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Brussels, 16th May 2022

Open letter: Ban on production, import and use of PMSG

Dear Ms Chaze,

We would like to thank you for your letter dated 16th February 2022 in which you responded to the concerns we expressed regarding the welfare of mares used for the production of the fertility hormone PMSG (Ref. Ares(2022)1134334). We understand from your reply that the Commission does not envisage to follow through with the call made by the European Parliament (EP) to ban both the import and domestic production of PMSG¹. Yet, we would like to reiterate that such a ban is urgently needed as this production, in addition to generating animal abuse, violates EU law.

If adopting a standalone ban is not possible, another approach could be adopted:

¹ "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;**" (P9_TA(2021)0425)

- Firstly, the European Commission should **clarify in official communication that domestic production violates EU rules**, namely Directive 2010/63/EU (see details below). It could also use the opportunity of the revision of EU animal welfare rules to make it explicit, as well as to prohibit the use of eCG.
- Secondly, as the new EU regulation on veterinary medicinal products (VMP) indicates that animal welfare should be included in the Good Manufacturing Practice (GMP)², the European Commission should ensure that **Directive 2010/63/EU on the protection of animals used for scientific purposes is listed in the rules to respect under GMP**, which exporters have to comply with. Under the VMP regulation, the deadline for the Commission to amend GMP is January 2025. We urge you to accelerate this process.

Several EU Member States, such as Austria and Denmark, have already expressed that they support the EP's call for an EU-wide import and production ban and/or envisage a national ban on PMSG. In the Netherlands, the parliament recently adopted a motion calling for a **European ban on PMSG production and import** as soon as possible³.

In support of our call, this letter provides details on:

1. PMSG production within the EU, and the arguments demonstrating that this activity is carried out in violation of EU legislation;
2. the WTO compatibility of restricting PMSG imports;
3. the on-farm use of PMSG potentially breaching EU Directive 98/58/EC;
4. the recent decision by the European Pharmacopoeia Commission to suspend the *Gonadotrophin, equine serum, for veterinary use (0719)* monograph in July 2022.

Finally, we would like to inform you that we have lodged a complaint against Iceland with the EFTA Surveillance Authority, as you suggested in your letter. In the meantime, we have also submitted an infringement complaint against Germany to the European Commission.

With all these elements in mind, we kindly ask you to **examine the suggested options to put an end to the production, import and use of PMSG**, and to inform us of the measures the European Commission will take in order to stop the unlawful blood collections from pregnant mares and the systematic use of PMSG in animal breeding. Could we also kindly ask you to elaborate on the effects the suspension decided by the EDQM will have on the EU marketing authorisation of PMSG products and on the import and domestic production of PMSG? The EDQM was not in a position to reply to these questions (see annex 1). Furthermore, we urge the European Commission to **press for a definitive cancellation of the PMSG monograph**, which would make marketing authorisation within the EU difficult, if not impossible.

We are looking forward to your reply.

Yours sincerely,

² Recital 68 provides that “the good manufacturing practice for the purpose of this Regulation should take into account the **Union and international standards of animal welfare** when active substances are prepared from animals” and Article 93 states that “the Commission shall, by means of **implementing acts**, adopt measures on good manufacturing practices for veterinary medicinal products and active substances (...)”.

³ [Tweede Kamer: snel verbod op PMSG-hormoon gemaakt uit bloed van zwangere paarden - Europa - Partij voor de Dieren](#)

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Background Information

1. Domestic production of PMSG in violation of EU law - the case of Germany

PMSG is produced within the European Union. A Haflinger stud farm in Thuringia, Germany, has been extracting blood from pregnant mares for 40 years. According to a recent letter sent by the Polish Ministry to a parliamentarian, the hormone is also obtained in the Netherlands and the Czech Republic (see annex 2). This information is new to us and needs to be verified.

This domestic production of PMSG is **in breach of EU law, namely Directive 2010/63/EU** on the protection of animals used for scientific purposes. As confirmed by DG Environment, the use of animals for the **manufacture of drugs** and other substances is covered by this Directive.⁴

This Directive is based on the **principle of the 3 Rs: replacement, reduction and refinement**⁵. According to this principle, animal experiments must, whenever possible, be replaced by alternative methods not using live animals. As we explained in our letter dated 6th December 2021, there are **numerous synthetic drugs already available** that fulfil the same purpose as PMSG, namely the induction and synchronisation of oestrus in farmed animals (listed in annex 3).

To support this argument, we would like to draw your attention to **expert legal opinions** from Germany (see annex 4 and 5), where EU Directive 2010/63 is incorporated in the Animal Welfare Act. One of the attached legal opinions was written by Lutz Schäffer, a lawyer who specialises in pharmaceutical law, the other was written by Prof. Dr Markus Ogorek who specialises in administrative law. Both experts 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 if there are no alternatives available, which is not the case with PMSG. Both legal experts came 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 authorised by the authorities, since the condition of “indispensability” (which corresponds to the principle of the 3 Rs of the underlying EU Directive 2010/63) is not fulfilled.

