Council of the European Union

Brussels, 20 November 2025
(OR. en)

15717/25

VETER 121
AGRILEG 182
PHARM 170
MI 934

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	19 November 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2025) 699 final
Subject:	REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the Commission assessment of the situation as regards the treatment with medicinal products of animals of the equine species and their exclusion from the food chain, including with regard to imports of animals of the equine species from third countries

Delegations will find attached document COM(2025) 699 final.

Encl.: COM(2025) 699 final

EUROPEAN
COMMISSION

Brussels, 19.11.2025
COM(2025) 699 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the Commission assessment of the situation as regards the treatment with medicinal products of animals of the equine species and their exclusion from the food chain, including with regard to imports of animals of the equine species from third countries

1. INTRODUCTION

This report fulfils the Commission's obligation as set out in Article 158 of Regulation (EU) 2019/6 of the European Parliament and of the Council[1] on veterinary medicinal products (the VMP Regulation) to assess the situation regarding the treatment of animals belonging to the equine species (e.g. horses, donkeys, mules, etc.) with veterinary medicinal products (VMPs), and their exclusion from the food chain, including with regard to imports from third countries (TCs).

It also outlines the Commission's conclusions on the possible actions to be taken to improve the current situation and their potential impact on public health, animal welfare, the risk of fraud and the level playing field with TCs.

2. BACKGROUND

Under EU legislation[2], animals of the equine species (also known as 'solipeds', 'equids', 'equine animal(s)' or '*Equidae*') are deemed to be food-producing animals[3]. To protect public health, equids must be irreversibly excluded[4] from the food chain if they have been treated with medicinal products containing active substances prohibited for use in food-producing animals[5] or that are not allowed according to Regulation (EC) No 470/2009[6] (the MRL Regulation). The slaughter of food-producing equids should be delayed for six months where they have been administered substances included in the list of essential substances for the treatment of *Equidae*[7] (the essential substances list – ESL). Under certain conditions, VMPs authorised for other

---

1 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/OJ).

2 Commission Implementing Regulation (EU) 2021/963 of 10 June 2021 laying down rules for the application of Regulations (EU) 2016/429, (EU) 2016/1012 and (EU) 2019/6 of the European Parliament and of the Council with regard to the identification and registration of equine animals and establishing model identification documents for those animals, Article 38 (OJ L 213, 16.6.2021, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2021/963/OJ).

3 Regulation (EU) 2019/6, Article 4(38).

4 Commission Implementing Regulation (EU) 2021/963, Articles 38 to 42.

5 Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p. 3, ELI: http://data.europa.eu/eli/dir/1996/22/OJ), read in combination with Annex I, Table 2 of Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1, ELI: http://data.europa.eu/eli/reg/2010/37(1)/oj).

6 Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11, ELI: http://data.europa.eu/eli/reg/2009/470/OJ).

7 Commission Implementing Regulation (EU) 2025/901 establishing a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months (OJ L, 2025/901, 20.5.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/901/OJ) and Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae (OJ L 367, 22.12.2006, p. 33, ELI: http://data.europa.eu/eli/reg/2006/1950/OJ), as amended.

animal species or medicinal products for human use can be administered to food-producing equids where there is no product authorised or available on the market for a given indication[8].

Under the current rules[9], only the veterinarian responsible or the competent authority (CA) can exclude equids from the food chain. Many animals bred and raised in the EU and ending up in the food chain are former companion, sport or breeding animals. The social perception of equids as companion, sport or breeding animals and food-producing animals is often a challenge for the implementation of legal requirements related to the food safety risks linked to their treatment with medicinal products.

In general, the market in veterinary medicines is split between food-producing animals and companion animals; both sectors are to cover the treatment needs of many species. This results in a fragmented market[10]. For livestock farmers, animal treatment must be cost-effective. In addition, considerations by the animal health industry on return on investment and the cost of keeping a VMP on the market have been shown to deter the development of new veterinary medicines. This situation has a greater impact on medicines for less common indications and for animal species with lower population numbers. For example, the cost of providing the required data for setting maximum residue limits (MRLs) for the active substance contained in a VMP may not justify the return on sales of that product in the case of food-producing equids.

One of the aims of the VMP Regulation, which became applicable in January 2022, is to increase the availability of VMPs, while guaranteeing the highest level of public and animal health and environmental protection. The VMP Regulation lays down specific provisions aimed at increasing the availability of medicinal treatments for equids and therefore improving their health and welfare, while also protecting public health.

