of the Union, the numbers of animals used may be reduced by resorting to other methods and by implementing testing strategies, such as the use of in vitro and other methods that would reduce and refine the use of animals.*
>
> *(12) Animals have an intrinsic value which must be respected. There are also the ethical concerns of the general public as regards the use of animals in procedures. Therefore, animals should always be treated as sentient creatures and their use in procedures should be restricted to areas which may ultimately*

benefit human or animal health, or the environment. The use of animals for scientific or educational purposes should therefore only be considered where a non-animal alternative is unavailable. Use of animals for scientific procedures in other areas under the competence of the Union should be prohibited.

(31) Animal-welfare considerations should be given the highest priority in the context of animal keeping, breeding and use. Breeders, suppliers and users should therefore have an animal-welfare body in place with the primary task of focusing on giving advice on animal-welfare issues. The body should also follow the development and outcome of projects at establishment level, foster a climate of care and provide tools for the practical application and timely implementation of recent technical and scientific developments in relation to the principles of replacement, reduction and refinement, in order to enhance the life-time experience of the animals. The advice given by the animal-welfare body should be properly documented and open to scrutiny during inspections.

4 Article 1(1), (2) and (5) of the Directive, entitled 'Subject matter and scope', reads:

1. This Directive establishes measures for the protection of animals used for scientific or educational purposes.

To that end, it lays down rules on the following:
(a) the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures;
(b) the origin, breeding, marking, care and accommodation and killing of animals;
(c) the operations of breeders, suppliers and users;
(d) the evaluation and authorisation of projects involving the use of animals in procedures.

2. 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.

This Directive shall apply until the animals referred to in the first subparagraph have been killed, rehomed or returned to a suitable habitat or husbandry system.

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.

5. 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.

5 Article 3 of the Directive, entitled 'Definitions', reads, in extract:

For the purposes of this Directive the following definitions shall apply:

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 Article 4 of the Directive, entitled 'Principle of replacement, reduction and refinement', reads:

1. 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.

2. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project.

3. Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.

4. This Article shall, in the choice of methods, be implemented in accordance with Article 13.

7 Article 5 of the Directive, entitled 'Purposes of procedures', reads:

Procedures may be carried out for the following purposes only:

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

(i) the avoidance, prevention, diagnosis or treatment of disease, ill-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;

(d) protection of the natural environment in the interests of the health or welfare of human beings or animals;

(e) research aimed at preservation of the species;

(f) higher education, or training for the acquisition, maintenance or improvement of vocational skills;

(g) forensic inquiries.

8 Article 13 of the Directive, entitled 'Choice of methods', reads:

1. 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.

2. In choosing between procedures, those which to the greatest extent meet the following requirements shall be selected:

(a) use the minimum number of animals;
(b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;
(c) cause the least pain, suffering, distress or lasting harm;
and are most likely to provide satisfactory results.

3. Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to:

(a) result in the deaths of as few animals as possible; and
(b) reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as possible, ensure a painless death.

National law

9 Article 20(1) and (4) of Act No 55/2013 on Animal Welfare (*Lög nr. 55/2013 um velferð dýra*) ('the Animal Welfare Act'), entitled 'Experimental, educational and medical activities' (*Tilraunir, kennsla og læknisfræðileg starfsemi*), reads:

> *(1) 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 licensing, provided that the issued licence authorises the use of live animals for the abovementioned purposes.*
>
> *(4) The Minister shall issue a Regulation containing more detailed provisions on animal testing, including on the care of experimental animals and the supervision of animal testing, and on the education and training of persons using animals for experimental purposes.*

10 Article 1 of Regulation No 460/2017 on the protection of animals used for scientific purposes (*Reglugerð nr. 460/2017 um vernd dýra sem eru notuð í vísindaskyni*) 'Regulation No 460/2017' reads:

> *The purpose of the Regulation is to promote the restriction of the use of animals for scientific and educational purposes, to promote the welfare and respect of animals used for such purposes, and to ensure that animals used for such purposes are not subjected to unnecessary stress.*