It is important to note that good fertility can also be achieved without using any hormones. Prof. Dr Axel Wehrend from the Justus Liebig University Giessen, a veterinarian specialised in reproductive medicine, led over two years a government-funded training project for farmers and veterinarians in Germany⁶. According to him, scientific studies as well as practical experience show that ***“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***

⁴ “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)” - European Commission, Spokesperson’s Service, correspondence with Sueddeutsche Zeitung, 18.09.2015

⁵ EU Directive 2010/63, Articles 1, 4, 13 and 38

⁶ www.mud-tierschutz.de/mud-tierschutz/wissen-dialog-praxis/schweine/brunstsynchronisation-ohne-pmsgceg

available, as are **zootechnical measures such as boar contact**" (see attached letter of Axel Wehrend, annex 6).

In Switzerland, the Swiss pig breeders' association has recently made the decision to prohibit the use of PMSG⁷. This **voluntary ban on the use of PMSG by the industry** proves that pig breeding without PMSG is indeed possible. In Denmark, a representative of the pig industry stated that **farmers would not miss PMSG products much** if they were taken off the market⁸.

Blood collection for PMSG production is thus unlawful according to EU Directive 2010/63, but this **EU law is not correctly applied by all Member States**. Germany is in breach of this EU law and possibly other countries as well, as suggested by the letter received from the Polish Ministry. To address this implementation issue, the European Commission could either **introduce an EU-wide ban on PMSG production or include such a prohibition in the relevant EU Directive 2010/63**.

2. A restriction on PMSG imports from non-EU countries would be WTO compatible

Seven years after the first publication regarding blood farms in South America⁹, pregnant mares continue to be abused and to suffer physical and psychological torture. Foals are still systematically aborted. The mares suffer needlessly for the production of a fertility hormone which could easily be replaced by alternative methods. Due to the high-volume blood extractions, the mares become anaemic, emaciated and weak. Injured and sick mares do not receive any veterinary care, some die unattended. This abuse was again recently documented by the Animal Welfare Foundation (report in progress). In Iceland as well, the semi-wild mares are subjected to violence, they risk injury and suffer from repeated traumatisations, as we pointed out in our previous letter. According to an Icelandic veterinarian, this repeated experience can lead to so-called "learned helplessness" (see attached statement of Ingunn Reynisdóttir, annex 7).

In this context, we would like to draw your attention to a recent **legal opinion** on the revision of the German Animal Welfare Act, which states that the **GATT does not oppose an import ban on PMSG** but allows, in its Article XX, trade restrictions to protect public morals, which has been recognised to cover animal welfare (see attached legal opinion page 673/674, annex 8). Therefore, an import ban on PMSG would be compatible with WTO rules.

3. Effect of the use of PMSG on farmed animals

In addition to raising serious welfare concerns with regard to horses, the use of PMSG also has a **negative impact on the welfare of farmed animals**. PMSG promotes **unnatural rates of reproduction** and gives the animals no time to recover in between pregnancies. In sows, PMSG also induces superovulation, which results in larger litter sizes. Surplus piglets often die or are killed when a sow does not have enough teats to feed them all. **Larger litter sizes**

⁷ www.srf.ch/news/schweiz/weniger-tierleid-schweizer-schweinezucht-verzichtet-definitiv-auf-stutenblut

⁸ www.bt.dk/nyheder/hestemishandles-i-chokerende-video-fra-islandske-blodfarme

⁹ www.sueddeutsche.de/wirtschaft/handel-grausamer-bluttransfer-1.2668283

are clearly associated with higher piglet mortality¹⁰. Furthermore, PMSG can be used for **induction of puberty** in young sows, but early pregnancy shortens pubertal development and usually leads to early infertility and slaughter.

Because of these effects, not only would the production of PMSG be in breach of Directive 2010/63/EU, but its use also appears **not to be compliant with Council Directive 98/58/EC** on the protection of animals kept for farming purposes. Council Directive 98/58/EC clearly states that *“natural or artificial breeding or breeding procedures which cause or are likely to cause suffering or injury to any of the animals concerned must not be practised.”*

4. Marketing authorisation of PMSG products

In your letter dated 16th February 2022, you stated that PMSG is authorised as a veterinary medicinal product in a number of EU Member States and that the Commission is not aware of any plans for such authorisations to be revoked. In this context, we would like to draw your attention to the fact that the European Pharmacopoeia Commission has decided to **suspend the Gonadotrophin, equine serum, for veterinary use (0719) monograph** in July 2022, as you can see on EDQM's website¹¹.

Attachments:

- Annex 1: EDQM's reply
- Annex 2: letter of the Polish Ministry regarding the origin of PMSG
- Annex 3: response of the German Government to a parliamentary question (*translation of an extract*)
- Annex 4: legal expert opinion of Prof. Dr Ogorek (*only for internal use, must not be shared with third parties*)
- Annex 5: legal expert opinion of lawyer Schäffer (*translation of extracts*)
- Annex 6: letter of Prof. Dr Wehrend regarding alternatives to PMSG (*translation*)
- Annex 7: statement of veterinarian Ingunn Reynisdóttir (*translation*)
- Annex 8: legal expert opinion on the revision of the German Animal Welfare Act (*only available in German*)

¹⁰ Rutherford et al. The welfare implications of large litter size in the domestic pig I: biological factors Animal Welfare 2013, 22: 199-218

¹¹

www.edqm.eu/en/news/ph-eur-commission-suspends-monograph-gonadotrophin-equine-serum-veterinary-use