Some provisions are more general and are aimed at incentivising[11] the authorisation of VMPs intended for limited markets[12], such as for equids. Under certain conditions, the VMP Regulation also allows the use of medicinal products outside the terms of the marketing authorisation[13], the so-called 'cascade use'. These conditions are specific to food-producing and to non-food-producing animals (such as equids excluded from the food chain). To increase the availability of medicines for food-producing equids, the VMP Regulation also provides for the establishment of a list[14] of substances essential for the treatments of equids or which bring added clinical value compared to other treatment options available to equids and for which the withdrawal period must be six months.

To ensure traceability and reliable exclusion from the food chain, equids in the EU must be identified by the following means[15]: a unique code, physical means of identification (injectable

---

8 Regulation (EU) 2019/6, Article 113 in combination with Article 115.

9 Commission Implementing Regulation (EU) 2021/963, Article 38.

10 Commission Staff Working Document Impact Assessment accompanying the Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products /* SWD/2014/0273 final */.

11 Regulation (EU) 2019/6, Article 23 (possibility to submit an application for limited markets without providing certain documentation) or Articles 39 and 40 (e.g. 14 years of initial data protection).

12 *Ibid.*, Article 4(29).

13 *Ibid.*, Articles 112, 113 and 115.

14 *Ibid.*, Article 115(5) and Commission Implementing Regulation (EU) 2025/901. Commission Regulation (EC) No 1950/2006, as amended by Regulation (EC) 122/2013, applies until 21 May 2027.

15 Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health, Article 114(1) (OJ L 84, 31.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/429/OJ).

transponder or ear tag)[16] and a single lifetime identification document (also referred to as a 'passport')[17]. In general, equids need to be identified within a period to be determined by the Member State (MS) and before they reach 12 months of age, or before they leave their establishment of birth for a period exceeding 30 days[18]. Delays in identification, as well as the loss of the passport or the physical identification of the animals must result in their exclusion from the food chain[19], unless the operator can satisfactorily substantiate that the status of the equid as intended for slaughter for human consumption has not been compromised by any medicinal treatment[20]. The passport also contains information on whether an individual equid is excluded from slaughter for human consumption or has received a medicinal treatment with substances in the ESL[21]. MSs are to establish and maintain databases[22] containing the unique code, the identification code displayed by the transponder and details of the passport and of the animal[23], as well as information on the animal's status with regard to the food chain[24] ('food chain status').

The management of equids that have been excluded from the food chain can be challenging where their keeping is no longer wanted or possible for their owners. Since those animals are excluded from the food chain, they need to be kept until they die or be euthanised. However, in some MSs they cannot be euthanised without a reasonable cause. In some cases, the price of euthanasia and rendering may be prohibitive to owners. Therefore, the problem arises that some equids may end up without treatment to avoid being excluded from the food chain, and if excluded from the food chain, being neglected or abandoned. Both situations would create serious animal health and welfare issues. In establishments especially dedicated to equid meat production - despite their relatively low number in Europe - exclusion from the food chain renders equids without any value whatsoever. Overall, these factors create conditions that may incentivise illegal and fraudulent practices, as evidenced by past and more recent cases[25]. This may include manipulating the passport, omitting to exclude equids from the food chain after treatment with medicines not allowed for food-producing animals, not recording the treatments with such medicines, and forgery of equids' identification. All this could lead to the slaughtering of equids that should have been excluded from the food chain.

---

16 Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs, Articles 58 and 59 (OJ L 314, 5.12.2019, p. 115, ELI: http://data.europa.eu/eli/reg_del/2019/2035/OJ), as amended.

17 Commission Implementing Regulation (EU) 2021/963.

18 *Ibid.*, Article 21.

19 *Ibid.*, Article 25(1) and (2)(d).

20 *Ibid.*, Article 38(2)(b).

21 Commission Delegated Regulation (EU) 2021/577 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the content and format of the information necessary to apply Articles 112(4) and 115(5) and to be contained in the single lifetime identification document referred to in Article 8(4) of that Regulation (OJ L 123, 9.4.2021, p. 3, ELI: http://data.europa.eu/eli/reg_del/2021/577/OJ).

22 Regulation (EU) 2016/429, Article 109.

23 Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs, Article 64 (OJ L 314, 5.12.2019, p. 115, ELI: http://data.europa.eu/eli/reg_del/2019/2035/OJ), as amended.

