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## **PROPOSAL**

| From:            | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director   |
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| То:              | Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union   |
| No. Cion doc.:   | COM(2023) 770 final   |
| Subject:         | Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of animals during transport and related operations, amending Council Regulation (EC) No 1255/97 and repealing Council Regulation (EC) No 1/2005 |

Delegations will find attached document COM(2023) 770 final.

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## Proposal for a

## REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of animals during transport and related operations, amending Council Regulation (EC) No 1255/97 and repealing Council Regulation (EC) No 1/2005

(Text with EEA relevance)

 $\{ SEC(2023) \ 397 \ final \} - \{ SWD(2023) \ 399 \ final \} - \{ SWD(2023) \ 401 \ final \} - \{ SWD(2023) \ 402 \ final \}$ 

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#### **EXPLANATORY MEMORANDUM**

#### 1. CONTEXT OF THE PROPOSAL

## Reasons for and objectives of the proposal

#### Reasons

In the context of the Farm to Fork Strategy<sup>1</sup>, the Commission announced its intention to revise the EU legislation on animal welfare, including on the welfare of animals during transport. This revision is part of the Commission work programme for 2023<sup>2</sup>. The EU animal welfare legislation has been developed since 1974, with the objectives of improving animal welfare and ensuring the smooth functioning of the internal market. The current legislation on the protection of animals during transport was adopted in 2004 (Regulation (EC) No 1/2005<sup>3</sup>, 'the Transport Regulation').

The Commission carried out a Fitness Check of the EU animal welfare legislation<sup>4</sup>, which was finalised in 2022. This showed that the opportunities provided by significant developments in science and technology, shifts in societal preferences and increasing sustainability challenges, are not reflected in the current regulation. In addition, current rules are difficult to implement and enforce, which leads to a fragmented and sub-optimal level of animal welfare during transport and an uneven playing field in the EU internal market. The Commission's evaluation of the EU Strategy on animal welfare (2012-2015)<sup>5</sup> also found that some compliance risks related to animal transport remain.

Several Council Conclusions have consistently highlighted the need for higher animal welfare standards when animals are moved in the context of an economic activity<sup>6</sup>. In particular, the Conclusions on animal welfare<sup>7</sup> of 16 December 2019 emphasise that animal welfare should be ensured during international long-distance transport of live animals including to third countries.

In its Resolution on the Farm to Fork Strategy<sup>8</sup>, the European Parliament underlined 'the importance of taking into account the latest advances in animal welfare science and responding to public, political and market demands for higher animal welfare standards'. Furthermore, in 2022, further to the report by the EP enquiry committee on animal transport

Communication from the Commission "A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system", COM(2020)381 final.

European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Commission work programme 2023, A Union standing firm and united, COM(2022) 548 final

Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 OJ L3 5.1.2005, p. 1–44

European Commission, Commission Staff Working Document, Fitness Check of the EU Animal Welfare Legislation, SWD(2022)328 final

<sup>&</sup>lt;sup>5</sup> SWD(2021) 77 final

<sup>&</sup>lt;sup>6</sup> Council of the EU, Council Conclusions on an EU-wide animal welfare label, 15 December 2020 (Ref 14047/20); Council of the EU, Council conclusions on animal welfare during maritime long distances transport to third countries, 28 June 2021 (Ref 10235/21).

Council conclusions on animal welfare - an integral part of sustainable animal production – Council Conclusions (16 December 2019)

European Parliament resolution of 20 October 2021 on a farm to fork strategy for a fair, healthy and environmentally-friendly food system (2020/2260(INI)

(ANIT committee), the European Parliament adopted its recommendation on the protection of animals during transport with recommendations for the revision of the Transport Regulation<sup>9</sup>

In its Special report from 2018<sup>10</sup>, the European Court of Auditors (ECA) found that weaknesses persist during transport. In January 2023, ECA published a Review on the EU legislation on the welfare of animals during transport<sup>11</sup> where similar concerns were raised.

## **Objectives**

This revision seeks to contribute to sustainable agricultural and food production by ensuring a higher level of animal welfare, and avoiding distortions on the internal market, thereby contributing to a shift towards an economically, environmentally, and socially sustainable food system, as set out in the Farm to Fork strategy. For this reason, this proposal introduces measures which favour slaughter of animals locally, thus replacing transport of live animals with transport of carcasses and meat. In doing so, these measures will help strengthening the principle of short supply chains while protecting animals by preventing long transports to slaughter.

Transports for purposes other than slaughter should be limited as well with an intention to eventually have them replaced as much as possible with transports of embryos, semen and similar which are much more efficient in terms of the numbers of animals transported, as well as environmentally friendly and creating less expenses.

The general objectives of the proposal are to:

- contribute to sustainable agricultural and food production;
- ensure a higher level of animal welfare;
- bring animal welfare requirements closer to the latest scientific evidence;
- address societal demands;
- make rules easier to enforce (including through digitalisation);
- ensure a smooth functioning of the internal market, both for farmed animals and for animals transported for other economic purposes.

More specifically, this revision's specific objectives are, among others, to:

- reduce animal welfare problems linked to long journeys and repetitive unloading and re-loading linked to several rest periods;
- ensure that animals have more space when transported;
- improve the conditions of transport of vulnerable animals;
- avoid exposing animals to extreme temperatures;

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European Parliament recommendation of 20 January 2022 to the Council and the Commission following the investigation of alleged contraventions and maladministration in the application of Union law in relation to the protection of animals during transport within and outside the Union (2021/2736(RSP))

Animal welfare in the EU: closing the gap between ambitious goals and practical implementation, European, Court of Auditors, 2018.

Transport of live animals in the EU: challenges and opportunities, European Court of Auditors, 2023

- facilitate enforcement of EU rules on the protection of animals, including trough digitalisation;
- better protect animals exported to non-EU countries;
- better protect cats and dogs transported in connection with an economic activity.

This legislative proposal is adopted at the same time as a legislative proposal on the welfare of dogs and cats and their traceability. The two proposals are coherent with each other.

## Consistency with existing policy provisions in the policy area

The proposal is consistent with EU rules on official controls in agri-food chain<sup>12</sup>. The proposal is also coherent with the Commission proposal to establish rules for the welfare of dogs and cats bred and kept in establishments and improve the traceability of dogs and cats place on the market and supplied in the Union.

## Consistency with other Union policies

The proposal is consistent with the objectives of the European Green Deal and the Farm to Fork Strategy.

The proposal is intended to work in synergy with other EU initiatives and policies affecting both live animals and transport, in particular the EU animal health policy<sup>13</sup>, EU's rules on driving times, breaks and rest periods for truck drivers<sup>14</sup>, and rules on the protection of animals used for scientific purposes<sup>15</sup>.

The EU's trade policy also plays a role in promoting higher welfare standards. The proposal includes new and clearer provisions on animal welfare rules applicable for the transport of live animals from a third country into the Union, as well as provisions on animal welfare rules applicable for the transport of live animals from the Union to a third country of destination. In both cases (imports and exports), operators are to ensure that EU animal welfare rules are complied with from the point of departure to the point of destination. A transition period of 5 years is provided in both cases allowing operators to adapt.

Finally, data protection rules (in particular, the General Data Protection Regulation) apply to the provisions on real-time tracking of vehicles.

## 2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

#### Legal basis

The legal basis of the proposal is Article 43 of the Treaty on the Functioning of the European Union (TFEU) since it is necessary to eliminate barriers to the transport of live animals affects the internal market of products of animal origin in order to ensure the smooth

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (Official Controls Regulation), OJ L 95, 7.4.2017, p. 1–142.

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, OJ L 84, 31.3.2016, p. 1.

Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport, OJ L 102, 11.4.2006, p. 1.

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276 20.10.2010, p. 33.

functioning of market organisations in animals and products of animal origin, while ensuring a high level of protection of animal welfare.

The proposal is also based on Article 114 TFEU since since the proposal also aims at ensuring the smooth functioning of the internal market, not only for animals covered under the CAP but also for other animals, such as cats and dogs, fur animals, certain types of wild animals, and animals used for scientific purposes, thus going beyond agriculture and food production.

## • Subsidiarity (for non-exclusive competence)

Animals are often transported across borders and 1.4 billion terrestrial animals are transported each year between EU Member States. The identified animal welfare problems, including their underlying drivers, occur across the EU, albeit to different degrees in different Member States. Finally, the identified animal welfare problems have transboundary consequences including threats to public health, such as antimicrobial resistance. Indeed, as established by EFSA<sup>16</sup>, transport of animals increases the risk of transmitting bacteria resistant to antimicrobials between animals (due to several risk factors, such as contact between animals, the duration of transport, airborne transmission in the vehicle, adverse environmental conditions such as temperature). This increased of spread of AMR among animals has indirect consequences for AMR affecting human.

Action taken at national level is not expected to lead to considerably improved animal welfare and would only partially be able to meet citizens' concerns. Although the area is already regulated by Regulation 1/2005, thus limiting Member States' margin to adopt national rules, there remain important divergences in national rules on key aspects (e.g. conditions for transport of vulnerable animals within a Member State, requirements for the export of animals, requirements for the transport of animals by sea), which negatively affect the smooth functioning of the internal market and the level playing field between operators. Continued action at national level would lead to further fragmentation of requirements and increased differences in the levels of animal welfare between Member States. Member States also apply certain provisions and enforce rules differently, thereby also creating obstacles to the smooth functioning of the internal market. Furthermore, national rules cannot apply to cross-border transports from other Member States and therefore, thereby rendering cross-border movements a driver for lower animal welfare standards.

Animal welfare requirements linked to transport at EU level require a harmonised approach and thus can effectively be regulated at EU level. With a homogenous set of rules, this proposal will lead to uniform and clearer requirements for the transport of animals and a better use of available technologies. The revision will thus ensure a level-playing field for operators within the internal market, facilitate intra-EU trade of animals and provide a more efficient regulatory oversight.

Considering these elements, EU action is justified: it would achieve a consistent approach more effectively and efficiently than Member States acting individually and independently.

EFSA Panel on Biological Hazards (BIOHAZ), Koutsoumanis, K. et al., 'Transmission of antimicrobial resistance (AMR) during animal transport', *EFSA Journal*, Vol. 20, Issue 10 (e07586), Wiley, 2022, pp. 1-93. 10.2903/j.efsa.2022.7586

## • Proportionality

The measures proposed strive to balance a high level of animal welfare with the impact on operators concerned. Further conditions on exporting animals to third countries ensure compliance with the provisions of this Regulation until the point of destination in the third country, thus codifying the case law of the European Court of Justice in this regard. Given that the alternative of banning exports of live animals to countries outside the EU would have detrimental effects on the sector, the stricter conditions for export aim to improve their welfare while maintaining the operations economically feasible. Similarly, measures on maximum journey times are designed to keep most transport activities unaffected.

Proportionate mitigation measures to be applied when transporting animals during high or low temperatures will allow transport without hindering the welfare of the animals transported.

This proposal provides for transition periods to allow actors to adapt gradually. For the new rules on maximum journey times, including maximum journey times for unweaned calves, space allowances, exports, imports, minimum age and weight of unweaned calves, and real time tracking, the transition period is set at 5 years. For the new rules on the transport of cats and dogs, the transition period is 3 years.

#### Choice of the instrument

Given that the current provisions are laid down in a Regulation, the appropriate instrument to address this amendment is a Regulation.

# 3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

## • Ex-post evaluations/fitness checks of existing legislation

The EU animal welfare legislation has been subject to a Fitness Check, including on the transport of live animals.

The Fitness Check established that there is a suboptimal level of animal welfare in the EU, and certain distortions to the internal market for farmers and other food business operators. There are still challenges associated with long journeys, transport in extreme temperatures and the transport of vulnerable animals, such as unweaned calves and pregnant animals. In addition, there are practical difficulties to reconcile the species-specific journey times for animals in the Transport Regulation and the driving times under Regulation (EC) No 561/2006 on certain social rules relating to road transports<sup>17</sup>. Furthermore, scientific and technological developments and future sustainability challenges are not properly addressed by current rules.

In May 2022, the Regulatory Scrutiny Board gave a positive opinion on the Fitness Check, with certain recommendations.

#### Stakeholder consultations

Overview of the consultation activities

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Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport, OJ L 102, 11.4.2006, p. 1

The Commission published in July 2021 an Inception Impact Assessment<sup>18</sup> presenting the policy options to be addressed in the impact assessment. After analysing the 983 contributions received, four campaigns were identified and 525 individual contributions were considered relevant to the protection of animals during transport.

A Public Consultation<sup>19</sup> from October 2021 to January 2022 received almost 60 000 responses on the fitness of the current rules and on how they could be improved.

In addition, the Commission organised a one-day stakeholder conference<sup>20</sup> regarding animal welfare on 9 December 2021 with almost 500 participants.

The Inception Impact Assessment, the public consultation and the stakeholder conference covered different aspects of the ongoing revision of the EU animal welfare legislation, including as regards animal welfare rules during transport.

In the external study supporting the impact assessment, targeted consultation activities have been carried out, including 9 exploratory interviews, a targeted survey with 68 responses analysed, 43 interviews for case studies and further contributions through 2 focus groups and 1 workshop.