11 Article 2(1)(a), (4) and (5) of Regulation No 460/2017 read:

> *1. This Regulation applies to animals in the following cases:*
>
> *a. when used or intended to be used in experiments, or*
>
> *4. The provisions of this Regulation shall also apply when sedatives, analgesics, anaesthesia or other methods are used to ensure that the animal does not experience pain, fear, permanent damage or other forms of stress. The Regulation applies until the animals have been killed, rehomed or returned to a suitable habitat or into an appropriate breeding system.*
>
> *5. The Regulation does not apply to the following:*
>
> *a. non-experimental agricultural or aquaculture usages;*
> *b. non-experimental clinical veterinary practices,*
> *c. clinical trials of veterinary medicinal products when required for the issuance or maintenance of marketing authorisations;*
> *d. practices related to recognised animal husbandry,*
> *e. practices involving simple identification of animals, or*

f. practices not likely to cause pain, suffering, distress, or lasting harm equivalent to or higher than that caused by introduction of a needle in accordance with good veterinary practice.

12 Article 3 of Regulation No 460/2017 reads:

> *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.*

III FACTS AND PROCEDURE

13 The Plaintiff, Ísteka, is a pharmaceutical biotechnology company founded in 1990 that manufactures eCG from blood plasma obtained from pregnant mares. The practice has been described to the Court in the following way. The mares are always naturally mated by a stallion. At around day 40 of pregnancy, a blood sample is taken to determine whether the mare is producing eCG hormone. Once the mare tests positive, her blood may be collected. The collection takes place in specially designed stalls located on blood collection farms. This is subject to surveillance by the Defendant and under the supervision of veterinarians working under the Plaintiff's auspices.

14 The mare is led into the stall where she is tied up and handled by a veterinarian. Before the procedure begins, the veterinarian administers a local anaesthetic to numb the area around the jugular vein. A hypodermic needle is then inserted into the jugular vein and the blood is collected. The blood flows into a designated container and no more than five litres are taken at any one time. The collection itself typically lasts around 10 to 15 minutes. The collection process may be repeated once per week during a season, which lasts approximately two and a half months from late summer to autumn, provided that the hormone remains present in the mare's blood. In practice, blood may be collected up to eight times per mare. After each session, the mare is released into a paddock where she has access to water and salt and is reunited with her foal. The pregnancies progress to term and are not terminated by inducing abortions.

15 Once the blood is collected at the operational facility, it is transported to the Plaintiff's serum separation facility, where the blood plasma is separated from the blood cells. The eCG is then manufactured at the Plaintiff's Reykjavík factory where the final product is dried and packaged.

16 The Plaintiff's production is based, inter alia, on a production licence from the Icelandic Medicines Agency (*Lyfjastofnun*). The most recent production licence was issued on 3 March 2025 and it expires on 4 December 2027. In addition, the Plaintiff applied to the Defendant for a licence to collect blood on 28 November 2022. The Defendant granted

the requested licence on 13 December 2022 for 2022–2025, pursuant to Article 3 of Regulation No 900/2022 and on the basis of Article 20(1) of Act No 55/2013.

17 On 10 May 2023, ESA sent Iceland a letter of formal notice. The letter indicated, *inter alia*, that blood collection from pregnant mares constituted a procedure within the meaning of Article 3(1) of the Directive. However, under Icelandic law, Regulation No 460/2017 on the protection of animals used for scientific purposes, by which the Directive was transposed, was not applied to the collection of blood from mares. As a result, Iceland was considered by ESA to be in breach of its obligations under the EEA Agreement.

18 Subsequently, the Defendant notified the Plaintiff on 15 September 2023 that changes were planned to the regulatory framework pertaining to blood mare farming (*blóðmerahald*) and the collection of blood from pregnant mares. The notification indicated that the Ministry of Food, Agriculture and Fisheries ('the Ministry') had instructed the Defendant to notify the Plaintiff that the Ministry had accepted the reasoning set out by ESA in the aforementioned letter of formal notice, and that the 'regulation on blood collection from pregnant mares' would therefore 'be repealed as of the upcoming 1 November [2023]. From that time onward, all activities associated with blood mare farming will fall within the scope of Regulation No 460/2017'.

