COMPLAINT FORM PART 2/2
TO THE EFTA SURVEILLANCE AUTHORITY CONCERNING
FAILURE TO COMPLY WITH EEA LAW

6. Field and place(s) of activity:

This complaint concerns the high-volume blood extraction from pregnant mares for the production of the hormone PMSG, carried out in Iceland. PMSG (pregnant mare serum gonadotropin), also called eCG (equine chorionic gonadotropin), is a fertility hormone that is obtained from the blood of pregnant mares and is used in industrial animal breeding to increase the reproductive performance of farmed animals - in particular sows, but also cattle, sheep, and goats - through synchronising cycles and increasing the number of offspring produced per year. There is no medical indication for the frequent use of PMSG in farmed animals. The practice only serves economic interests by stimulating and accelerating physiological processes in animals.

7. EFTA State or public body alleged by the complainant not to have complied with EEA law:

This complaint is directed against Iceland and its veterinary authority MAST, which is responsible for the authorisation of animal experiments.

The use of animals for the production of drugs and other substances is covered by the EU Directive 2010/63 on the protection of animals used for scientific purposes (text with EEA relevance).

In Iceland, the national legislation on animal experimentation (Regulation 460/2017) is in line with the EEA law, but it is not correctly applied.

8. Fullest possible account of facts giving rise to complaint:

The production of PMSG only takes place in a few countries worldwide: Argentina, Uruguay, China, Iceland and Germany (please note that NGOs are currently taking legal actions against the PMSG production in Germany, which is in breach of German and EU law).

In Iceland, blood collections for PMSG production cause the pregnant mares severe stress, fear and suffering, as recently documented by *Animal Welfare Foundation (AWF)* and *Tierschutzbund Zürich (TSB)*: https://youtu.be/SkHP65O4RUg. The semi-wild horses are subjected to violence, the risk of injury and they suffer from repeated traumatisation. The amount of blood taken (5 litres per week) exceeds any international guidelines existing on the topic.

At international level, it has been recognized that procedures using animals for the manufacture of drugs - such as blood collections - are classified as animal experiments and that the animals used are protected under relevant legislation and guidelines. We would like to mention just a few official statements, which confirm this legal categorisation (a copy of the statements can be provided upon request):

- *"On the specific issue of blood production, the keeping of animals for the production of products such as tissue and sera for research purposes within the EU is covered by Directive 2010/63/EU on the protection of animals used for scientific purposes."* (Commissioner Andriukaitis, correspondence with Eurogroup for Animals, 2015)

- *"DG ENV confirmed that when animals are used for the production of tissue, sera etc. their use is fully covered under our Directive (2010/63/EU)."* (EU Commission, correspondence with Süddeutsche Zeitung, 2015)

- *"The European Parliament recalls that structural animal experiments that are not indispensable should have no place in the food chain as Directive 2010/63/EU prescribes the replacement and reduction of the use of animals in procedures; calls on the Commission and Member States to stop the import and domestic production of Pregnant Mare Serum Gonadotropin (PMSG), which is extracted from the blood of pregnant horses that are systematically impregnated and exposed to blood collections, involving health and welfare issues;"* (EU Parliament, resolution on a Farm to Fork Strategy, 2021)

- *"(...) the relevant OIE standards applicable for this kind of production are Chapter 7.8 Use of animals in research and education and Chapter 7.1. Introduction to the recommendation for animal welfare of the Terrestrial Animal Health Code. I draw your attention to the Preamble of Chapter 7.8. which defines the term 'research' in the context of this chapter as 'includes the production of biological materials'."* (OIE World Organisation for Animal Health, correspondence with TSB|AWF, 2018)

- *"A production of PMSG in Germany, should it indeed take place, is classified as animal experiment according to § 7a paragraph 1 no 4 of the Animal Protection Act (use of animals in the context of the development and manufacture as well as testing of the quality, effectiveness or safety of drugs, food, feed-stuffs or other substances or products) and therefore subject to approval." (translation)* (German Federal Government, answer to a parliamentary question, 2019)

Thus, it is clear that EU Directive 2010/63 on the protection of animals used for scientific purposes applies to blood extraction for the purpose of PMSG production. Indeed, it defines in its article 3 that **'procedure'** means any **use of an animal** for experimental or **other scientific 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." Article 5 stipulates that procedures may be carried out for certain purposes only, including the **manufacture of drugs**.