24 Commission Implementing Regulation (EU) 2021/963, Articles 6(1) and 7(2)(c).

25 Professor Paddy Wall's Report on equine identification, registration, and traceability in Ireland, available here.

Among others, the requirements for entry into the EU set out in Commission Delegated Regulation (EU) 2022/2292[26] apply to food-producing equids and their products. That is to say that equids intended for slaughter for human consumption that have been treated with the substances prohibited under Directive 96/22/EC, with the prohibited substances in Table 2 of the Annex to Commission Regulation (EU) No 37/2010 or with substances not included in Table 1 of that Regulation, or meat derived from such equids slaughtered in TCs, are not allowed to enter the EU. Only some countries are currently authorised to export live equids to the EU[27] or meat from equids[28].

To collect and analyse evidence gathered between 2018 and 2022 on the current situation, the Commission appointed a contractor to conduct a study ('the study'). In its report[29], the contractor examined several study questions, looked at the actions proposed by MS CAs and stakeholders to improve the current situation, and assessed the potential impact of those actions on public health, animal welfare, the risk of fraud and the level playing field with TCs. For the conduct of the study, the contractor carried out a literature search, identified the sources of relevant evidence and designed a consultation strategy. In a second step, the contractor gathered data and opinions from relevant CAs and stakeholders and analysed the available information.

3. ASSESSMENT OF THE CURRENT SITUATION

As very limited or no data were available to the CAs and stakeholders for a number of study questions, it was not possible for the contractor to reach valid and representative conclusions at EU level. Gaps included, among others, accurate data on the reasons for exclusion from the food chain, the resort to euthanasia as a result of exclusion from the food chain, or the percentage of animals treated with VMPs outside the terms of the marketing authorisation (MA) in the observation period 2018-2022. The assessment presented below focuses on the core subject of Article 158 of the VMP Regulation, i.e. the treatment with medicinal products of equids and their exclusion from the food chain, including with regard to imports from TCs.

The share of equids excluded from the food chain differs significantly between MSs, ranging from 5 to 95%. In some MSs with higher numbers of animals, the share ranges from 6 to 60%. Accurate information on the reasons for exclusion is not widely available. This makes it difficult to conclude whether exclusion due to veterinary treatment or to a decision by the CAs (e.g. late identification; duplicate or replacement passports) is more likely. This is an important aspect, since the root causes leading to exclusion and the possible actions to avoid it may be different.

---

[26] Commission Delegated Regulation (EU) 2022/2292 of 6 September 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption (OJ L 304, 24.11.2022, p. 1, ELI: http://data.europa.eu/eli/reg_del/2022/2292/OJ).

[27] Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2021/404/OJ).

[28] Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118, ELI: http://data.europa.eu/eli/reg_impl/2021/405/OJ).

[29] OPERA Srl, Study on the situation as regards the medicinal treatment of animals of the equine species and their exclusion from the food chain - Final Report, EW-01-25-072-EN-N, European Union, Luxembourg, 2025, ISBN 978-92-68-28492-6, doi:10.2875/8634652, available at http://data.europa.eu/doi/10.2875/8634652

When it comes to the exclusion of equids from the food chain due to medicinal treatment, the main root cause is the lack of medicinal products that would allow the treated animal to stay in the food chain.

The study captured opinions on the limitations to developing and authorising new VMPs for food-producing equids, which included the relatively small equine market when considering the costly MA procedures. This is compounded by the uncommon nature of some indications in equids, and the cost of providing the required data for setting MRLs, for determining the withdrawal period of the specific VMP and for maintaining that VMP on the market. For the provisions in EU law aimed at incentivising the availability of medicines for food-producing equids, MRL extrapolation under the MRL Regulation has proven to be of limited help, since the cost of the studies on the withdrawal period for the specific VMPs is the main limiting factor. More time is necessary to assess the impact of the new provisions in the VMP Regulation aimed at incentivising medicines availability (e.g. submission of applications for limited markets)[30].

The study could not provide data on the percentage of animals treated with a VMP that required their exclusion from the food chain, treated with a substance on the ESL or with medicinal products used outside the terms of their MAs. However, it was reported as common that, when authorised VMPs available in other MSs are required under Article 113 of the VMP Regulation, the urgency of the treatment often results in the use of medicinal products which leads to the animal being excluded from the food chain.