19 On 18 February 2025, the Plaintiff applied to the Defendant for an extension without a time limit of its licence to collect blood from pregnant mares, and in the alternative for a period of 4 years, on the basis of Article 20(1) of Act No 55/2013. In its request, the Plaintiff contended that Regulation No 460/2017 on the protection of animals used for scientific purposes does not apply to the Plaintiff's activities.

20 By letter dated 24 March 2025, the Defendant rejected the Plaintiff's application on the grounds that the Plaintiff's activity involving blood collection from pregnant mares was considered to constitute a procedure (*tilraun*) within the meaning of Regulation No 460/2017, and to fall within its scope of application. The letter indicated that a licence would not be granted unless the criteria of Regulation No 460/2017 were satisfied, but also communicated to the Plaintiff that it was entitled to appeal the authority's decision to 'treat the entire activity as falling within the scope of Regulation No 460/2017'. The Plaintiff disagrees with the Defendant's assessment, contending that Regulation No 460/2017 does not apply to its activities. Subsequently, the Plaintiff brought proceedings before the District Court of South Iceland (*Héraðsdómur Suðurlands*) contesting the Defendant's assessment.

21 Against this background, on 16 October 2025, the District Court of South Iceland decided to request an advisory opinion from the Court. The request, dated 16 October 2025, was registered at the Court on the same day. The District Court of South Iceland has referred the following questions to the Court:

1. *Must the provision of Article 1(2) of 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, cf. its Article 3(1), be interpreted as meaning that*

blood collection from pregnant mares for the production of PMSG/eCG hormone constitutes a "procedure" (Icelandic: "tilraun") using animals that falls within the scope of that directive?

2. *If the first question is answered in the affirmative, so that blood collection from pregnant mares for the production of PMSG/eCG hormone is held to constitute a procedure within the meaning of the Directive, must the provisions of points (a), (d) or (f) of its Article 1(5) be interpreted in such a way that that directive nevertheless does not apply to the blood collection if the view is taken that it has been practised in Iceland to produce PMSG/eCG hormone for approximately 40 years?*

22 Reference is made to the written observations published on the Court's website for a fuller account of the arguments and proposed answers submitted to the Court. Arguments of the parties are mentioned or discussed hereinafter only insofar as is necessary for the reasoning of the Court.

IV ANSWER OF THE COURT

The first question

23 By its first question, the referring court essentially asks whether the practice of collecting blood from pregnant mares in Iceland in order to produce PMSG/eCG hormone constitutes a 'procedure' within the meaning of the Directive.

24 The Plaintiff contends that the collection of blood from pregnant mares in order to subsequently produce PMSG/eCG does not constitute a procedure within the meaning of Article 3(1) of the Directive. The Plaintiff submits that the activity of blood collection does not make use of animals for 'experimental or other scientific purposes', which it asserts must be understood as aiming to generate knowledge or technology within the field of science, in other words, involving the systematic pursuit of knowledge. Rather, the Plaintiff argues that the activity constitutes a commercial, routine industrial harvesting of biological starting material used in downstream veterinary medicinal production following good manufacturing practice, and not a study, test, training or experiment on the mares themselves.

25 At the outset, the Court notes that the delimitation of the definition of procedures in relation to other activities not coming within the material scope of the Directive must be made having regard to the specific objective laid down in Article 1(1) thereof, namely the protection of animals used for scientific or educational purposes. Consequently, given the objective of the Directive, which is to provide for a high level of protection of animals, the provisions which delimit the Directive's scope, in particular those setting out the activities envisaged by the Directive, must be interpreted broadly.

26 The term 'procedure' is defined in Article 3(1) of the Directive as meaning 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.