In Iceland, the national legislation on animal experimentation, Regulation 460/2017, is largely in line with EU Directive 2010/63 (see attached table comparing EU and Icelandic legislation, annex 1).

EU Directive 2010/63, as well as the corresponding Icelandic Regulation 460/2017, are based on the **principle of the 3 Rs: replacement, reduction and refinement**. According to this principle, animal experiments must, whenever possible, be replaced by alternative methods not using live animals. In the case of PMSG, there are **numerous alternatives 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. In Germany alone, there are **36 synthetic hormones** available for different animal species and indications (see attached response of the German Government to a parliamentary question, annex 2). Synchronisation of cycles is also possible with **hormone-free methods, so-called zootechnical measures**, such as exercise, optimal nutrition and lighting, contact with sows in oestrus and boar contact. Such measures are, for instance, used in organic farming, where the systematic use of fertility hormones is prohibited.

It is important to note that PMSG is often used to treat fertility problems which are caused by the system, namely by poor husbandry conditions in intensive farming.

According to Prof. Dr Axel Wehrend, who is a veterinarian specialising in reproductive medicine and is leading a government-funded training project for farmers and veterinarians in Germany, *"**PMSG does not need to be used in piglet production**. Good management in the area of husbandry, feeding and insemination can produce **similar fertility performance parameters to those achieved using PMSG**. For farmers who wish to synchronise or stimulate oestrus in sows, approved synthetically produced veterinary medicines are available, as are zootechnical measures such as boar contact"* (see attached letter of Axel Wehrend, annex 3).

In Switzerland, the Swiss pig breeders' association has recently decided to prohibit the use of PMSG: www.srf.ch/news/schweiz/weniger-tierleid-schweizer-schweinezucht-verzichtet-definitiv-auf-stutenblut This voluntary ban on the use of PMSG by the industry shows that **pig breeding without PMSG is indeed possible**. PMSG has only been used in pigs in Switzerland and will now disappear from the market.

A representative of the Danish pig industry recently stated that farmers would **not miss PMSG products** much if they were taken off the market: www.bt.dk/nyheder/heste-mishandles-i-chokerende-video-fra-islandske-blodfarme

Since there are numerous synthetic drugs available that fulfil the same purpose as PMSG, and since good fertility in farmed animals can also be achieved without using any hormones, **two important preconditions** for animal experiments are not fulfilled in the case of PMSG production: **indispensability and ethical justifiability**.

The commercially conducted high-volume blood extraction from pregnant mares is an **unnecessary "animal experiment", which must not be authorised or tolerated by the authorities.**

While EU Directive 2010/63 has been incorporated into Icelandic national legislation (Regulation 460/2017), **Iceland's administrative measures are incompatible with provisions and principles of EEA law**. In the past, the production of PMSG was approved by MAST as "animal experiment", based on Regulation 460/2017, which was incompatible with the principle of the 3 Rs, thus in breach of EEA law. On 8th March 2022, we were informed by MAST that this **license was not renewed**, which means that the **"animal experiment" is currently carried out without authorisation**, which is also in breach of EEA law (see below point 11). Regardless of whether Iceland has approved PMSG production or if the blood collections are carried out without authorisation, Iceland is in breach of EEA law. Indeed, non-compliance with EEA law means failure by an EFTA State to fulfil its obligations under EEA law. This failure may consist either of an action or an omission.

The undersigned NGOs therefore urge the EFTA Surveillance Authority to ensure the EEA laws are correctly applied in Iceland.