Finally, and in the framework of the EU Animal Welfare Platform, a sub-group on the transport of animals was created, comprised of experts from Member States, business organisations, civil society organisations and one independent expert. The Commission organised 10 meetings to discuss the main policy options under consideration for the proposal, the minutes of which are published on the Commission's website.

Third countries with experience transporting livestock contributed to these consultations.

## Main outcomes of the consultation activities

#### Citizens

Citizens support limiting journey times and banning exports to third countries, especially if animals are intended for slaughter. With regards to vulnerable animals, particularly the unweaned ones, citizens prefer to ban their transport.

Citizens also support specific species requirements.

## Animal welfare NGOs

Similarly, animal welfare organisations would like a limit in journey times and a ban of exports to third countries. Some organisations would like a ban on transport altogether. In their views, vulnerable animals should not be transported.

Available on the European Commission Have Your Say platform: <a href="https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12950-Animal-welfare-revision-of-EU-legislation\_en">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12950-Animal-welfare-revision-of-EU-legislation\_en</a>

<sup>18</sup> 

Available on the European Commission Have Your Say platform: <a href="https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12950-Animal-welfare-revision-of-EU-legislation/public-consultation">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12950-Animal-welfare-revision-of-EU-legislation/public-consultation</a> en

EU Animal welfare today & tomorrow, an opportunity for stakeholders to validate the preliminary findings of the Fitness Check of the current EU animal welfare legislation.

https://commission.europa.eu/events/eu-animal-welfare-today-tomorrow-2021-12-09 en

For other animal categories, they support specific species requirements and an upgrade in the use of technological means to achieve a better enforcement. Animal welfare organisations also want a harmonisation of penalties.

## **Business operators**

Business operators (in particular producers) show the lowest support to limiting journey times. Most of business operators are in favour of species-specific requirements rather than a ban on the transport of certain categories of animals.

Operators stress the need for better enforcement rather than new rules and support the use of new technologies for this purpose.

#### National authorities

Generally, national authorities are not in favour of a total ban of live animal exports, but there is widespread support for the introduction of stricter measures regarding unweaned and other vulnerable animals, as well as for the introduction of maximum journey times.

Regarding new technologies, introducing a digital application at EU level to reduce administrative costs and facilitate data exchange between Member States was generally supported by national authorities.

## Consideration of results by the Commission

The results from the consultation activities have been used to inform the challenges faced with the current implementation of the Regulation, but also to inform the policy options and to assess their impacts, for instance when it comes to the impact on operators or the extent to which citizens' concerns would be addressed.

The evidence gathered from stakeholders also contributed to define the transition periods and to ensure the proportionality of the measures.

#### Collection and use of expertise

## Methodology used

The Commission sought the expertise of the EFSA, which issued in 2022 five scientific opinions (see recital 4 of the proposal) on the protection of animals during transport on equids, bovines, small ruminants, pigs, domestic birds and rabbits.

The proposal also considered international standards on the protection of animals during transport by sea, by road and by air adopted by World Organisation for Animal Health <sup>21</sup>.

All the relevant audits reports performed by the Commission services were used as well as relevant statistical sources or databases (Eurostat, Trade Control and Expert System (TRACES), etc.).

An external study<sup>22</sup> supporting the impact assessment accompanying the revision of the EU legislation on the welfare of animals during transport was carried out. This study gathered information and data on impacts and costs for stakeholders of the initially proposed measures and options.

World Animal Health Organisation, Animal welfare standards during transport

European Commission, Directorate-General for Health and Food Safety, *Study supporting the Impact Assessment accompanying the revision of the EU legislation on the welfare of animals during transport*, Publications Office of the European Union, 2023, section 5.2.1., doi: 10.2875/110728. (Transport study).

In addition, a study<sup>23</sup> on the assessment of the cumulative impacts of the two proposed packages of measures and options was carried out. This study presents the results of a supply chain analysis (performed by an external expert), and a modelling (performed by the Commission's Joint Research Centre) of the impacts of changes in production costs, as identified in this supply chain analysis, on production levels, consumer prices, exports and imports. The study contains an assessment of the impacts of the two packages on food security and food affordability (performed by the Commission's Joint Research Centre).

In addition, the studies from two pilot projects, commissioned by Commission on request of the European Parliament, on the transport of unweaned dairy calves<sup>24</sup> and of end-of-career dairy cows <sup>25</sup>, were considered. Also, the Court of Auditors' review<sup>26</sup> on the transport of live animals in the EU was considered.

Finally, the Commission consulted in 2022 and 2023 the subgroup on transport under the EU Animal Welfare Platform. The Commission also held a number of consultative meetings with various stakeholders affected by the revision.

## Summary of advice received and used

EFSA recommendations were taken into account in the proposal, particularly concerning:

- limiting journey times,
- increasing space allowances,
- establishing upper critical temperatures during transport.

The recommendations were modulated in the proposal to ensure the technical and economic feasibility of the changes proposed.

Audit reports and consultations with National Contact Points for the transport of animals provided for information and best practices.

### Means used to make the expert advice publicly available

EFSA opinions, international recommendations, audit reports and minutes of discussions with National Contact Points, and with the Animal Welfare Platform subgroup on transport, are all publicly available on the Internet. The two external studies supporting the impact assessment have also been published by the European Commission.

## Impact assessment

The impact assessment addresses six measures: journey times and space allowance, exports to third countries, transport of vulnerable animals, transport in hot temperatures, new technologies for monitoring and controls, and transport of cats and dogs.

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European Commission, Directorate-General for Health and Food Safety, Modelling of policy options to support the Impact Assessment accompanying the revision of the EU legislation on the welfare of animals during transport, 2023, doi: 10.2875/061480

European Commission, Directorate-General for Health and Food Safety, *Study on shifting from transport of unweaned male dairy calves over long distance to local rearing and fattening: final report*, Publications Office of the European Union, 2022

European Commission, Directorate-General for Health and Food Safety, *Study on economic models to prevent the transport of unfit end-of-career dairy cows: final report*, Publications Office of the European Union, 2022

European Court of Auditors, Review 03/2023 "Transport of live animals in the EU: challenges and opportunities". https://www.eca.europa.eu/Lists/ECADocuments/RV-2023-03/RV-2023-03\_EN.pdf

The measures satisfy the principle of no significant harm as the implementation of all the measures chosen (limiting journey durations but increasing space allowance for animals within trucks) would overall represent a negligible impact on greenhouse gas emissions (GHG).

In addition, the proposal meets the principle of digital by default as it intends to digitalise certificates and authorisations that under the current Regulation are handled on paper.

## Maximum journey times and space allowances during transport

The options assessed in the impact assessment are:

- 1. maximum journey times of 12 hours for all animals, and revision of rules on space allowance in line with EFSA, or
- 2. maximum journey times of 9h for animals for slaughter, and 21h (with a minimum 1h rest after 10h) + 24h rest with unloading + 21h (with a minimum 1h rest after 10h) for other animals, and revision of rules on space allowance in line with EFSA.

The impact assessment concludes that the second option is preferred. This option is well articulated with EU rules on social rights of drivers<sup>27</sup>. This proposal reflects this preferred option, providing for a 5 years' transition period for these measures.

The limitation of journey times will have a high positive impact on animal welfare, both animals transported for slaughter and other reasons. This not only due to the limitation of the journey duration, but also because of the limitation of the frequency of unloading and reloading, which is associated with stress and welfare problems (while today there is no limitations in the number of unloading for a rest of 24h, the new rules will not allow it in the case of animals for slaughter and will allow only one such rest with unloading for animals transported for other purposes). 2.6 million of mammals are transported annually for a duration of over 9 hours for slaughter, and 1 million are transported annually for over 42 hours for other types of journeys between Member States.

As regards animals transported for slaughter, the option is not expected to have major economic impacts since relatively few of journeys above 9 hours are performed in the EU (between 0.3% and 3.4% of animals transported for slaughter across Member States, depending on the species).

Within the EU, the journey times proposed for animals transported for fattening and production would impact 1,4% of bovines and 0.2% of pigs. The journey times proposed for animals transported for breeding would impact between 9% and 16% of cows, goats, pigs and sheep moved between Member States. This is therefore also expected to have limited economic impacts on operators.

Combined with increased space allowances, in trucks, aligned with EFSA opinion, this is expected to bring significant animal welfare benefits, as well as additional costs for

The measure of maximum 9h journey times for animals for slaughter is in line with EU rules on social rights of drivers, which foresee maximum 9h when there is only one driver. The measure for animals transported for other purposes also allows alignment with the EU legislation on social rights of drivers, in the case where there are two drivers. Indeed, for two drivers, the EU legislation on social rights of drivers provides for a maximum 19h of drive. Since journey times in this proposal includes loading and unloading the animals (and estimating 1h of time for loading the animals and 1h for unloading), this corresponds to the maximum journey time of 21h.

transporters due to the necessity to buy additional trucks, as the new rules are expected to result in an increase in the number of transport hours and costs.

On EU level, the yearly net aggregated costs vary depending on the animal species and categories transported, going from EUR 35 million for the transport of laying hens to EUR 1 069 million for the transport of beef cattle. The majority of these costs comes from increased space allowance, and fall on transporters. This aggregate data is linked to the large quantities of food of animal origin produced in the EU (and thus, large number of animals transported). In average it corresponds to an increase of production costs of 1,4 Eurocents per kilo of meat, milk, or eggs produced. The impact on consumer prices, as described below under "overall assessment", corresponds to an improvement on animal welfare conditions during transport which largely responds to the request of Union citizens, as illustrated by the results of the 2023 Eurobarometer where 83% asked to improve such conditions.

In terms of social impacts, an increase in the number of transports needed would increase the need for drivers. In terms of environmental impacts, while the reduction of journey times reduces emissions, the increases in space allowance leads to an increase in emissions. The impact assessment shows that the combined effect of these measures is a marginal increase in emissions.

## Export of live animals

The options assessed in the impact assessment are:

- 1. a ban on exports of ruminants; or
- 2. new reinforced rules on import, including rules to ensure that measures on journey times and space allowance are applied until the place of destination, an animal welfare officer on board of vessels, and requiring that vessels are flying a white or grey flag under maritime safety rules.

The impact assessment concludes that the second option is preferred. This proposal reflects this preferred option, and provides for a 5 years' transition period for these measures.

Exporting under stricter conditions (including rules on maximum journey times for road transports and stricter maritime safety requirements for livestock vessels) would mean significant improvements to animal welfare.

For road transport, while the number of kilometers travelled may be reduced, operators will need to upgrade the trucks to increase space allowance.

Regarding maritime transport, the average cost of training of an animal welfare officer per person per year is estimated to EUR 241. An increase of the enforcement costs associated with the option of upgrading standards for livestock vessels could be expected.

The emissions by trucks and livestock vessels are not expected to vary significantly, as the number of animals transported is not expected to vary significantly.

#### *Transport of unweaned calves*

The option examined in the impact assessment consists of two measures for unweaned calves:

- 1. maximum journey times of 19h for unweaned calves (9h + 1h rest + 9 h), provided that an efficient feeding system exists (transition period of 5 years); and
- 2. a minimum age of 5 weeks and minimum weight 50kg for transporting unweaned calves (transition period of 2 years).

The impact assessment confirms these two measures in the preferred option. This legislative proposal deviates from this conclusion concerning the duration of the transition period for the minimum age and weight of unweaned calves to be transported, and provides for a transition period of 5 years also in this case. This is to mitigate impacts on dairy farmers who will need to adapt in order to keep the calves longer on farm.

Maximum journey times and minimum age and weight of transported animals would improve the welfare of unweaned calves, considered vulnerable animals especially exposed to welfare and health risks during transport.

Technological developments in establishing an effective system for feeding the calves on the trucks are well advanced, but are not yet in general use, would allow for the transport of calves up to 19 hours (9h drive, 1h rest and feeding, 9h drive). This would mitigate the negative economic impacts of a maximum journey times of 8h in case no effective feeding system is in place, although the three Baltic states would still be impacted, as they are currently the point of departure of long journeys for unweaned calves exceeding 19 hours. A transition period of 5 years is proposed, as Member States impacted by this measure need time to restructure their sector. While the feeding interval would be 9h in all cases, where calves are transported by Ro-Ro vessels (e.g. from Ireland to the continent), the part of the journey spent on the Ro-Ro vessel is not counted in the above-mentioned maximum journey time.

The cost for installing a feeding system in an existing truck is estimated to be between EUR 25 000 – EUR 30 000, while a new truck equipped with such a feeding system is estimated to cost around EUR 500 000. Due to the higher age of the calves, the current three-decked trucks will need to be transformed in two-decked trucks, which will incur limited costs for transporters.

The new requirements are estimated to increase the cost for dairy farmers of keeping the animals longer on farms. However, the selling price of the calves would be higher since they are stronger. An improved health status and reduced mortality of calves upon arrival due to increased resilience is also beneficial for fattening farms. Therefore, overall the impact for is expected to be positive for most farmers.

The option would have a positive environmental impact, since more limited maximum journey times would reduce transport related GHG emissions.