The study also identified a general lack of knowledge, misunderstanding or disregard for complex regulations, legal texts and guidelines on the use of VMPs among veterinarians and keepers of equids as contributing to the exclusion of equids from the food chain. This includes a lack of understanding of what constitutes the use of VMPs outside the terms of the MA in accordance with Article 112(4) or 113 of the VMP Regulation versus the so-called 'off-label' use, which is not allowed by the EU legislation.

Animal welfare issues linked to exclusion from the food chain, for example animals being abandoned or euthanised, seem to be rather rare. However, such issues seem to be more common for equids intended for meat production, which are often not provided with optimum treatments in order to avoid them being excluded from the food chain. This leads to a consequent negative effect on the health and welfare of these animals.

Excluding equids from the food chain may result in fraudulent activity in the areas of identification and documentary traceability in order to illegally reintroduce excluded animals into the food chain. Data from the EU Alert and Cooperation Network identified 60 cases of such reintroduction between 2018 and 2024 in the EU. Beyond animal welfare considerations, such fraudulent activities may lead to public health concerns since excluded animals may have been treated with prohibited substances for which no safe MRL can be established (i.e. no safe withdrawal period can be set). More broadly, these fraudulent activities have a negative and unfair impact on the reputation of animal keepers and food operators who do uphold EU legislation.

The study found that the existing control mechanisms have been able to detect fraudulent activity and non-compliances with EU rules. However, it also identified room for improvement

[30] According to the information available on EMA's website, since the VMP Regulation became applicable a total of 17 VMPs intended for equine animals have been assessed for eligibility under Article 23, with 10 products having been considered as eligible.

in terms of cooperation and coordination among the involved CAs, setting-up whistleblowing procedures and strengthened control activities to facilitate early detection and appropriate follow-up of that fraudulent activity. The study also pointed to a number of actions to improve cooperation, notably the sharing of information contained within the national databases of MSs between CAs and with equine operators, and enhanced communication with stakeholders.

In relation to imports from TCs of food-producing equids or their products into the EU, no imports of live animals intended for slaughter took place during the observation period. Data shows that in 2022 almost 14 000 tonnes of the meat traded in the EU were imported and, in line with the previous years, Argentina was the main exporter, followed by Uruguay, Canada, Australia and the United Kingdom. A decreasing trend was observed over the study period in tonnes of meat imported from TCs, most notably from Canada and Australia.

The Commission's latest audit reports[31] recommended that more robust systems and stricter enforcement of regulations are needed in TCs to increase the effectiveness of animal traceability. These measures would make it possible to identify and track any issues that may arise, while ensuring that animals treated with certain VMPs are not intended for human consumption.

Finally, the study flags discrepancies between the import requirements laid down in Commission Delegated Regulation (EU) 2022/2292 and Council Directive 96/22/EC and the attestation included in the official import certificates (which currently requires attestation of compliance for a six-month period prior to slaughter). This results in a lack of a level playing field.

4. ASSESSMENT OF THE VIEWS OF STAKEHOLDERS AND CAS ON POTENTIAL EU ACTIONS TO IMPROVE THE CURRENT SITUATION

The study compiled suggestions from national CAs and relevant stakeholders on actions that, in their view, would contribute to improving the current situation. Suggestions could be classified into four categories: (i) those that had already been addressed in current EU legislation (so requiring no further assessment); (ii) those that were under implementation; (iii) those that can be implemented under the current EU legal framework, and (iv) those requiring changes to the relevant EU legislation to be implemented. The study assessed these suggestions considering their potential impact on public health, animal welfare, the risk of fraud and the level playing field with TCs.

According to the assessment, most of the suggested actions that have been implemented or can be implemented under the current legal framework will improve the health and welfare of food-producing equids, allowing more animals to legally stay in the food chain. This would, in turn, reduce the risk of no treatment to avoid exclusion from the food chain and the associated welfare risks such animals being abandoned or neglected. Reducing exclusion rates would also decrease the incentive for criminal activity and fraud. Public health would also benefit through the decreased risk of excluded animals treated with prohibited and non-allowed substances re-entering the food chain illegally.

4.1 Actions that were under implementation

[31] See audit reports for Uruguay DG(SANTE)2018-6457 and DG(SANTE) 2022-7448; Canada DG(SANTE)2018-6458; Argentina DG(SANTE)2018-6459 and DG(SANTE) 2022-7442; Australia DG(SANTE)2019-6653 and DG(SANTE) 2019-6679.