27 The Court observes that the term ‘or other scientific purposes’ in Article 3(1) of the Directive indicates that the scope is wider than scientific experiments in the pursuit of new knowledge. The wording is deliberately open-ended as the outcome may be ‘known or unknown’. Therefore, while the technical process of producing PMSG/eCG from mares’ blood may be well-known, having been practised in Iceland for almost 40 years, this does not exclude it from coming within the scope of the definition of a ‘procedure’ within the meaning of the Directive.

28 An interpretation entailing that activities of commercial, routine industrial harvesting of biological starting material used in downstream veterinary medicinal production are not excluded from the scope of the Directive finds further support in its objective. As noted in recital 10, the 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 by seeking to facilitate and promote the advancement of alternative approaches while seeking to ensure a high level of protection for animals that still need to be used in procedures.

29 Moreover, Article 5 of the Directive sets out in points (a) to (g) a series of closed categories where procedures may be carried out. These include (a) basic research and (b) translational or applied research with any of the identified aims set out in points (i) to (iii). Further, pursuant to point (c), procedures may be carried out 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.

30 The Court observes that, in circumstances such as the present case, the collection of blood from pregnant mares would fall within Article 5(c) of the Directive, as the blood collection is undertaken to manufacture a fertility drug for certain species of farm animals which seeks both to (ii) modify physiological conditions in animals and (iii) improve the production conditions for animals reared for agricultural purposes.

31 The Plaintiff further contends that the practice is 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.

32 In this regard, the Court observes that, as was confirmed at the hearing, before the blood is collected from the mare a veterinarian administers a local anaesthetic to numb the area around the jugular vein. A hypodermic needle is then inserted into the jugular vein and the blood is collected. In light of this characterisation, the Court notes that, in circumstances such as those in the present case, such administration of local anaesthetic followed by the introduction of needle in order to begin collecting the blood is liable to cause or reasonably capable of causing pain, suffering, distress or lasting harm higher than that caused by the introduction of a needle in accordance with good veterinary practice (‘needle threshold’).

33 The Court notes that Article 1(2) of the Directive explicitly provides that 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. Therefore, the needle threshold in Article 3(1) of the Directive is exceeded.

34 It follows from the above that the answer to the first question referred must be that Article 1(2) of the Directive, read in conjunction with Article 3(1), must be interpreted as meaning that blood collection from pregnant mares, in circumstances such as those in the main proceedings, for the production of PMSG/eCG hormone constitutes a 'procedure' that falls within the scope of that directive.

The second question

35 By its second question, the referring court essentially asks whether the practice of approximately 40 years of collecting blood from pregnant mares in Iceland in order to produce PMSG/eCG hormone is excluded from the scope of the Directive by points (a), (d) or (f) of Article 1(5) of the Directive.

36 The Plaintiff has contended that the manner in which the blood of pregnant mares is collected in Iceland is a non-experimental agricultural practice, within the meaning of Article 1(5)(a) of the Directive. The Plaintiff contends that that wording of that provision must be given its ordinary meaning. The Plaintiff asserts that since such a practice has been undertaken for approximately 40 years in Iceland it is therefore non-experimental. Further, the Plaintiff submits that the practice is plainly agricultural as the mares are kept and managed by farmers; the activity is embedded in livestock husbandry, subject to veterinary supervision, strict limits and welfare safeguards and forms part of the farmers' income streams. Furthermore, in Icelandic agricultural usage and practice, the activity has been understood as a farm-based harvesting of an animal product as the blood plasma contains a naturally occurring hormone. Therefore, the practice is analogous to other recurring harvests from live animals.

37 The Court recalls that the interpretation of a provision of EEA law requires account to be taken not only of its wording, but of its context and the objectives and purpose pursued by the act of which it forms part. The legislative history of a provision of EEA law may also reveal elements that are relevant to its interpretation. Moreover, where a provision of EEA law is open to several interpretations, preference must be given to the interpretation which ensures that the provision retains its effectiveness (see the judgment of 7 May 2025 in *TC and AA*, Joined Cases E-1/24 and E-7/24, paragraph 92 and case-law cited).