## Transport in hot temperatures

The option examined in the impact assessment consists in an approval of transport for long journeys subject to weather forecasts. If the weather forecast is between 25°C and 30°C, only short journeys (max 9 hours) would be allowed during daytime, with access to water for the animals. If weather forecast is higher than 30°C, only animal transport at night (i.e. between 21h00 and 10h00) would be allowed. A transition period of 5 years is foreseen. The impact assessment confirms this as the preferred option, which is also reflected in this proposal.

The option would improve the welfare of the animals as it would allow them to avoid heat stress.

Many Member States today do not approve long journeys when temperatures above 30°C are forecasted, further to recommendations from the Commission. Therefore, the economic impacts of this measure could be expected to be mainly linked to the logistical challenge of transporting animals by night when the daytime temperature is forecast above 30°C, but will provide a uniform rules for such cases in the EU. Transporters will see an increase in their costs due to higher wages for night-time driving but also higher administrative costs when

inspections and checks have to be performed during the night. A limited impact is also expected on farmers and slaughterhouses.

No environmental impact is expected. With regards to social impact, workers in the sectors, specifically drivers, slaughterhouse personnel, official veterinarians, may need to perform an increased number of nightshifts which may have an additional impact on labour needs.

#### New technologies

Two options have been assessed in the impact assessment. The first option is composed of these 2 measures:

- 1. Real-time positioning of trucks; and
- 2. A central database and digital application.

The second option consisted of retrospective checks based on trachographs, combined with the central database and digital application referred to above.

The impact assessment concludes that the first option is the preferred option, which is reflected in this proposal. It provides that GPS data of trucks will be communicating with an automated system (the EU central database), itself connected to TRACES so that competent authority can access information about the timing when the truck reached certain points (place of departure, control post, border crossings between Member States, place of destination) so that the competent authorities can carry out official controls based on such information. Since the reduction of maximum journey times is one of the main measures to achieve the animal welfare policy objective, this is necessary to provide Member States' competent authorities with tools to be able to perform official controls in an effective manner.

Real-time tracking systems will make it possible to better target and perform more efficiently official controls with the help of the central EU database, resulting in improved animal welfare.

Since more than 77% of the current transport trucks are already equipped with a tracking system, the operators' costs for meeting the new standards would be marginal.

The administrative burden for transporters is expected to decrease substantially with the use of an automated tracking system and IT platform.

The main cost, although limited, would be associated for the Commission to develop modules in the existing TRACES system (see Legislative financial statement). Member States administrations would incur limited costs related to training of staff.

Although digitalisation, reducing the use of paper, is expected to reduce the GHG emissions associated with paper, a small increase in GHG emissions associated with the higher energy use is expected.

A slight positive social impact is expected. While less administrative staff may be needed among the business operators, the number of staff needed in public administration for processing the data collected might increase. For operators, the simplification thanks to digitalization will mean improved working conditions.

Better protection of cats and dogs transported for commercial purposes

The options assessed in the impact assessment are:

- 1. updated and more specific requirements for the transport of cats and dogs for economic purposes, including temperature conditions and a minimum age of 15 weeks for transport; or
- 2. updated and more specific requirements for cats and dogs but with a minimum age of 12 weeks for transport.

The impact assessment concludes that the second option is the preferred one, and this is reflected in this legislative proposal, with a 3-year transition period.

The measure would improve the welfare of cats and dogs transported in the context of an economic activity, for which specific provisions are largely missing at present. For instance, a minimum age for being transported will allow for a better development of immunity against infectious diseases.

Regarding economic impacts, additional veterinary health checks of the cats and dogs may cost between EUR 10 and EUR 40 per animal. The economic impact of the new requirements for feeding and watering are expected to be limited, since relatively similar rules apply already. Additional costs for transporters may also be expected, related to the improvement or replacement of their current vehicles to meet the new standards may be expected. A commercially available new dog trailer without air conditioning but properly designed is estimated to cost between EUR 1 000 and EUR 3 000 for two to four dogs.

No significant environmental impacts are expected. Considering social impacts, including on human health, the additional vaccination requirements and the higher age at transport proposed in this measure may result in fewer sick animals after arrival, which would have a positive impact also on human health.

#### Overall assessment

The impact assessment report also presents the expected cumulative impacts of two packages of options, as well as their impact on international competitiveness, food security, food affordability and distributional effects. This showed that, for measures concerning journey times, space allowance, transport of unweaned calves, hot temperatures and new technologies, the cumulative impact on production costs for the preferred package (package 2) represents at EU level on average an increase in production costs of 1,4 Eurocent per kilo of meat, milk or eggs per year. This increase in cost is expected to take place during the 5year transition period. The modelling performed showed that the impacts of this limited increase in production cost on production levels, levels of imports, of exports, as well as consumer prices are limited. Consequently, the measures are expected to have very limited impacts on the international competitiveness of EU's livestock sector. Similarly, no significant impact was identified concerning the availability dimension of food security (with only a marginal reduction in poultry consumption). Concerning food affordability, the modelling shows impacts on consumer prices between 0.06% and 4.37% depending on the commodity. This represents an additional expenditure ranging from EUR 2.81 to EUR 14.09 per person per year, depending on diet and income.

The impact assessment shows that this proposal will contribute to the Sustainable Development Goals (SDGs): it will contribute to SDG 3 "Good health and well-being" as improving animal welfare during transport will contribute to combat AMR in both humans and animals; it will also contribute to SDG 12 "Responsible consumption and production" since producing food with higher animal welfare standards equates to a more responsible production system.

Opinion of the Regulatory Scrutiny Board on the impact assessment:

The impact assessment was submitted to the Regulatory Scrutiny Board for approval on 30 October 2023, and received a positive opinion with reservations on 17 November 2023. The RSB opinion asked to present the analysis of costs and benefits more clearly, to complement the analysis of impacts on competitiveness, distributional impacts in the supply chain, and to clarify the comparison of options. The impact assessment was revised to address these RSB recommendations. In particular, the supply chain analysis was updated to be made more comprehensive and better reflect impacts on producers, and the relation between the supply chain analysis and the analysis of impacts on competitiveness was clarified.

## Regulatory fitness and simplification

Providing more uniform requirements – such as common rules on the maximum journey times – will bring a simplification for the operators, as well as for the competent authorities, compared to the current rules that differ per species and categories of animals. Furthermore, clearer definitions and less use of open norms will make the legislation more efficient and easier to comply with, as business operators no longer need to make their own assessments to decide on the thresholds to use for different provisions to apply.

A greater use of digital tools will simplify the communication between businesses and public authorities. Real-time tracking of vehicles would allow to better plan, target and streamline all official controls on animal transport.

No derogations are foreseen for SMEs as they represent the quasi total of business operators impacted and therefore, their particularities are taken into account already for the selection of the measures and definition of transition periods.

## Fundamental rights

Provisions on real-time positioning of vehicles were designed to ensure that the protection of personal data is safeguarded, in compliance with the General Data Protection Regulation.

## 4. **BUDGETARY IMPLICATIONS**

This proposal has the following budgetary implications for the EU budget over the period 2022-2027 of the EU Multiannual Financial Framework (MFF). Details are provided in financial statement attached to this proposal.

Human resources for the implementation of the proposal, the studies, audits, tertiary legislation and international activities: 6,5 full-time equivalents (FTE) per year as from 2026.

Under heading 1 "Contributing to a high level of health and welfare for humans, animals and plants" of the multiannual financial framework: EUR 2,4 million for the period 2024- 2027.

This covers:

One-off costs: Study on modalities for the use of new technologies and digitalization to facilitate the implementation and enforcement of rules on animal welfare during transport: EUR 250.000.

One-off costs: developing module in TRACES: EUR 1.400.000.

Recurring costs: Maintenance of TRACES: EUR 450.000 per year.

One-off cost: Development of digital app: EUR 300.000

#### 5. OTHER ELEMENTS

## • Implementation plans and monitoring, evaluation and reporting arrangements

The Commission regularly audits Member States to monitor the extent to which they comply with EU law<sup>28</sup>. The proposal contains an article on the network of liaison bodies in Member States for animal welfare during transport. This network will play an important role to promote a uniform implementation of the new Regulation across the Union.

The Commission designated EU reference centres for animal welfare providing technical assistance for the implementation of the EU animal welfare legislation, including on transport. The Commission also supports continuous training<sup>29</sup> that covers the protection of animals during transport within the Better Training for Safer Food programme. The implementation of the new rules will also be discussed in the EU Animal Welfare Pltform.

All these activities will contribute to the implementation of this revision. In addition, the level of implementation will be visible through new requirements to monitor and report on indicators, primarily using real-time TRACES data in addition to reports from competent authorities. Such a monitoring report on the state of animal welfare in the Union with regards to transport shall be presented 5 years after the date of entry into force of the new Regulation, and at least every 5 years hereafter.

In order to be able to gather robust evidence after the 5 years transition periods, an evaluation report should be presented 10 years after the entry into force of the Regulation.

## • Detailed explanation of the specific provisions of the proposal

## Chapter I: Subject matter, scope, definitions, and general provisions

This chapter clarifies the scope of application of the proposal, provides for definitions, and includes general requirements applicable to all transport operations.

## Chapter II: Organiser and transporter authorisations

This chapter establishes the rules and conditions for authorisation of organisers to arrange the transport of animals and for authorisation of transporters to transport animals.

## Chapter III: Means of transport

This chapter provides for the conditions for the approval of road vehicles for transport of animals, that already exist in the present legislation. Transport by air must be carried out by carriers that are members of IATA.

## Chapter IV: Obligations prior to departure

This chapter requires journey logs for both long and short journeys. Keepers are to be responsible for the fitness for transport of the animals loaded.

## Chapter V: Obligations during transport and at the place of destination

This chapter addresses obligations for transporters during the journey. Assembly centres are also covered.

This chapter provides for the obligation for real-time tracking of road vehicles.

Audits can be consulted at: https://ec.europa.eu/food/audits-analysis/audit-report

https://food.ec.europa.eu/horizontal-topics/official-controls-and-enforcement/legislation-official controls/better-training-safer-food\_en

Transporters are also obliged to collect information on the basis of certain indicators, analyse them and take corrective measures to improve welfare of transported animals.

## Chapter VI: Conditions for transport of terrestrial animals

This chapter provides for maximum journey times both for animals for slaughter and animals transported for other purposes. Specific maximum journey times are also set out for the transport of unweaned animals.

Journeys under extreme temperatures are limited in time with additional conditions to be met.

### Chapter VII: Transport to and from third countries

This chapter includes new rules for the transport of animals to third countries, such as certification for organisers and attestations signed by third country competent authorities prior to a journey by livestock vessel.

Control posts in third countries must comply with equivalent standards to those applicable in the Union.

## Chapter VIII: Obligations of competent authorities

This chapter contains provisions on the training and certificates of competence of operators as well as the requirement to designate exit points. The chapter also includes rules on national liaison bodies for transport of animals, as well as on analysis of data gathered on the basis of the indicators referred to in Chapter V.

## **Chapter IX Sanctions**

This chapter contains provisions on sanctions for infringements of the Regulation, including in particular in the case of serious infringements.

## Chapter X: Procedural provisions

#### Chapter XI: Other provisions

This chapter contains provisions on stricter national measures, the creation of a digital app to facilitate implementation and enforcement of the Regulation, as well as a derogation with respect to existing national provisions concerning outermost regions.

## Chapter XII: Transitional and final provisions.

This chapter amends Council Regulation (EC) No 1255/97 on control posts, requiring them to be adequately equipped for the relevant species and categories of animals and to have a booking system available to organisers.

## Proposal for a

#### REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of animals during transport and related operations, amending Council Regulation (EC) No 1255/97 and repealing Council Regulation (EC) No 1/2005

(Text with EEA relevance)

#### THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION.

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43(2) and 114(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>30</sup>,

Having regard to the opinion of the Committee of the Regions<sup>31</sup>,

Acting in accordance with the ordinary legislative procedure,

#### Whereas:

Council Regulation (EC) No 1/2005<sup>32</sup> established common minimum rules for the (1) protection of animals during transport. Since its adoption, science and technology have evolved. There is a better understanding of space allowance requirements and of the needs of animals during transport, in particular those of unweaned and aquatic animals. There have been significant developments in the availability of digital solutions for the administrative steps involved in the transport of animals. With increasing citizens' awareness and concerns about animal welfare and the trend towards more sustainable production methods, many Member States are revising or adopting national rules going beyond the Union minimum requirements. In addition, the Fitness Check of the EU animal welfare legislation<sup>33</sup>, revealed, in relation to Regulation (EC) No 1/2005, difficulties in interpreting, applying, and enforcing certain provisions, thus contributing to an uneven playing field for the different actors. It is therefore necessary to revise the rules on the protection of animals during transport to align them with the latest science and technology, as well as to make them easier to apply and enforce.

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<sup>&</sup>lt;sup>30</sup> OJ C, , p. .

OJ C, , p. .

Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 OJ L 3, 5.1.2005, p. 1–44.