4.1.1 Revision of the ESL

The ESL was last updated in 2013. In line with Article 115(5) of the VMP Regulation, the Commission has adopted Commission Implementing Regulation (EU) 2025/901. This Regulation is based on a scientific evaluation[32] carried out by the European Medicines Agency. The new list set by Regulation (EU) 2025/901 provides for a range of substances that will address therapeutic or diagnostic needs that cannot currently be addressed by existing medicinal products[33], or that will bring an added clinical benefit compared to other available options.

4.2 Actions that can be implemented under the current EU legal framework

4.2.1 Increasing the availability of VMPs for food-producing equids

Specific provisions in the MRL Regulation and in the VMP Regulation were introduced with the aim to increase the availability of authorised VMPs and, as such, are considered as key enablers to improve the current situation. These provisions include, among others, MRL extrapolation[34], the possibility to grant MAs for limited markets[35], the increase of data protection periods[36], the possibility to grant more than one MA for a specific VMP to the same MA holder[37], etc. However, the study also signalled that additional time will be needed for the application of the said provisions in the VMP Regulation to deliver its full potential.

The study also found that the availability of VMPs already authorised in other MSs could be further supported by actions such as the smooth implementation of the subsequent recognition procedure (SRP)[38] and the adoption of an attractive fee policy that would reduce the authorisation and maintenance costs of these VMPs in the new targeted MS(s).

The study identified other possible actions, such as research or new modelling approaches on MRLs for equids being funded/sponsored by the EU. However, funding measures for individual applicants would need to be approached with caution since it might create a market distortion. Furthermore, the Commission is already supporting the development of innovative tools and methods for assessing exposure to chemicals and reducing animal testing via EU-funded instruments, such as the Partnership for the assessment of risks from chemicals - PARC[39]. Nevertheless, funding support or other actions such as an increased collaboration at EU level to generate clinical, evidence-based data would be a partial contribution. The costs of authorising the new VMPs (with the cost of the depletion studies necessary to set a safe withdrawal period being very high), their maintenance costs (e.g. annual fees, fees linked to variations either requiring or not requiring an assessment), and

---

[32] Scientific advice under Article 115(5) of Regulation (EU) 2019/6 for the establishment of a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months (EMA/CVMP/159047/2023, 18 July 2024), available here.

[33] VMPs authorised for food-producing equids or the medicinal products referred to in Article 113 of the VMP Regulation.

[34] Regulation (EC) 470/2009, Article 5.

[35] Regulation (EU) 2019/6, Article 23.

[36] *Ibid*., Articles 39 and 40.

[37] *Ibid*., recital 54.

[38] *Ibid*., Article 53.

[39] Partnership for the Assessment of Risks from Chemicals | Parc (eu-parc.eu)

the low return of investments linked to a limited market, also represent financial challenges for companies, in particular SMEs.

4.2.2. Improving knowledge about available medicines that may be used in food-producing equids

The study identified a number of actions requiring collaboration among veterinarians, industry stakeholders, regulators and researchers to share knowledge, best practices and advances in treatment for equids, including at international level. This would involve organising conferences, research initiatives and creating up online databases. The preparation of treatment protocols with available VMPs and with essential substances could provide meaningful guidance. This could include updates on changes in relevant EU or national legislation so that veterinary practitioners become aware of their latest obligations.

4.2.3. Reinforcing controls on the use of VMPs in food-producing equids

A strengthened enforcement of the relevant legislation concerning the use of medicines in food-producing equids would help decrease food fraud and thereby protecting public health, while also having a positive effect on animal welfare. The study found the need for a coordinated approach among the relevant CAs and their divisions, both within and between MSs, with an efficient exchange of information and knowledge. To improve controls in this area, the study referred to the current national veterinary prescribing systems for collecting data on prescriptions. However, in order to have more detailed information on the prescription and use of VMPs according to the food-chain status of the treated animals, communication with the national identification database would be required.

4.2.4 Improving the traceability of equids

The study identified several actions to improve traceability, such as (i) the creation and use of a common EU identification database, (ii) granting private veterinary practitioners direct access to databases so that they can immediately record changes in the food chain status of the animals, and (iii) the digitalisation of animal passports. However, the objectives behind these actions can be achieved by applying the current EU legislation.