9. To the extent possible, please specify the provisions of EEA law *(EEA Agreement, Protocols, Acts referred to in Annexes to the Agreement)* considered to have been infringed by the EFTA State concerned:

Directive 2010/63/EU on the protection of animals used for scientific purposes is incorporated into the EEA Agreement and is in force in Iceland (see attached statement by MAST, annex 4). The provisions of Directive 2010/63 have been correctly incorporated into Icelandic national legislation, namely into Regulation 460/2017 on the protection of animals used for scientific purposes (see attached table comparing EU and Icelandic legislation, annex 1).

By tolerating the blood extraction from pregnant mares for PMSG production, which is covered under EU Directive 2010/63 and thus also under Icelandic Regulation 460/2017, the Icelandic authorities – in particular the competent veterinary authority MAST – is infringing the following provisions of EEA law, Directive 2010/63/EU:

- Article 4: **Principle of replacement, reduction and refinement** 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**.

- Article 13: **Choice of methods**. 1. (…) 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 20: Authorisation of breeders, suppliers and users 1. (…) **Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the requirements of this Directive**.

- Article 36: **Project authorisation**. 1. Member States shall ensure, (…), that **projects are not carried out without prior authorisation** from 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 38: **Project evaluation**. 2. The project evaluation shall consist in particular of the following: (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**; 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;

Iceland is also ignoring the following recitals of Directive 2010/63/EU:

- Recital 11: "(…) 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**."

- Recital 12: "(…) 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**."

In this context, we would like to draw your attention to legal expert opinions from Germany (see annex 5 and 6). The legal situation is actually the same in both Iceland and Germany since EU Directive 2010/63 applies to both countries. One of the attached legal opinions was written by lawyer Lutz Schäffer who specialises in pharmaceutical law, the other was written by Prof. Dr Markus Ogorek who specialises in administrative law. Both opinions clearly state that blood collections for the manufacture of drugs are classified as animal experiments. They also state that animal experiments must only be approved if they are indispensable and there are no alternatives available, which is not the case with PMSG**. Both legal opinions come to the same conclusion, which is that the repeated high-volume blood collections from pregnant mares for PMSG production are unlawful and must not be approved by the authorities**, since the precondition of "indispensability" (which corresponds to the principle of the 3 Rs of the underlying EU Directive 2010/63) is not fulfilled.

10. Details of any earlier contacts with the EFTA Surveillance Authority (if appropriate and possible, please attach copies of correspondence):

This is our first contact with the EFTA Surveillance Authority.

11. Contacts already made with national authorities, whether central, regional or local (if appropriate and possible, please attach copies of correspondence):

On 9th September 2019, representatives of AWF and TSB met with a lawyer of the Icelandic veterinary authority MAST in Reykjavik. During this meeting, **MAST's lawyer explained that the Icelandic legislation on the protection of animals used in experimentation applies to the production of PMSG in Iceland** (Regulation 460/2017, which is based on the EU Directive 2010/63). He also stated that the **license issued to the pharmaceutical company Isteka to take blood for PMSG production is based**

on Regulation 460/2017 (see attached meeting minutes, annex 7). Therefore, he confirmed what MAST had previously communicated to AWF and TSB in a written statement (see attached statement by MAST, annex 4).

After publication of the NGO's documentary film on 19th November 2021, MAST contacted AWF and TSB and asked for the investigation report, the name of the farms shown in the film, the dates of filming, and the unedited video clips from the farms. AWF and TSB replied on 1st December 2021 that they are willing to hand over the original footage to the police or to the public prosecutor's office. The NGOs further stated that the **approval of the PMSG production by MAST is unlawful**, since alternatives are available (synthetical hormones, zootechnical measures), and they urged MAST to stop the blood collection from pregnant mares for economic purposes (see attached open letter to MAST, annex 8).