Commission Staff Working Document 'Fitness Check of the EU Animal Welfare legislation', SWD(2022) 328 final, 4.10.2022

- (2) Animal welfare is a Union value enshrined in Article 13 of the Treaty on the Functioning of the European Union ('TFEU'). In addition, the Union and several Member States are signatories to the revised European Convention for the protection of animals during international transport<sup>34</sup>.
- (3) The transport of live animals is an important part of the agri-food chain. The protection of animals during transport is a matter of public concern that affects consumers' attitudes towards agricultural products. This Regulation aims to simplify procedures, reduce administrative burden and facilitate easier enforcement of harmonised rules, while ensuring a high level of protection of animals during transport. Ensuring the protection of animals during transport has a positive impact on the health and welfare of the animals and contributes to better quality of animal products.
- (4) This Regulation aims at ensuring the smooth functioning of the internal market, including for animals not used for food production, such as cats and dogs, fur animals, certain types of wild animals, and animals used for scientific purposes.
- (5) In 2022, the European Parliament adopted recommendations on the protection of animals during transport based on the report of the Committee of Inquiry on the Protection of Animals during Transport within and outside the Union (ANIT Committee). The recommendations call on the Commission and the Council to carefully review EU legislation on protection of animals during transport based on a rigorous scientific investigation into the impact of transport on animals of all species and ages and on an in-depth socio-economic, environmental and health impact assessment taking into account the diversity of geographical situations and specificities, and farming models across the Union. The report of the ANIT Committee also pointed out shortfalls of existing implementation throughout the Union and recommended measures such as restricting journey times, banning transports in extreme temperatures, ensuring that transport of animals to third countries take place respecting principles of protection of animals throughout the journey until they reach their destinations in third countries. In addition, the European Parliament pointed out the need to replace transport of live animals with a more efficient ethical system which favours the transport of semen or embryos over breeding stock, and carcasses and meat over animals being transported for slaughter.
- (6) In September 2022, the European Food Safety Authority ('EFSA') published five scientific opinions relating to various welfare consequences and hazards arising during transport of small ruminants<sup>35</sup> (sheep and goats), equidae<sup>36</sup> (horses and donkeys), bovines<sup>37</sup> (cattle and calves), pigs<sup>38</sup> and animals in containers<sup>39</sup>, including

European Convention for the Protection of Animals during International Transport, Council of Europe, Chişinau, 6.XI.2003, European Treaty Series-No. 193.

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare) Scientific Opinion on the welfare of small ruminants during transport. EFSA Journal 2022; 20(9):7404, 101 pp

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare) Scientific Opinion on the welfare of equidae during transport. EFSA Journal 2022; 20(9):7444, 113 pp.

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare) Scientific Opinion on the welfare of small ruminants during transport. EFSA Journal 2022; 20(9):7404, 101 pp.

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare) Scientific Opinion on the welfare of pigs during transport. EFSA Journal 2022; 20(9):7445, 108 pp.

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare) Scientific Opinion on the welfare of domestic birds and rabbits transported in containers. EFSA Journal 2022; 20(9):7441, 188 pp.

domestic birds (chickens, laying hens, turkeys etc.), and rabbits ('EFSA opinions'). The EFSA opinions broadly conclude that providing more space, lowering maximum temperatures and keeping journey times to a minimum, are all required to improve the protection of animals during transport. Therefore, Regulation (EC) No 1/2005 should be replaced by a new Regulation that is in line with the latest developments in scientific and technical knowledge in this field and with consumers' demands, while avoiding barriers to the functioning of the internal market and trade in live animals and ensuring the enforceability of the new rules.

- (7) To ensure a consistent and effective application of this Regulation across the Union in the light of its basic principle, according to which animals must not be transported in a way likely to cause injury or undue suffering to them, it is appropriate to set out detailed provisions addressing the specific needs of the different species arising in relation to the various types of transport. Such detailed provisions should be interpreted and applied in accordance with the aforesaid principle and should be updated in a timely manner, in particular in light of new scientific knowledge, taking account of new EFSA opinions.
- (8) Technology for navigation systems and electronic databases has advanced considerably since the entry into force of Regulation (EC) No 1/2005. This makes it possible to simplify procedures and strengthen controls and inspections on the protection of animals during transport, thus leading to better enforcement of Union rules. It is therefore important to make use of new technologies and expand the possibilities provided by Trade Control and Expert System (TRACES-NT), the digital certification and management platform for all sanitary and phytosanitary requirements, which is embedded in the Integrated Management System for Official Controls (IMSOC)<sup>40</sup>.
- (9) This Regulation provides for rules so that the TRACES database can incorporate digital authorisations, certificates of approval, certificates of competence, journey logs, live tracking of road vehicles and temperature forecasts. TRACES should also contain lists of control posts in third countries and EU exit points. It also allows for more realistic journey planning, efficient traceability, better monitoring of operations and animal welfare indicators, timely emergency measures and complete analysis of data, with the overall objective of ensuring more effective application and better enforcement of the Union rules on the protection of animals during transport, as well as considerably reducing administrative burden.
- (10) The obligation of Union operators to protect animals during transport does not end at the external borders of the Union. Organisers of transport of animals from the Union to a place of destination in a third country must ensure compliance with Union rules on the protection of animals during transport also during the stages of the journey that take place outside the Union, and until the animals arrive at the final place of destination in the third country. This is coherent with the case law of the Court of Justice of the EU in Case C-424/13<sup>41</sup>. This Regulation should therefore apply to the transport of animals for which the place of departure is in the territory of the Union

Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation), C/2019/7005, OJ L 261, 14.10.2019, p. 37–96.

Judgment of 23 April 2015, Zuchtvieh-Export GmbH, C-424/13, ECLI:EU:C:2015:259, paragraph 56

- and regardless of whether the place of destination is in the territory of the Union or in a third country.
- (11)Transport of live animals from third countries to the Union territory mainly concerns certain species of animals and it is usually carried out through direct routes. When live animals are imported into the Union, operators who transport such animals from a third country to a place of destination within the Union should ensure that the animals are protected at least in an equivalent manner to animals transported within the Union territory, and this from the moment when the animals are loaded onto the means of transport in the third country until the place of destination in the Union. This is necessary in light of Union citizens' concerns related to the welfare of animals during transport, which extends to all animals transported to, from or within the Union. This Regulation should therefore apply to the transport of animals for which the place of departure is in the territory of a third country and the place of destination is in the territory of the Union. In order to ensure proper application of the requirements for such transport at the place of departure, it is necessary for the competent authority of the third country to check the planning of the journey concerned, and to certify in the official health certificate for imports of the animals into the Union and via its approval of the journey log, that the planning of the journey has been done in accordance with this Regulation, or with equivalent requirements. The transporter of the animals should be responsible for ensuring that this planning is respected until the point of destination and should comply with the obligation to complete the journey log.
- (12) For transit of animals from a third country to another or to the same third country via the Union territory, Union rules should apply during the part of the journey taking place on the Union territory. Although neither the place of origin nor the place of destination of that transport is in the Union, for the benefit of the animals and given citizens' concerns, this Regulation should apply to the part of the journey that takes place within the territory of the Union. Transporters should ensure that the animals are transported in conditions that comply with this Regulation, notably with respect to space allowances, feeding and watering, since these are essential for the welfare of animals transported on the Union territory. However, compliance with rules on journey times should not be required in such cases, as this could lead to even longer journeys for the animals concerned by requiring third country operators to circumvent the Union territory via longer routes, which would potentially have a worse impact on animal welfare.
- (13) The World Organisation for Animal Health (WOAH) Terrestrial Animal Health Code<sup>42</sup> contains guidelines setting minimum standards at global level as regards animal behaviour, the responsibilities and competence levels of the different actors involved in the transport of animals, the documentation to be provided, journey planning, loading, and actions in the event of a refusal of the animals, among others. This Regulation takes into account those guidelines.
- (14) Experience enforcing Regulation (EC) No 1/2005, as well as case law of the Court of Justice of the EU such as in Case C-301/14<sup>43</sup> show that economic activity in relation

WOAH Terrestrial Animal Health Code, 2023, <u>Terrestrial Code Online Access - WOAH - World</u> Organisation for Animal Health.

Judgement of 3 December 2015,

to transport of animals should be construed in a broad sense. Transport of animals in connection with an economic activity should not be considered as limited to cases involving an immediate exchange of money, goods or services or where transport is carried out with the intention of making a profit. If a transport forms part of an offering of goods or services on a given market, it should be considered as a transport in connection with the economic activity.

- (15) The main species of animals transported within the Union and from the Union to third countries for economic purposes are vertebrate animals including small ruminants, equidae, bovines, pigs, domestic birds, rabbits, and aquatic animals, namely fish, cephalopods, and decapods. To ensure proportionality, the scope of this Regulation should be limited to those species.
- Ornamental fish are usually transported in small boxes by express couriers in bags of water especially adapted to their needs and the duration of the journey is usually less than 24 hours. Therefore, the transport of ornamental fish rarely represents a major risk for animal welfare and should be excluded from the scope of this Regulation.
- Directive 2010/63/EU of the European Parliament and of the Council<sup>44</sup> regulates the (17)protection of animals used for scientific purposes. Due to the strict requirements on the quality of animals needed for research and testing, any compromises to the health or welfare status of animals on arrival at their place of destination have a direct impact on the possibility to use them for those purposes. In addition, scientific procedures may require the use of animals that can potentially be considered unfit for transport according to this Regulation such as some genetically modified animals and animals which have undergone surgical procedures for the purpose of the projects in line with Directive 2010/63/EU. Transport of live animals for scientific purposes is undertaken by specialist operators with specially designed vehicles equipped to ensure the health and welfare of the animals throughout the planned journeys. While a distinction can be made with regard to the purpose for which these animals are transported, their welfare should be guaranteed. However, it would be neither coherent nor acceptable to include them completely in the scope of this Regulation. For these reasons, speciesspecific rules related to fitness for transport, watering and feeding intervals and certain provisions concerning journey times, temperatures and rest periods should not apply to transport of animals used or destined to be used for scientific purposes in a project authorised under Directive 2010/63/EU of the European Parliament and of the Council.
- (18) Experience with the application of Regulation (EC) No 1/2005 shows that operators often prolong journeys beyond the limits set out in the relevant provisions by transporting animals from a holding to several assembly centres consecutively. The animals are grouped together with animals from other holdings in these assembly centres and only the last assembly centre is recorded as the place of departure. Therefore, a mandatory stay of the animals at both the place of departure and destination should be imposed and assembly centres should only be allowed to be places of departure if they are situated locally, with the aim of preventing the practice of "assembly centre hopping".

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

- (19) Only organisers of the transport of animals who have the means to comply with the requirements of this Regulation should be allowed to transport animals for long journeys. Therefore, it is appropriate to establish an authorisation system for organisers. Organisers should be responsible for ensuring compliance with Union rules from the place of departure to the place of destination. They may subcontract the transport of animals to a transporter and should remain responsible for ensuring compliance with Union rules by that transporter and any other persons involved in that transport. The organiser should provide proof to the competent authorities of their ability to ensure that Union rules on transport are met until the animals' arrival at the place of destination.
- (20) Transporters and their staff play a central role in the transport of animals significantly influencing the welfare conditions of the transported animals. Welfare conditions of animals during transport are significantly impacted by the day-to-day conduct of transporters. They should have the necessary competence to ensure compliance with this Regulation, as well as compliance by their staff, and the necessary approval of the means of transport used, together with contingency plans to address emergencies. Therefore, it is appropriate to have an authorisation system for transporters. They should be accountable and transparent concerning their status and operations. In particular, they should report any difficulties and keep precise records of their actions and the results.
- (21) Means of transport should be designed to avoid injury or suffering to the animals. Therefore, it is appropriate to set out technical requirements to be fulfilled for a means of transport to be approved and taking account of the needs of specific species and categories of animals on board.
- (22) The transport of animals by air is significantly less common compared to transport by road and sea. Due to the costs associated with this type of transport, in the majority of cases, animals transported by air are pets and high-value animals intended for breeding or sport activities. Air transport of animals is carried out in line with International Air Transport Association (IATA) technical rules set out in Live Animals Regulations (LAR), designed and annually updated by the Live Animals and Perishables Board (LAPB) to balance the principles of protecting welfare of animals and safety on board of aircraft, as well as taking into account the specificities and limitations of air transport. Carriers that are members of IATA are obliged to follow the standards in the regulations in carrying out transport operations, as well as in equipping their aircraft. Transport of animals by air should therefore only be allowed in aircrafts belonging to carriers that are members of IATA.
- (23) As evidenced by Commission audits and competent authorities' inspections, a significant number of livestock vessels currently operating in the Union do not meet the appropriate standards of maritime safety and pose a risk both for animals and crew. To ensure compliance of these livestock vessels with safety standards and the proper functioning of essential systems such as power generation, stability, ventilation, water desalination and drainage systems, among others, only livestock vessels flying flags identified as white or grey under the Paris Memorandum of Understanding on Port State Control<sup>45</sup> should be approved for the transport of animals by the relevant competent authorities in the Member State. In addition, competent

https://www.parismou.org/

- authorities should only allow loading of animals to these vessels if their ship risk profile is identified as low risk or standard risk according to the Paris Memorandum of Understanding on Port State control.
- Records for approvals of livestock vessels are currently kept in the information system supporting the New Inspection Regime stemming from Directive (EU) 2009/16/EC on Port State Control<sup>46</sup>. The Hybrid European Targeting and Inspection System (THETIS) is a database facilitating official controls of sea vessels in the Union, including livestock vessels. This database includes a module specific for official controls focusing on requirements for the protection of animals. Information on authorised livestock vessels should also be available in TRACES, to enable the digital creation, update and completion of journey logs in TRACES. The Competent authorities should be responsible for regularly updating this information.
- (25) In accordance with Implementing Regulation (EU) 2023/372,<sup>47</sup> following approval and before any renewal of approval of a livestock vessel, an official veterinarian should accompany the consignment of animals for the first journey. This allows the veterinarian to perform official controls throughout that first journey to check that the mechanical and management systems of the livestock vessel are not detrimental to the welfare of the animals on board during the journey.
- Journey logs are important tools to allow all actors involved in the transport of animals, and competent authorities, to be aware of the planned route and timing of the journey, and to check if the planned route is followed in practice, therefore facilitating enforcement. Specific elements of the journey log should be designed to ensure better enforcement of animal welfare standards, in particular by increasing the traceability and transparency of transport operations. Competent authorities in the Member States should approve journey logs for long journeys both within the Union and to third countries, as well as short journeys to third countries. The use of journey logs should be fully digitalised by making use of and expanding the possibilities provided by TRACES. Digitalisation of the journey log will improve data collection and allow better analysis and risk identification.
- (27) To ensure that journeys do not exceed the planned length and to provide for better traceability, a simplified journey log for short journeys within the Union should be introduced. Completed by the organiser and without the requirement for approval of the competent authority, these journey logs will help competent authorities to assess the performance of operators during inspections and checks. In addition, this will allow both competent authorities and the Commission to have information on all transport operations.
- (28) Pregnant animals are especially vulnerable during transport. As it is not always possible for the transporter to assess the stage of pregnancy of such animals, the keeper should be responsible for providing information to the transporter about the pregnancy stage or the insemination date, when applicable.