For example, by granting read-only access to the MS national database to CAs of other MSs (or, as applicable, delegated bodies in those MSs), it would be possible to implement an EU-wide online system within which CAs could view and exchange information on animal identification, food chain status and movements. Veterinarians responsible could also have read-write access to that system to obtain the most up-to-date food chain status of an animal, and to update that status as required. A digital form of the passport (plastic cards, smart cards or digital applications on portable electronic devices) can also be authorised alongside a standard (paper) version. Finally, the envisaged action to create awareness groups at national level focused on animal identification could be grouped with other actions aimed at improving cooperation within national CAs and at raising awareness among veterinarians and animal keepers.

4.3 Actions that would require changes to EU legislation to be implemented

4.3.1. Promoting a more flexible use of VMPs

According to the study, stakeholders have requested that further derogations from Article 106(1) of the VMP Regulation should be allowed so that VMPs could be used in

line with the latest scientific advice, even if such advice is not in line with the summary of product characteristics (SPC). One example would be allowing the veterinarian to reduce or increase the dose, or change the frequency or the route of administration. According to the VMP Regulation, derogation from that article in food-producing equids is only possible in accordance with Article 113, read in combination with Article 115. Stakeholders consider that allowing such flexibility would enable a better management of diseases or injuries in animals and provide veterinarians with legal certainty when treating those animals. However, since the exclusion of the treated animals from the food chain is only triggered by the active substance contained in the medicinal product used, the proposed flexibility would not improve the current situation.

Nevertheless, deviations from the SPC would mean that VMPs are used outside the conditions that have been evaluated by the CAs granting the MA and that guarantee the quality, safety and efficacy of the VMP concerned. Such deviations may therefore lead to public health concerns due to the potential effects of using higher doses or longer dose regimes on the safety of the authorised withdrawal periods and the presence of residues in food. Furthermore, there is a public health concern linked to antimicrobial resistance (AMR). In that respect, any deviation from the SPC resulting in a lower efficacy of a given VMP would also negatively impact on the welfare of the treated animal.

4.3.2. Amendment of criteria for exclusion from the food chain

The study reported possible actions to remove the permanent exclusion from the food chain, including a temporary withdrawal period clause (e.g. six months to one year) when VMPs leading to exclusion are used or for administrative reasons, such as late identification of the animal or the issuing of a replacement passport[40].

According to the study, stakeholders claimed that a one-year withdrawal period could be enough to cover almost all residues of VMPs. Nevertheless, withdrawal periods should be calculated on a case-by-case basis, taking into account the full composition of the VMP (e.g. active substance and excipients), the administration route and its dose regime. This measure would prospectively allow animals to receive a wider range of veterinary treatment while remaining in the food chain. However, these animals would not be allowed to be treated with prohibited substances, and strict monitoring processes would be necessary to ensure that the withdrawal period is adhered to.

According to some stakeholders, this suggestion would create a level playing field for imports from TCs. However, such a measure would entail a differential treatment of food-producing equids under EU legislation, resulting in a lower level of consumer protection for this species compared to other animal species (e.g. cattle, sheep, pigs, poultry, etc.). This could, in turn, undermine the reputation and consumer acceptance of horse meat.

This proposal could contribute to addressing some animal welfare issues (e.g. animals not receiving necessary treatment in order to avoid exclusion) and to reducing the number of excluded animals in future, thus preventing their illegal reintroduction into the food chain. However, the removal of the permanent exclusion from the food chain and the inclusion of

[40] Unless the operator can satisfactorily substantiate that the status of the equid as intended for slaughter for human consumption has not been compromised by any medicinal treatment.

a temporary withdrawal period clause could not be applied to animals currently excluded since it could result in animals treated with prohibited substances re-entering the food chain.

4.3.3. Systematic exclusion of equids from the food chain

This proposed measure would concern all equids except for those specifically bred for food production. As reported in the study, segregation between leisure/competition and food-producing animals would be difficult since an equid does not fit into only one category during its entire lifespan. Therefore, creating a standard category of 'equine companion animal' excluding the animal from the food chain as a foal would lead to several issues. The need for lifelong maintenance could have welfare implications for animals that become an expensive burden and have no alternative use, with unpredictable consequences in terms of neglected or abandoned animals. As a result, fraudulent and criminal activity aimed at illegally reintroducing these excluded animals into the food chain are likely to increase. This would, in turn, have an obvious negative impact on public health since these animals might have been treated with prohibited substances for which no safe MRL can be established.