On 13th January 2022, Eurogroup for Animals, AWF and TSB participated in a public survey of the Icelandic parliament in the context of a bill which aims at prohibiting PMSG production. The NGOs' submissions **asked the Icelandic Government to immediately ban the blood collection from pregnant mares for economic purposes**, stating that the approval of the blood collection as "animal experimentation" is **not legally tenable** (see attached submission by AWF|TSB, annex 9). Other signatories of this complaint, in particular Anima, Deutscher Tierschutzbund (Animal Welfare Academy), Fundación Franz Weber, Green REV Institute, Italian Horse Protection (Sonny Richichi), Samtök grænkera á Íslandi, and Welfarm, also submitted comments to the survey, which can be found on the parliament's website:
https://www.althingi.is/thingstorf/thingmalin/erindi/?ltg=152&mnr=15&fbclid=IwAR0djs_rof_2nKMTl8lOWlnMTVJU-GDuahlbRCtajy_2QtrNdfCcKNSfRYY

On 8th March 2022, AWF and TSB were invited to a meeting with a working group that had been established by the agriculture minister in order to examine the activities, the regulations and the supervision concerning the production of PMSG. Among other things, the NGOs emphasized that a ban is the only option because the **production of PMSG is illegal according to EU Directive 2010/63**, which applies to EEA countries. They explained that blood collections for the manufacture of drugs are classified as **animal experiments, which must only be approved if they are indispensable and ethically justifiable**, thus if there are no alternatives available, which is not the case with PMSG (see attached meeting minutes, annex 10).

On the same day, 8th March 2022, the Icelandic animal welfare organisation *Samtök um dýravelferð á Íslandi (SDÍ)* was also invited to meet with the ministerial working group. A representative of MAST is a member of this working group and she told SDÍ that Isteka's license to take blood for PMSG production was not renewed after it expired in 2020. **MAST is now of the opinion that the activity is not an animal experiment but an agricultural production, which does not fall within the scope of Regulation 470/2017** and thus does not need an authorisation.

11.1. Administrative actions, such as complaints to relevant national administrative authorities (whether central, regional or local) and/or to national or regional ombudsman:

The Icelandic animal welfare organisation *Samtök um dýravelferð á Íslandi (SDÍ)* is currently taking into consideration administrative and/or legal actions.

11.2. Recourse to national courts or other legal procedures such as arbitration or conciliation. Please state whether a decision or award has already been adopted and, if appropriate, attach a copy:

No

12. Specify any evidence or documents supporting the complaint, including any national measures (if possible, please attach copies):

- Annex 1: table comparing EU and Icelandic legislation
- Annex 2: response of the German Government to a parliamentary question (translation of an extract)
- Annex 3: letter of Prof. Dr Wehrend regarding alternatives to PMSG (translation)
- Annex 4: statement by MAST regarding EEA law
- Annex 5: legal expert opinion of Prof. Dr Ogorek (only for internal use, must not be shared with third parties)
- Annex 6: legal expert opinion of lawyer Schäffer (translation of extracts)
- Annex 7: minutes of the meeting of AWF|TSB and MAST
- Annex 8: open letter of AWF|TSB to MAST
- Annex 9: submission by AWF|TSB to public survey in Icelandic parliament
- Annex 10: minutes of the meeting of AWF|TSB and ministerial working group
- Annex 11: EU Directive 2010/63
- Annex 12: Icelandic Regulation 460/2017

13. Confidentiality (please tick one of the boxes):

x 'I authorise the EFTA Surveillance Authority to disclose my identity in its contacts with the authorities of the EFTA State against which the complaint is made.'

o 'I request the EFTA Surveillance Authority not to disclose my identity in its contacts with the authorities of the EFTA State against which the complaint is made.'

14. Date and place of submission of complaint:

28.03.2022, Brussels

The undersigned NGOs:

Anima, Denmark
Animal Welfare Foundation (AWF), Germany
Animals' Angels Inc., United States of America
Canadian Horse Defence Coalition, Canada
Deutscher Tierschutzbund, Germany
Dier&Recht, Netherlands
Dyrenes Beskyttelse, Denmark
Eurogroup for Animals (EfA), Brussels
FOUR PAWS, Austria
Fundación Franz Weber, Spain
Green REV Institute, Poland
Italian Horse Protection Onlus (IHP), Italy
Samtök grænkera á Íslandi, Iceland
Samtök um dýravelferð á Íslandi (SDÍ), Iceland
Tierschutzbund Zürich (TSB), Switzerland
Viva, United Kingdom
Welfarm, France