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Directive 2009/16/EC of the European Parliament and of the Council of 23 April 2009 on port State control (recast) (Text with EEA relevance) OJ L 131, 28.5.2009, p. 57–100.

Commission Implementing Regulation (EU) 2023/372 of 17 February 2023 laying down rules on the recording, storing and sharing of written records of official controls performed on livestock vessels, on contingency plans for livestock vessels in the event of emergencies, on the approval of livestock vessels and on minimum requirements applicable to exit points. OJ L 51, 20.2.2023, p. 32–39.

- (29) The scarcity of specific provisions in Union law on transport of cats and dogs, in particular pups and kittens of various breeds, as well as divergent interpretation and enforcement of existing Union rules by Member States, have led to the frequent transportation of these animals in circumstances that pose risks to their welfare and lead to an uneven level playing field for operators. Therefore, it is necessary to better define specific rules regarding the minimum age of transported cats and dogs and the feeding intervals during the journey, to require preventive veterinary treatments to avoid stress related and species-specific diseases, and thus to expand the specific and harmonised rules on commercial transport of cats and dogs. For that same purpose, it is necessary to provide for rules, such as on temperature and humidity requirements and the necessity of a journey log for long journeys.
- (30)The WOAH guidelines on the welfare of farmed fish during transport set the level and standards for compliance at international recommendations as regards responsibilities, planning, vehicles design, equipment, handling, water, preparation, species specific issues, contingency planning, documentation, loading and unloading. Based on these guidelines, specific provisions for aquatic animals should be set and updated based on new science when the relevant opinions of EFSA are available. An important element for the welfare of transported animals is the space allocated to them on board the means of transport, which depends on their species, categories, and size. In the EFSA opinions, it is recommended that, while on board, animals should have enough space to change position, drink and rest. Therefore, the space allowance requirements laid down in Regulation (EC) No 1/2005 should be increased in line with EFSA recommendations.
- (31) The real time positions of aircrafts, sea vessels and trains are currently publicly available and accessible for reasons of safety and information. Most road vehicles are already equipped with a satellite navigation system that keeps records of the actual route followed and the length of the journey. This information is of crucial importance for the competent authorities to implement and better target on a risk basis their official controls. However, this information with respect to road vehicles is not available to competent authorities.
- (32) Limiting the length of the journey plays a fundamental role in the protection of animals during transport. There is evidence that in practice the estimated duration of journey times in the initial planning are often exceeded, which can have serious detrimental effects on the welfare of the transported animals. Currently, there is no means for the competent authority to check the location of consignments during the journey in order to target their controls and inspections in relation to journey and rest times, carried out in accordance with Regulation (EU) 2017/625. This makes it difficult for competent authorities to control that the actual journey duration corresponds to that declared. Many of these challenges would to be solved with information gathered via an information sytem using of real-time positioning tools.
- (33) Accessing information concerning the time at which road vehicles have reached certain key points in the journey, such as control posts or place of destination, would allow competent authorities to strengthen and better plan and target their controls. They could in particular better detect transports that are exceeding maximum journey times, thus identifying transports that are more likely to end with animals in compromised state of welfare. Therefore, all road vehicles should have a real time positioning system capable of communicating their location throughout the journey

and after the journey has been completed to an information system connected to TRACES.

- (34) Data concerning the length of the journey and rest periods should be recorded and kept for all journeys, for the purpose of processing the information only for official control and other official activities linked to those official controls. The retention period of these data should be 6 years so that these data are accessible to the competent authorities, in particular with a view to checking whether the organiser or transporter fulfils the conditions required in order to obtain a renewal of an authorisation after the expiry of the 5-year period of validity. Positioning data recorded in the information system connected to TRACES should only be recorded and kept for the purposes of offical controls and other official activities llinked to those controls. The retention period of these data should also be 6 years.
- (35) In addition to Regulation (EU) 2016/679<sup>48</sup> and Regulation (EU) 2018/1725,<sup>49</sup> and to provide specific adequate guarantees regarding data protection, the provisions concerning processing and controlling of data laid down in Implementing Regulation (EU) 2019/1715<sup>50</sup> concerning the database where these data will be stored should apply.
- (36) It is important for the competent authorities at the place of departure to be aware of the fitness of the animals on arrival at the place of destination. Both drivers, or when relevant, attendants, and keepers at the place of destination should declare the condition of the animals arriving at the place of destination in TRACES, including information on animal welfare indicators. The electronic version of the journey log will allow the competent authorities at both the place of departure and the place of destination to receive this information, allowing them to take action when the condition of animals is not adequate or there is a discrepancy between information provided by keepers, drivers or attendants.
- (37) In general, scientific evidence suggests that longer journeys affect animal welfare more negatively than shorter journeys. In light of the current distribution of slaughterhouses in Member States, the latest scientific opinion on welfare of animals during transport and with the intention of keeping journeys as short as possible, journeys to slaughter should not last more than 9 hours. In general, slaughterhouses currently in use are technologically adapted to the species and categories of animals which they slaughter. To prevent a situation when slaughter would not be possible because there is no appropriately equipped slaughter in the area within the 9-hour transport, an exemption to the 9-hour limit should be foreseen to exceptionally allow long journeys to appropriately equipped slaughterhouses, provided that this is authorised by the competent authority.

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Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation); OJ L 119, 4.5.2016, p. 1–88.

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC; OJ L 295, 21.11.2018, p. 39–98.

Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation) C/2019/7005, OJ L 261, 14.10.2019, p. 37–96.

- (38) EFSA opinions confirmed that too many stops with unloading and loading in control posts along the journey are detrimental to animal welfare, as they lead to additional handling of animals, with consequent additional stress and increased risk of exposure to injury and infections. Therefore, long journeys should not include more than one rest period with unloading and loading. For journeys by road or rail longer than 9 hours for purposes other than for slaughter, in addition to the latest scientific advice from the EFSA, the maximum driving periods and minimum rest periods for road drivers provided for in Regulation (EC) No 561/2006<sup>51</sup> should be taken into consideration in order to better coordinate with the journey times and rest periods of the animals transported.
- (39) Unweaned animals are particularly vulnerable during transport and feeding them on board in accordance with their needs should be ensured. Following EFSA's scientific advice, the minimum age and weight of these animals before they can be transported should be increased so that they are more resilient and fit for transport. In addition, these animals should be transported for a maximum period of 8 hours unless a system is in place on board the means of transport, allowing unweaned animals to be effectively fed with milk or milk replacement at body temperature under the appropriate conditions.
- (40)Experience with the application of Regulation (EC) No 1/2005 shows that providing adequate feeding for unweaned animals is a challenging requirement to fulfil. Unweaned animals must be fed species-specific milk or appropriate milk replacement at body temperature under conditions similar to natural milk feeding and with intervals that prevent onset of long-term hunger. Feeding systems should be designed to allow delivery of the milk or milk replacement to every animal on board, with minimal need for intervention by attendants or drivers. Maintenance should allow appropriate cleaning and disinfection to prevent contamination of the milk. The feeding system should be adapted to the circumstances and the type of transport in which it is intended to be used. In particular, when animals are transported by roll-onroll-off vessel, the limited space around the means of transport and the motion of the vessel should be taken into account. In order to avoid the development of inconsistencies in feeding systems, the Commission should approve these systems based on the scientific and technical evidence of their effectiveness of intended use and conformity with the rules set out in this Regulation. The Commission should also be assisted in this task by EFSA.
- (41) While EFSA scientific opinions identify motion stress as an important risk for the welfare of animals transported in road vehicles, they do not reach the same conclusion with respect to motion stress in means of transport at sea. Journey times on means of transport by road and rail are limited and rest periods are required with the purpose of mitigating the effects of motion stress on the welfare of transported animals. Animals transported by sea are not exposed to the same type of motion as animals transported by road or rail. Motion on sea vessels does not impact animals' stability in the same way as motion on road vehicles, where they are subjected to repeated and unexpected sudden movements. Consequently, the impact of sea transport on animals is less

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Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport and amending Council Regulations (EEC) No 3821/85 and (EC) No 2135/98 and repealing Council Regulation (EEC) No 3820/85,OJ L 102, 11.4.2006, p. 1–14.

- detrimental for their welfare. Provided that animals on board of sea vessels such as livestock vessels, container vessels and roll-on-roll-off vessels have sufficient space to be able to lie down and rest, have feed and water in sufficient amounts and at appropriate intervals, the time spent at sea should not be counted as journey time.
- (42) The temperature experienced by animals during transport is an important factor impacting their welfare. Measuring inside temperatures while on the road has proven difficult and does not easily allow for remedial actions to be taken. Maintaining temperature limits within a vehicle is difficult as it depends on many factors, including humidity and space provided on board. Transporting animals in trucks equipped with air conditioning is costly and likely unsustainable. Therefore, it is appropriate to limit journey times during extreme temperatures to reduce the exposure of animals to these and, in the most extreme cases, to allow the transport of animals only during the night. In addition, measures palliating potential negative effects of the temperature on board should also be taken, such as opening the truck vents and providing more space for the animals.
- Organisers transporting animals to a place of destination in a third country must arrange an evaluation of the first journey by a certification body in order to determine the organiser's ability to ensure compliance with this Regulation until the arrival of the animals at the place of destination in the third country. If the conditions laid down in this Regulation are not fulfilled, the competent authority should suspend the organiser's authorisation with respect to transport to third countries. The certification body should regularly evaluate journeys to third countries arranged by the organiser with a view to determining continues to have the means to comply with this Regulation. Certification bodies should have the required knowledge and qualifications, provide guarantees of continued independence from organisers, transporters and any other person or entity involved in the transport or handling of animals during transport and should be accredited by national accreditation bodies established pursuant to Regulation (EC) No 765/2008<sup>52</sup>.
- (44) Council Regulation (EC) No 1255/97<sup>53</sup> establishes requirements for control posts and on the use of these control posts in the Union. To ensure that the transport of animals from the Union to third countries complies with this Regulation in particular as regards journey times, rest periods and the conditions of accommodation of the animals during rest periods, control posts in third countries should meet equivalent standards to those laid down in Union legislation, in particular Council Regulation (EC) No 1255/97.
- (45) Operators of control posts in third countries or organisers may request their inclusion in a list to be adopted by the Commission provided they demonstrate compliance with requirements at least equivalent to the Union rules, in particular Regulation (EC) No 1255/97. For this purpose, control posts in third countries may provide proof of certification of compliance with requirements at least equivalent to those laid down in Union law, in particular Council Regulation (EC) No 1255/97 by a certification body.

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30–47

Council Regulation (EC) No 1255/97 of 25 June 1997 concerning Community criteria for staging points and amending the route plan referred to in the Annex to Directive 91/628/EEC, OJ L 174, 2.7.1997, p. 1–6.