38 In this regard, the Court observes, firstly, that, as exemptions from the Directive, points (a) to (f) of Article 1(5) of the Directive should be interpreted strictly (see, to that effect, the judgment of 18 June 2021 in *ACADA Immobilien AG PCC in Konkurs*, E-10/20, paragraph 47). Secondly, the term 'non-experimental agricultural practices' must be interpreted autonomously and uniformly (see the judgment of 9 February 2021 in *Kerim*, E-1/20, paragraph 46 and case-law cited).

39 Further, Article 4 of the Directive sets out the directive's guiding principle of replacement, reduction and refinement (the '3Rs'), which, as noted in recital 11, are internationally established principles governing the care and use of live animals for scientific purposes. These principles must be considered systematically when implementing the Directive, and further, when choosing methods, these principles should be implemented through a strict hierarchy of the requirement to use alternative methods. Article 4 requires that EEA 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 while the number of animals used in projects shall be reduced to a minimum without compromising the project's objectives. Moreover, EEA States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals. The choice of methods themselves is set out in Article 13.

40 Therefore, as a matter of contextual interpretation, Article 1(5)(a) of the Directive must be read in light of the 3Rs in Article 4. Consequently, Article 1(5)(a) must be understood as referring to standard or typical agricultural practices. In that regard, the Court notes that it was common ground among the parties that the practice of collecting blood from pregnant mares, within the EEA, is only conducted in Iceland.

41 Turning to the Plaintiff's submissions regarding the interpretation of Article 1(5)(d) of the Directive, as held above, Article 1(5)(d) as an exemption from the directive must be interpreted strictly. In addition, the notion of 'practices undertaken for the purposes of recognised animal husbandry' must be interpreted autonomously. Further, as a matter of contextual interpretation, Article 1(5)(d) must be read in light of the 3Rs in Article 4 as well as the statement in recital 31 that animal-welfare considerations should be given the highest priority in the context of animal keeping, breeding and use. The term 'recognised animal husbandry' in Article 1(5)(d) must therefore be understood as referring to standard or typical animal husbandry practices, as regards the breeding, rearing, and caring for animals, which give animal-welfare considerations the highest priority.

42 However, the Court observes that, in circumstances such as the present case, the collection of blood from pregnant mares does not constitute a standard or typical animal husbandry practice, unlike equine blood donations for veterinary purposes, as the blood drawn does not give the highest priority to the welfare of horses, the animals themselves, or other animals in the vicinity.

43 The Plaintiff further submits that the collection of blood from pregnant mares is exempted from the Directive pursuant to Article 1(5)(f), as it submits that the practice is 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.

44 The Court observes that the same 'needle threshold' is found in both Article 3(1) and Article 1(5)(f) of the Directive, which as the Court has found above is exceeded in

circumstances such as the present case. Therefore, the needle threshold in Article 1(5)(f) of the Directive is exceeded.

45 It follows from the above that the answer to the second question referred must be that points (a), (d) and (f) of Article 1(5) of the Directive must be interpreted as not excluding from the Directive's scope the collection of blood from pregnant mares, in circumstances such as those in the main proceedings, for the production of PMSG/eCG hormone.

V COSTS

46 Since these proceedings are a step in the proceedings pending before the national court, any decision on costs for the parties to those proceedings is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds,

THE COURT

in answer to the questions referred to it by the District Court of South Iceland hereby gives the following Advisory Opinion:

1. **Article 1(2) of 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, read in conjunction with Article 3(1), must be interpreted as meaning that blood collection from pregnant mares for the production of PMSG/eCG hormone constitutes a 'procedure' that falls within the scope of the directive.**

2. **Points (a), (d) and (f) of Article 1(5) of Directive 2010/63/EU must be interpreted as not excluding from the Directive's scope the collection of blood from pregnant mares, in circumstances such as those in the main proceedings, for the production of PMSG/eCG hormone.**

Páll Hreinsson Bernd Hammermann Michael Reiertsen

Delivered in open court in Luxembourg on 16 September 2026.

Ólafur Jóhannes Einarsson
Registrar

Páll Hreinsson
President