5. CONCLUSIONS

The exclusion of equids from the food chain due to medicinal treatment is mainly driven by the lack of medicinal products that would allow the treated animal to stay in the food chain.

In this respect, cooperation among all stakeholders contributing to innovation and the development of VMPs for food-producing equids (animal keepers, veterinarians, academia, animal health industry and regulators) would be crucial to identify existing needs, prioritise research on them, and facilitate technology transfer, product development and the regulatory steps leading to a VMP being authorised and kept on the market.

More time will be needed for the VMP Regulation to achieve its full potential and increase medicines availability. The progressive submission of applications for the authorisation of VMPs that have been deemed eligible for limited markets will contribute to this. Wider EU availability of VMPs already authorised in other MSs could be further enhanced by a smooth implementation of the SRP and the adoption of an attractive fee policy that would reduce the authorisation and maintenance costs of these products in the new targeted MS(s). Furthermore, the new ESL will also help to increase medicines availability by addressing therapeutic or diagnostic needs that cannot currently be addressed by medicinal products that can be used in food-producing equids.

Veterinarians play a key role in the prescription and use of VMPs in accordance with EU and national rules. This includes the exclusion of equids from the food chain due to medicinal treatment. The veterinary profession, in close cooperation with national CAs, should continue helping to raise awareness among veterinary practitioners and animal keepers of the relevant legislation; namely on the identification of equids and the use and recording of veterinary treatments. This may involve the design of national guidelines or specific treatment protocols, including on the use of medicinal products outside the terms of the MA and of substances on the ESL, or the organisation of specific training campaigns (including on updates to the relevant national or EU legislation).

Reinforced cooperation and coordination among the national CAs involved, as well as strengthened enforcement, are crucial to identify fraudulent activities and non-compliance with

the applicable EU rules. That reinforced cooperation would involve sharing information contained within the national databases between MS CAs and also with equine operators on identification, movement and food chain status, maximising the potential of the current legislation. It could also be complemented by enhanced communication and awareness rising campaigns with relevant stakeholders. Sound, well-established whistleblowing procedures are also crucial for the early detection of fraud signals and the triggering of the relevant control actions by CAs.

Implementing the actions mentioned above will contribute to improving the current situation. Animal welfare will be enhanced through the availability of more appropriate medicinal treatments for equids, avoiding their exclusion from the food chain and the potential welfare risks (e.g. animals not being treated to avoid exclusion). Reducing the number of excluded animals will also decrease the chances of criminal activity and fraud, and the risks that these activities pose to public health and animal welfare. Finally, the strengthened enforcement of EU law will also help to create a more dissuasive environment for fraud.

Against this background, the Commission will promote, in close cooperation with MS CAs and stakeholders, the implementation of the actions mentioned above under the existing EU legal framework in order to: (i) increase medicines availability for food-producing animal of the equine species; (ii) increase awareness among veterinarians and animal keepers of the EU rules on the use of medicinal products in food-producing equids and their exclusion from the food chain; and (iii) reinforce cooperation and coordination among national CAs, as well as enforcement activities.

On the level playing field for imports from TCs, the Commission is working on a proposal to amend Annex III to Commission Implementing Regulation (EU) 2020/2235[41] and Annex II to Commission Implementing Regulation (EU) 2021/403[42] as regards the model certificates required for entry into the EU of consignments of certain products of domestic and wild game solipeds and certain categories of equine animals, respectively. This amendment will align the attestation in the relevant certificates with the lifetime EU requirements laid down in Commission Delegated Regulation (EU) 2022/2292 and Council Directive 96/22/EC to ensure a level playing field for the rules currently in force.

Furthermore, the Commission will continue to audit exporting countries to evaluate their official control systems for animal products intended for export to the EU, including horse meat.

[41] Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2020/2235/OJ).

[42] Commission Implementing Regulation (EU) 2021/403 of 24 March 2021 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates and model animal health/official certificates, for the entry into the Union and movements between Member States of consignments of certain categories of terrestrial animals and germinal products thereof, official certification regarding such certificates and repealing Decision 2010/470/EU (OJ L 113, 31.3.2021, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2021/403/OJ).

LIST OF ABBREVIATIONS

AMR	Antimicrobial resistance
CA	Competent authority
ESL	Essential substances list
MA	Marketing authorisation
MRL	Maximum residue limit
MS	Member State
SPC	Summary of the product characteristics
SRP	Subsequent recognition procedure
TCs	Third countries
VMP	Veterinary medicinal product