- The list of approved control posts in third countries should be adopted by the Commission by means of implementing acts.
- (46) To better ensure that control posts meet the needs of the animals resting at their premises, these should be adapted to the relevant species and categories. A booking system should be put in place to avoid delays or overbooking of control posts. Therefore, Regulation (EC) No 1255/97 should be amended accordingly.
- (47) Experience shows that the designation of an exit point in the Union is important for ensuring the smooth transport of live animals from the Union to third countries. Animals should leave the Union through designated exit points that meet the necessary requirements for animal welfare checks as referred to in Article 21(2), point (c) of Regulation (EU) 2017/625<sup>54</sup> and are capable of ensuring communication between competent authorities at places of departure, assembly centres, control posts and establishments of destination in this regard. Competent authorities should record such designations in TRACES.
- (48) Experience has shown that there is a risk that consignments of animals transported by sea may be rejected by the country of destination on the basis of the documents presented, for example, health certificates. In certain cases, this may affect the welfare of the animals, as they cannot be returned to the place of departure for animal health reasons. The competent authorities at the place of departure should approve a journey log only when the operators provide them with an attestation of acceptance of documentation for the international transport of live animals by sea signed by the competent authority of the seaport of the country of final destination. Accordingly, it is appropriate to establish a model attestation.
- (49) Member States should lay down effective, proportionate, and dissuasive penalties for infringements of this Regulation and ensure that they are applied. To ensure a consistent and effective application of this Regulation across the Union, it is necessary to avoid different levels of enforcement and that the differing severity of the penalties applied for non-compliance with this Regulation in different Member States leads to transport operations being planned in accordance with the lesser severity of the penalties imposed in certain Member States. It is appropriate to identify those infringements of this Regulation that cause significant risks to animal welfare and establish minimum levels of financial penalties in relation to the value of animal consignments in such cases. The degree of frequency of occurrence of the infringement should also be a factor and repeated infringements should be regarded as more serious. This should deter future infringements and improve the enforcement of the Regulation.

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Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) OJ L 95, 7.4.2017, p. 1–142

- (50) The Fitness Check of the EU animal welfare legislation has shown difficulties in assessing the effectiveness of Regulation (EC) No 1/2005 in improving animal welfare due to the lack of indicators provided for in that Regulation. It is appropriate to create a system of monitoring of animal welfare indicators.
- (51) Transporters and keepers should be required to collect data on the basis of animal welfare indicators relevant to their transport activities. Analysis of the data will allow transporters and keepers to identify deficiencies in relation to animal welfare and to put in place appropriate corrective measures when needed. Data on indicators should also be made available to competent authorities and to the Commission in TRACES.
- In order to update the technical rules in Chapters I, II, V and VII of Annex I and (52)Annex II, to align these rules to the latest scientific and technical knowledge when these are available, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. In order to facilitate proper implementation of this Regulation, the power to adopt, in accordance with Article 290 TFEU, acts to update the model of journey log in Annex III and the model of attestation in Annex IV should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultation during its preparatory work including at expert level and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 of April 2016 on Better Law-Making<sup>55</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of the Commission expert groups dealing with the preparation of delegated acts.
- (53) To ensure uniform conditions for the implementation of this Regulation, including elements of contingency plans and their templates, technical rules concerning approval of livestock vessels, the technical elements needed to set up the live tracking navigation system recordings, the approval of feeding systems for unweaned animals on board, the content of the evaluations needed for the certification of organisers transporting animals to third countries and the frequency by which they are needed, the lists of control posts meeting equivalent standards to those laid down in Council Regulation (EC) No 1255/97 and definitions of welfare indicators and the methods to monitor them, and technical rules on the use of TRACES, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>56</sup>.
- (54) It is important to ensure that national rules are not used by Member States in a way to prejudice the correct application of the provisions of this Regulation or to affect the functioning of the internal market. Member States should notify the Commission of any such national rules. The Commission should bring them to the attention of other Member States. Where national rules fall within the scope of Directive (EU)

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Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making, OJ L 123, 12.5.2016, p. 1–14

Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, p. 13–18.

- 2015/1535 of the European Parliament and of the Council, they should be notified to the Commission in accordance with that Directive.
- (55) The impact assessment performed to prepare this Regulation indicates that some of the new requirements set out in this Regulation call for planning and investment from the operators impacted by them. New rules concerning journey times and feeding of unweaned animals during transport will require changes in transport patterns, and investments in new trucks to provide more space for the animals and possibly new feeding systems. Accordingly, this Regulation should provide for appropriate transition periods to take into account the necessary time to allow the operators concerned to adapt to the corresponding requirements set out in this Regulation.
- (56) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to the protection of animals during transport, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale, effects, and trans-border and international characters of the transport, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve that objective.
- (57) "The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on [DD/MM/YYYY]."

HAVE ADOPTED THIS REGULATION:

## CHAPTER I SUBJECT MATTER, SCOPE, DEFINITIONS AND GENERAL PROVISIONS

Article 1
Subject matter

This Regulation lays down rules for the protection of animals during transport in connection with an economic activity.

Article 2 Scope

- 1. This Regulation shall apply to the transport of animals:
  - within the Union;
  - from a place of departure in a third country to a place of destination in the Union;
  - from a place of departure in the Union to a place of destination in a third country; and
  - from a Border Control Post of entry into the Union until an exit point from the Union, when the transport of animals transits through the Union territory.
- 2. Transport for the following purposes shall only be subject to Article 4:

- (a) transport by farmers of their own animals using their own means of transport for the purpose of seasonal transhumance;
- (b) transport by farmers of their own animals using their own means of transport for purposes other than transhumance, for a distance of no more than 50 km from the holding in which they are kept.
- (c) transport of animals for the purposes of participating in training, exhibitions, competitions, cultural events, circuses, and equestrian sport and leisure activities;
- 3. This Regulation shall not apply to the following types of transport:
  - (a) the transport of animals which does not take place in connection with an economic activity;
  - (b) the transport of animals directly to or from veterinary practices or clinics;
  - (c) the transport of protected species, under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)<sup>57</sup>;
  - (d) the transport of animals between zoos as defined in Article 2 of Council Directive 1999/22/EC<sup>58</sup>.
  - (e) the transport of ornamental fish;
  - (f) direct deliveries of aquatic animals to food businesses supplying the final consumer.
- 4. Articles 4(2)(b), 20, 26, Chapters I and V of Annex I and point 4 of Annex II shall not apply to transport of animals for the purposes of an authorised project under Directive 2010/63/EU<sup>59</sup>.

# Article 3 Definitions

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

- 1. 'animals' means live vertebrate animals, cephalopods and decapods;
- 2. 'place of departure' means:
  - (a) the place where an animal has been accommodated for at least a week prior to departure and where it is first loaded onto a means of transport; or
  - (b) an assembly centre if the animal has been collected within a distance of no more than 100 km:

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Council Decision (EU) 2015/451 of 6 March 2015 concerning the accession of the European Union to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), OJ L 75, 19.3.2015, p. 1–3.

Council Directive 1999/22/EC of 29 March 1999 relating to the keeping of wild animals in zoos, OJ L 94, 9.4.1999, p. 24–26.

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010, p. 33–79.

- 3. 'place of destination' means a slaughterhouse or any other place where an animal is unloaded from a means of transport and accommodated for at least a week prior to the time of any subsequent departure;
- 4. 'journey' means the movement of animals effected by one or more means of transport starting with the loading of the first animal onto the first means of transport at the place of departure and ending with the unloading of the last animal at the place of destination, and the related operations including rest periods and transfer from one means of transport to another;
- 5. 'means of transport' means road or rail vehicles, vessels and aircraft used for the transport of animals;
- 6. 'aquatic animals' means fish, cephalopods and decapods;
- 7. 'organiser' means:
  - (a) a transporter who transports or has subcontracted the transport of animals for the whole journey or a part of the journey to at least one other transporter; or
  - (b) a natural or legal person who has contracted the transport of animals to a transporter; or
  - (c) a person who has signed Section 1 of the journey log in TRACES as set out in Annex III.
- 8. 'long journey' means a journey that exceeds 9 hours;
- 9. 'competent authority' means a competent authority as defined in Article 3(3) of Regulation (EU) 2017/625;
- 10. 'TRACES' means the computerised system for the purposes of exchanging data, information and documents referred to in Articles 133(4) of Regulation (EU) 2017/625;
- 11. 'transporter' means an operator whose economic activity consists of transporting animals on its own behalf, or on behalf of a third party;
- 12. 'short journey' means a journey that does not exceed 9 hours:
- 13. 'attendant' means a person directly in charge of the welfare of the transported animals who accompanies them during a journey on road or rail transport;
- 14. 'vehicle' means a means of transport fitted with wheels which is propelled or towed;
- 15. 'Animal welfare officer' means a person directly in charge of the welfare of transported animals by livestock vessel for the duration of the journey at sea;
- 16. 'livestock vessel' means a sea-going vessel which has been built or adapted to be used for the transport of terrestrial animals, other than domestic birds or rabbits;
- 17. 'container' means any crate, box, receptacle or other rigid structure used for the transport of animals which is not a means of transport;
- 18. 'container vessel' means a vessel carrying terrestrial animals, other than domestic birds or rabbits in moveable containers;
- 19. 'terrestrial animals' means kept equidae, and animals of the bovine, porcine, ovine, caprine species, cervids, rabbits and domestic birds, including poultry;

- 20. 'roll-on-roll-off vessel' means a vessel with facilities to enable road or rail vehicles to roll on and roll off the vessel;
- 21. 'container for large animals' means a container used for transport of terrestrial animals other than domestic birds and rabbits on means of transport by road, rail or container vessels;
- 22. 'official veterinarian' means an official veterinarian as defined in Article 3(32) of Regulation (EU) 2017/625;
- 23. 'assembly centre' means an establishment for assembly operations registered in accordance with Article 97(1) of Regulation (EU) 2016/429 where animals of the bovine, ovine, caprine, equine or porcine species originating from more than one holding are grouped together temporarily to form a consignment;
- 24. 'control posts' means control posts as defined in Article 1 of Regulation (EC) No 1255/97;
- 25. 'journey time' means the time period during which animals are moved by means of transport, including the time for loading and unloading the animals;
- 26. 'keeper' means any natural or legal person, except a transporter, in charge of or handling animals whether on a permanent or temporary basis;
- 27. 'exit point' means an exit point as defined in Article 3(39) of Regulation (EU) 2017/625:
- 28. 'border control post' means a border control post as defined in Article 3(38) of Regulation (EU) 2017/625.
- 29. 'positioning systems' means systems of infrastructures providing global, continuous, accurate and guaranteed timing and positioning services needed for the purpose of this Regulation;
- 30. 'rest period' means a continuous period in the course of a journey during which animals are not being moved by a means of transport;
- 31. 'biosecure transport' means the transport of animals for the purposes of Directive 2010/63/EU that provides a physical barrier protecting the animals from the transfer of microbial contaminants and ensures their welfare by the provision of feed, water and environmental conditions appropriate to the species and their stage of development, including sufficient space to rest and stretch;
- 32. 'certification body' means a legal entity accredited in accordance with Regulation (EC) No 765/2008 and operating in accordance with ISO/IEC/17065 for Conformity assessment Requirements for bodies certifying products, processes and services;
- 33. 'unbroken equine animal' means an equine animal that cannot be tied or led by a halter without causing avoidable excitement, pain or suffering.

## Article 4 General provisions on the transport of animals

- 1. No person shall transport animals or cause animals to be transported in a way that causes or is likely to cause undue suffering to it.
- 2. Any person transporting animals or causing animals to be transported shall ensure compliance with the following requirements:

- (a) all necessary arrangements have been made in advance to minimise the duration of the journey so that the most common animal welfare hazards, including suffering from hunger, thirst, fatigue, injuries or thermal discomfort are minimised:
- (b) the animals are fit for the entire journey;
- (c) the means of transport are designed, constructed, maintained and operated in a way to prevent injury or unnecessary suffering and to ensure the safety of the animals;
- (d) the loading and unloading facilities are designed, constructed, maintained and operated in a way to avoid injury and unnecessary suffering and to ensure the safety of the animals;
- (e) any natural person responsible for the animals at any stage of their transport, is competent for this purpose and for handling the animals transported, and carries out his or her tasks without using violence or any method likely to cause injury or unnecessary suffering to the animals;
- (f) the transport is carried out without undue delay;
- (g) the welfare condition of the animals is regularly checked and appropriately maintained;
- (h) the floor area and height of the means of transport and the unloading and loading facilities are adapted to the species, size, category of the animals concerned and to the planned journey;
- (i) water, feed and rest are offered to animals at regular intervals during the journey and are appropriate in quality and quantity to the animal's species and their physiological needs;
- (j) aquatic animals are provided with water in sufficient volume and quality.

## CHAPTER II ORGANISER AND TRANSPORTER AUTHORISATIONS

## Article 5

Application for organiser authorisation for long journeys

- 1. Organisers may only make arrangements for the transport of animals for long journeys if they hold an authorisation granted in accordance with Article 6.
- 2. The organiser shall submit an application for an authorisation to transport animals for long journeys to the competent authority in TRACES using the form in Section 1 of Annex V. The application shall specify whether the organiser intends to organise the transport of animals to third countries or not.
- 3. Organisers shall apply for an authorisation to no more than one competent authority, in no more than one Member State.
- 4. The application referred to in paragraph 2 shall contain evidence that the following conditions are met:

- (a) the organiser is established, or, in the case of an organiser established in a third country, is represented, in the Member State of the respective competent authority;
- (b) the organiser has the capacity to comply with Article 14.

Grant, renewal, suspension and withdrawal of organiser authorisations

- 1. The competent authority shall grant the authorisation referred to in Article 5 in TRACES using the form in Section 1 of Annex V, provided that the conditions set out in Article 5(4) are met.
- 2. The authorisation provided for in paragraph 1 shall specify the species and categories of animals and the type(s) of transport covered and whether it covers the transport of animals to third countries or not.

The authorisation shall be valid for a period of not more than 5 years from the date of issue.

- 3. One month before the expiry of the authorisation, the organiser may apply for a renewal in TRACES. An application for renewal shall include evidence that the conditions set out in Article 5(4) are met, the certificate provided for in Article 33 when relevant, and documented analysis of monitoring of indicators for the period of validity of the previous approval and where appropriate, documented evidence of measures put in place if values quantifying the indicators exceed the thresholds provided for in Article 26(3). The competent authority shall grant or reject the application for a renewal and record the renewal or rejection in TRACES and, in case of rejection, the reasons for it.
- 4. If the organiser no longer meets the conditions provided for in Article 5(4) or in Article 33(6), the competent authority shall order the suspension of the authorisation in accordance with Article 138(2), point (j), of Regulation (EU) 2017/625 and shall record the suspension in TRACES without delay. Where relevant, the competent authority shall suspend the part of the authorisation covering transport to a third country.

The competent authority shall provide the organiser with a written statement indicating the reasons for the suspension and recommendations to address the deficiencies found.

The competent authority shall lift the suspension if the organiser provides evidence that they have corrected the deficiencies on which the suspension of their application is based.

For transport within the Union, if the organiser has not corrected the deficiencies within one month of the suspension, the competent authority shall withdraw the authorisation.

For transport to a third country, if the organiser has not corrected the deficiencies within three months of the suspension, the competent authority shall withdraw the authorisation.

### Application for transporter authorisation for short journeys

- 1. Transporters may only transport animals for short journeys if they hold:
  - (a) an authorisation for short journeys granted in accordance with Article 9(1) for the species and categories concerned; or
  - (b) an authorisation for long journeys granted in accordance with Article 9(1) for the species and categories concerned.
- 2. The transporter shall submit an application for an authorisation to transport animals on short journeys to the competent authority in TRACES using the form in Section 2 of Annex V. The application shall contain evidence that the following conditions are met:
  - (a) the transporter is established, or, in the case of a transporter established in a third country, is represented, in the Member State of the respective competent authority;
  - (b) the transporter has sufficient and appropriate staff and equipment and has written instructions for staff as regards watering, feeding and care of animals and operational procedures in place to enable its staff to comply with this Regulation;
  - (c) the drivers and attendants employed by or providing services to the transporter have followed the relevant training courses and have certificates of competence as provided for in Article 38;
  - (d) neither the transporter nor their representatives in the Member State where the application is submitted have committed a serious infringement as provided for in Article 44 in the 5 years preceding the date of the application.

For the purposes of point (d), if the transporter or their representatives committed a serious infringement during that period, they shall demonstrate to the satisfaction of the competent authority that they have taken all necessary measures to avoid further infringements.

### Article 8

### Application for transporter authorisation for long journeys

- 1. Transporters may only transport animals for long journeys if they hold an authorisation granted in accordance with Article 9(1). Such authorisations shall also be valid for short journeys.
- 2. The transporter shall submit an application for an authorisation to transport animals for long journeys to the competent authority in TRACES using the form in Section 3 of Annex V. Transporters shall apply for an authorisation to no more than one competent authority, in no more than one Member State.
- 3. The application provided for in paragraph 2 shall contain evidence that the following conditions are met:
  - (a) the transporter complies with the conditions set out in Article 7(2); and
  - (b) the transporter holds the following documents:

- i. valid certificates of approval as provided for in Articles 12 or 13 for the means of transport to be used by the transporter for the long journey concerned;
- ii. a document setting out in detail the procedures enabling the transporter to trace and record the movements of vehicles and vessels under their responsibility, and the procedures to contact the drivers concerned at any time during long journeys;
- iii. a contingency plan in the event of emergencies during the intended transport.
- 4. In order to ensure the uniform presentation of contingency plans in the event of emergencies during long journeys provided for in paragraph (b), point (iii), the Commission is empowered to adopt implementing acts in accordance with Article 49 to lay down minimum requirements for the content of the contingency plan, for different types of journeys, and establish and update as necessary standard model forms for the submission of those contingency plans.

Grant renewal, suspension and withdrawal of transporter authorisations

- 1. The competent authority shall grant an authorisation to a transporter for short or long journeys as required under Article 7(1) and Article 8(1) in TRACES using the forms in Sections 2 and 3 of Annex V respectively, provided the conditions set out in Article 7(2) and Article 8(2) respectively are met.
- 2. The authorisation provided for in paragraph 1 shall specify the species and categories of animals and the type of transport covered and whether it covers long or short journeys.
  - The authorisation shall be valid for a period of not more than 5 years from the date of issue.
- 3. One month before the expiry of the authorisation for short or long journeys, the transporter may apply for the renewal of the authorisation in TRACES. An application for renewal shall contain the documents required under Article 7(2) or Article 8(2) and documented analysis of monitoring of indicators for the period of validity of the previous approval and where appropriate, documented evidence of measures put in place if values quantifying the indicators exceed the thresholds provided for in Article 26(3).
- 4. The competent authority shall grant or reject the application for a renewal and record the renewal or rejection in TRACES and, in case of rejection, the reasons for the rejection.
- 5. The transporter shall notify the relevant competent authority of any change in the documents referred to in Articles 7(2) and 8(2) no later than 5 working days from the date the change took place.
- 6. If the transporter no longer meets the conditions provided for in Article 7(2) or Article 8(2), the competent authority shall order the suspension of the authorisation in accordance with Article 138(2), point (j), of Regulation (EU) 2017/625 and shall record the suspension in TRACES without delay.

The competent authority shall provide the transporter with a written statement indicating the reasons for the suspension and recommendations to address the deficiencies found.

The competent authority shall lift the suspension when the transporter provides evidence that they have corrected the deficiencies on which the suspension of their application is based.

If the transporter has not corrected the deficiencies within one month of the suspension, the competent authority shall withdraw the authorisation.

### Article 10

Training of drivers, attendants and animal welfare officers

The transporter shall arrange for drivers, attendants, and the animal welfare officers referred to in Article 21, to follow one of the approved animal welfare training courses referred to in Article 37(1)(b). Such training shall be relevant to their tasks, the species, the categories of animals they handle, and the means of transport used.

### CHAPTER III MEANS OF TRANSPORT

### Article 11

General rules on means of transport

- 1. No person shall transport animals by road or by rail for a long journey unless the means of transport has been inspected and approved in accordance with Article 12.
- 2. No person shall transport animals by livestock vessel for more than 10 nautical miles from a Union port unless the livestock vessel has been inspected and approved in accordance with Article 13.
- 3. Paragraphs 1 and 2 shall apply to containers used in transport by road, rail or by container vessel of terrestrial animals other than domestic birds and rabbits.
- 4. Animals may only be transported by aircrafts belonging to carriers that are members of the International Air Transport Association.
- 5. Animals may only be transported by roll-on-roll-off vessel if the requirements set out in point 3 of Chapter II of Annex 1 are met.

### Article 12

Certificate of approval of means of transport by road or rail and of containers for large animals

- 1. The transporter shall submit an application for a certificate of approval of a means of transport of animals by road or rail for long journeys or of containers for large animals, to the competent authority in TRACES using the form set out in Section 5 of Annex V.
- 2. The competent authority shall grant a certificate of approval of the means of transport to the transporter in TRACES using the form set out in Section 5 of Annex V, provided it complies with the following conditions:

- (a) the means of transport is not the subject of an application submitted to, or a certificate of approval granted by, or the rejection of an application decided by another competent authority in the same or another Member State;
- (b) the means of transport has been inspected by the competent authority and found to comply with the requirements of Chapters II and VI of Annex I applicable to the design, the construction and the maintenance of means of transport by road used for long journeys.
- 3. The competent authority shall record any rejection of an application for a certificate of approval in TRACES and the reasons for its decision.

The certificate of approval shall be valid for a period of not more than 5 years from the date of issue.

- 4. One month before the expiry of the certificate of approval provided for in paragraph 2, the transporter may apply for a renewal in TRACES in accordance with the requirements in paragraphs 1 and 2.
- 5. The transporter shall notify the competent authority of any modification, refit or impairment of the means of transport that may affect the welfare of the transported animals within 5 days of such modification, refit or impairment.
- 6. If a means of transport no longer meets the conditions provided for in paragraph 2, the competent authority shall order the suspension of the certificate in accordance with Article 138(2), point (j), of Regulation (EU) 2017/625 and record the suspension in TRACES.

The competent authority shall provide the transporter with a written statement indicating the reasons for the suspension and recommendations to address the deficiencies found.

The competent authority shall lift the suspension if the transporter provides evidence that they have corrected the deficiencies on which the suspension of their certificate is based.

If the transporter has not corrected the deficiencies within 1 month of the suspension, the competent authority shall withdraw the certificate.

## Article 13 Certificate of approval of livestock vessels

- 1. The transporter shall submit an application for a certificate of approval of a livestock vessel for the transport of animals to the competent authority in TRACES using the form set out in Section 6 of Annex V. The application shall include the following documents:
  - (a) a document containing the applicant and livestock vessel details, including conversion date when applicable, plan of vessel with layout of pens, lighting, water drainage, firefighting and ventilation systems;
  - (b) a document describing how the systems listed in point (a) operate and how the power sources are capable of providing enough energy to support those systems.

- 2. The competent authority shall grant a certificate of approval of the livestock vessel in TRACES using the form set out in Section 6 of Annex V, provided that it complies with the following conditions:
  - (a) the vessel will operate its first journey from the Member State where the application is submitted;
  - (b) the vessel is not the subject of an application submitted to, or a certificate of approval granted by or the rejection of an application decided by, another competent authority in the same Member State or in another Member State;
  - (c) the vessel has been inspected by the competent authority and found to comply with the requirements of Chapter II and Chapter IV of Annex I applicable to the construction and equipment for livestock vessels;
  - (d) the vessel flies a flag with a flag performance rating of white or grey according to the Paris Memorandum of Understanding on port State control.

The approval of the livestock vessel shall be suspended unless an official veterinarian has carried out official controls on board of the livestock vessel during the entire first voyage of the vessel following approval and prior to the renewal of such approval, and those controls demonstrated that the construction and equipment of the livestock vessel are not detrimental to the welfare of the animals on board, or effective corrective measures have been taken.

- 3. The competent authority shall record any rejection of an application for approval in TRACES and the reasons for its decision.
  - The certificate of approval shall be valid for a period of not more than 5 years from the date of issue.
- 4. One month before the expiry of the certificate of approval of the livestock vessel provided for in paragraph 2, the transporter may apply for a renewal of the certificate in TRACES in accordance with the requirements in paragraphs 1 and 2.
- 5. The transporter shall notify the relevant competent authority of any modification, refit or impairment of the vessel that may affect the welfare of the transported animals within 5 days of such modification, refit or impairment or if the requirement in paragraph 2, point (d) is no longer met.
- 6. If the vessel no longer meets the conditions provided for in paragraph 2, the competent authority shall order the suspension of the certificate in accordance with Article 138(2), point (j), of Regulation (EU) 2017/625 and record the suspension in TRACES.

The competent authority shall provide the transporter with a written statement indicating the reasons for the suspension and recommendations to address the deficiencies found.

The competent authority shall lift the suspension if the transporter provides evidence that they have corrected the deficiencies on which the suspension of their certificate is based.

If the transporter has not corrected the deficiencies within one month of the suspension, the competent authority shall withdraw the certificate.

- 7. The Commission is empowered to adopt implementing acts in accordance with Article 49 regarding:
  - (a) the establishment of an electronic database for the recording of inspections on livestock vessels for the purposes of this Article and the official controls performed under Regulation (EU) 2017/625;
  - (b) the composition of the teams of inspectors to perform the inspections referred to in paragraph 1;
  - (c) detailed rules concerning the presence of an official veterinarian on board for the purpose of approving a livestock vessel.

## CHAPTER IV OBLIGATIONS PRIOR TO DEPARTURE

## Article 14 Obligations for organisers

- 1. Organisers shall be responsible for ensuring that the entire journey from the place of departure to the place of destination in the Union or in a third country complies with this Regulation.
- 2. Organisers shall be responsible for the planning of the journey from the place of departure until the place of destination. The organiser shall comply with the provisions relating to the journey log referred to in Article 15 and shall sign section 1 of the journey log in TRACES as set out in points 1 and 2 of Annex III.
- 3. The organisers shall ensure that for each journey:
  - a) the animals to be transported are accommodated at the place of departure for at least 1 week prior to departure;
  - b) the different legs of the journey are coordinated, especially when performed by different operators, in a way that the welfare of the animals is not compromised by insufficient coordination between different parts of the journey or different operators;
  - c) the organisation of the journey takes into account the temperature forecast when relevant for the species and categories of animals concerned in accordance with Article 31 and Chapter V of Annex I;
  - d) an individual is designated to provide information on the planning, execution, and completion of the journey to the competent authorities at the place of departure, assembly centres, control posts and establishments of destination at any time.

### Article 15

Journey log for all long journeys and short journeys to third countries

1. For long journeys and short journeys to third countries, organisers shall complete in TRACES section 1 of the journey log prior to the journey, as set out in point 1 of Annex III.

- 2. Where the journey log concerns a long journey or a short journey to a third country, the organiser shall submit in TRACES the journey log for approval by the competent authority at the place of departure at least 2 days, but not earlier than 5 days, before the planned departure date. The journey cannot start before the competent authority has approved the journey log in accordance with paragraph 4.
- 3. The journey log shall include confirmation of a reservation at a control post when, according to journey planning, the journey time is likely to exceed 21 hours.
- 4. The competent authority shall approve the journey log in TRACES provided the following conditions are met:
  - (a) the journey log is realistic and indicates compliance with this Regulation;
  - (b) the transporters indicated in the journey log have the corresponding valid transporter authorisations, the valid certificates of approval for means of transport and valid certificates of competence for drivers and attendants.
- 5. If the conditions provided for in paragraph 4 are not met, the competent authority shall require the organiser to change the arrangements for the intended journey so that it complies with this Regulation.
- 6. Competent authorities shall ensure that journey logs for long journeys and short journeys to third countries are retained in TRACES for a maximum period of 6 years for subsequent official controls in accordance with Article 21 of Regulation (EU) 2017/625.

## Article 16 Journey log for short journeys within the Union

- 1. For short journeys within the Union, organisers shall complete in TRACES the journey log as set out in point 2 of Annex III.
- 2. Journey logs for short journeys within the Union shall be retained in TRACES for a period 6 years for subsequent official controls in accordance with Article 21 of Regulation (EU) 2017/625.

## Article 17 Obligations for keepers prior to the journey

- 1. Keepers at the place of departure shall be responsible for ensuring that the animals to be loaded on the means of transport are fit for transport.
  - For pregnant animals, the keeper at the place of departure shall indicate in the journey log the date of insemination or the presumptive date of natural service.
- 2. Loading of animals on means of transport shall be supervised by a veterinarian.

# CHAPTER V OBLIGATIONS DURING TRANSPORT AND AT THE PLACE OF DESTINATION

## Article 18 General obligations for transporters

- 1. The transporter shall transport animals in accordance with this Regulation, in particular the relevant rules for the transported species set out in Annex I for terrestrial animals and in Annex II for aquatic animals, until arrival at the place of destination in the Union or in a third country.
- 2. The transporter shall be responsible for the fitness for transport of the animals from loading of the animals at the place of departure to the unloading of the animals at the place of destination.
- 3. For transport by road or rail, the transporter shall entrust the handling of animals to drivers and attendants who have the certificate of competence referred to in Article 38.
- 4. For transport by road or rail, the transporter shall ensure that an attendant accompanies all consignments of animals except in the following cases:
  - (a) where animals are transported in containers which are secured, adequately ventilated and, where necessary contain enough food and water, in dispensers which cannot be tipped over, for a journey of twice the anticipated journey time:
  - (b) where the driver performs the functions of attendant.
- 5. For transport by road or rail for which a leg of the journey includes transport by a roll-on-roll-off vessel, the transporter and the person responsible for loading the vehicles onto the vessel shall ensure that the vessel complies with the requirements set out in point 3 of Chapter II of Annex 1.

### Article 19

Obligations for organisers, transporters, drivers and attendants during transport by road or rail

- 1. The driver or attendant shall check on the animals at least every 4,5 hours to assess their welfare and fitness for transport.
- 2. The driver and attendant shall immediately notify the transporter and organiser in accordance with the procedures defined in the contingency plan referred to in Article 8 of any serious event that may negatively affect the welfare of the animals. The organiser shall transmit the information to the relevant competent authority.
- 3. The transporter shall be responsible for any animal that becomes unfit for transport during the journey due to the inappropriate performance by the attendant or driver of his or her tasks.
- 4. During transfers from one means of transport to another, the driver or attendant shall ensure compliance with the technical rules set out in Chapters I and III of Annex I in respect of the animals being transported.

Obligations for keepers at assembly centres, control posts and places of destination

- 1. Keepers of animals kept at assembly centres, control posts and places of destination shall ensure compliance with the technical rules set out in Points 1 to 3 of Chapter I of Annex I and in Point 4 of Annex II where applicable.
- 2. Keepers at assembly centres or at control posts shall record the condition in which the animals have arrived and shall complete and sign in TRACES section 3 of the journey log as set out in point 1 of Annex III.

## Article 21 Animal welfare officer on livestock vessels

- 1. For a journey by livestock vessel, the transporter shall designate an animal welfare officer who is trained and holds a certificate of competence in accordance with Article 38.
- 2. The animal welfare officer shall report to and operate under the direct authority of the transporter and shall report directly to them and the organiser on matters relating to animal welfare.
- 3. The animal welfare officer shall be responsible for:
  - (a) caring for the animals and checking them at least twice a day to assess their welfare and fitness for transport, and taking appropriate measure to maintain their welfare;
  - (b) notifying the competent authority at place of departure and the organiser in accordance with the procedures defined in the contingency plan referred to in Article 8 point (3)(b)(iii) of any serious event that may negatively affect the welfare of the animals:
  - (c) ensuring compliance with Regulation No 1099/2009, when animals are killed during the journey at sea to put an end to their suffering.
- 4. The organiser shall inform the captain of the livestock vessel of the responsibilities of the animal welfare transport officer laid down in paragraph 3.

## Article 22 Assembly centres

- 1. Operators of assembly centres shall provide their staff with training courses on the technical rules set out in Point 1 of Chapters I and III of Annex I.
- 2. Operators of assembly centres shall:
  - (a) entrust the handling of animals only to personnel who have completed training courses on the relevant technical rules set out in Annex I;
  - (b) regularly inform staff and other persons admitted to the assembly centre of their duties and obligations under this Regulation and of the penalties for any infringement of this Regulation;
  - (c) make permanently available to staff and other persons admitted to the assembly centre the contact details of the competent authority to which any infringement of this Regulation is to be notified;

- (d) in case of infringement of this Regulation by any person present at an assembly centre, take the necessary measures to remedy the infringement and prevent its recurrence, without prejudice to any action taken by the competent authority;
- (e) adopt, monitor and enforce the internal rules necessary to ensure compliance with points (a) to (d).
- 3. An assembly centre shall not be indicated as the place of destination in the journey log referred to in Articles 15 and 16.

## Article 23 Delay during transport

- 1. Organisers and, when relevant, the competent authority shall take the necessary measures to prevent or reduce to a minimum any delay during transport.
- 2. Competent authorities shall ensure that special arrangements are made at places of departure, assembly centres, control posts, establishments of destination, exit points and border control posts to give priority to the transport of animals, including the provision of fast lanes so that animals are inspected when required, without undue delays.

## Article 24 Means of transport positioning systems

- 1. Means of transport by road shall be equipped with a positioning system communicating with the information system referred to in paragraph 3 based on the technical requirements referred to in paragraph 8.
- 2. The positioning system referred to in paragraph 1 shall record the position of road vehicles on short intervals and be operational during the journey from the place of departure until arrival at the place of destination.
- 3. The records obtained from the positioning systems of the means of transport shall be kept in an information system accessible to TRACES, established by the Commission in accordance with paragraph 7.
- 4. When completing section 1 of the journey log as set out in point 1 of Annex III, organisers shall set the locations of the following points of the journey:
  - (a) place of departure;
  - (b) control posts;
  - (c) exit point from the Union and border crossings between Member States; and
  - (d) place of destination.
- 5. After the completion of the journey, TRACES shall retrieve data from the information system referred to in paragraph 3 on the time when means of transport reached the locations as set out in paragraph 4. This information will be stored in TRACES for the purpose of official controls, including the analysis of completed journeys.
- 6. The Commission may use the information referred to in paragraph 5 for the purpose of preparing the annual reports referred to in Article 114 of Regulation (EU)

- 2017/625, after anonymisation of the personal data, and for the purpose of organising audits in the Member States.
- 7. By [3 years from the date of entry into force of this Regulation], the Commission shall develop the information system referred to in paragraph 3.
- 8. By [3 years from the date of entry into force of this Regulation], the Commission shall, by means of implementing acts, establish the necessary technical protocols to enable the positioning systems referred to in paragraph 1 to communicate the position of the vehicle with a defined precision of its geographical location to the information system referred to in paragraph 3, for the use of the information system and the protocols for retrieving required information from the information system by TRACES.

## Article 25 Obligations at the place of destination

1. The driver or attendant, and the keeper at the place of destination shall record in TRACES the date and time of arrival of the animals and their condition, by completing and signing section 3 of the journey log as set out in point 1 of Annex III.

In case of disagreement on the condition in which the animals have arrived at the place of destination between the driver or attendant and the keeper at the place of destination, or where the journey log indicates that the animals have arrived in bad condition, the keeper and the driver or the attendant shall record the anomalies encountered in section 5 of the journey log as set out in point 1 of Annex III.

- 2. By way of derogation from paragraph 1, the driver or attendant transporting animals for the purposes of an authorised project under Directive 2010/63/EU shall only record in TRACES the date and time of arrival.
- 3. Unloading shall be supervised by a veterinarian.

## Article 26 Monitoring of indicators

- 1. For the purposes of Article 25(1), the driver or attendant and the keeper at the place of destination shall assess the condition of terrestrial animals on arrival using the following indicators:
  - (a) total number of animals;
  - (b) number of animals dead on arrival in each consignment;
  - (c) number of animals injured during transport in each consignment;
  - (d) health and physical problems other than injuries, including when relevant, heat or cold stress, prolonged thirst, and hunger in a consignment, observed in the animals.
- 2. The keeper shall record the findings regarding the indicators provided for in paragraph 1 in section 3 of the journey log in TRACES.
- 3. The organiser and the transporter shall monitor the indicators referred to in paragraph 1 and analyse the information collected upon completion of their

transports. When the results of the analysis indicates that the requirements of Article 4 have not been met or when values quantifying the indicators exceed the thresholds established by the Commission in accordance with paragraph 5, they shall take corrective actions.

- 4. The Commission shall adopt implementing acts in accordance with Article 49 establishing the health and physical issues to be monitored in accordance with of paragraph 1, point (d), as well as the methods to be used when quantifying the indicators referred to in paragraph 1.
- 5. The Commission may, based on the advice from the European Food Safety Authority ('EFSA'), adopt delegated acts in accordance with Article 48 establishing the thresholds requiring corrective actions to be taken.

# CHAPTER VI CONDITIONS FOR TRANSPORT OF TERRESTRIAL ANIMALS

### Article 27

Journey times, rest periods, feeding and watering intervals during transport of adult terrestrial animals by road and rail for long journeys

- 1. Without prejudice to stricter rules on journey times laid down in this Chapter and in Chapter V of Annex I, long journeys for the transport by road or rail of terrestrial animals other than domestic birds and rabbits, for a purpose other than slaughter, shall fulfil the following conditions:
  - (a) the journey consists of a maximum of two parts, each of them not exceeding 21 hours, after which time the animals shall reach the place of destination;
  - (b) after the first 21 hours from the start of the journey, and if the animals have not yet reached the place of destination, they are unloaded for a rest period of at least 24 hours at a control post before the transport may continue;
  - (c) both parts of the journey referred to in point (a) include rest periods of at least 1 hour after a maximum of 10 hours; during the rest period, the animals shall remain on the stationary means of transport;
- 2. For long journeys, the requirements set out in Chapter VI of Annex I shall apply.
- 3. The transport by road of domestic birds and rabbits for a purpose other than slaughter shall follow the specific rules laid down in point 2 of Chapter V of Annex I.
- 4. Terrestrial animals, other than domestic birds and rabbits, shall be offered water and feed in regular intervals, as laid down in Chapter V of Annex I.
- 5. For transport by rail, paragraph (1), point (c) shall not apply.
- 6. Paragraphs (1) to (5) shall not apply to animals transported in bio-secure transports for the purposes of an authorised project or breeding under Directive 2010/63/EU.

Journey times and rest periods for transport of terrestrial animals to slaughter by road or rail

- 1. Transport of terrestrial animals other than domestic birds and rabbits, to slaughter shall only be carried out in short journeys.
- 2. When, within the Union, no slaughterhouses adapted for slaughter of the species and categories of animals referred to in paragraph 1 can be reached within a short journey for a specific place of departure, the competent authorities at the place of departure may grant an authorisation for a long journey to the nearest slaughterhouse adapted to the species transported.
- 3. The transport of rabbits and poultry to slaughter shall follow the specific rules for these species laid down in point 2 of Chapter V of Annex I.

### Article 29

Journey times, rest periods, feeding and watering of unweaned calves, lambs, kids, piglets and foals

- 1. The journey time for the transport by road of unweaned calves, lambs, kids, piglets and foals shall not exceed 8 hours.
- 2. By way of derogation from paragraph 1, provided the means of transport is equipped with a feeding system approved in accordance with paragraph 5, unweaned calves, lambs, kids, piglets and foals may be transported for a maximum of 9 hours, after which a rest period of at least an hour without unloading shall take place before resuming the journey for a maximum of another 9 hours.
- 3. Where parts of a journey for transport of unweaned calves, lambs, kids, piglets and foals takes place at sea, that part of the journey shall not be counted as part of the journey time.
- 4. Unweaned calves, lambs, kids, piglets and foals shall be provided with water *ad libitum* and be fed species-specific milk or appropriate milk replacement at 9-hour intervals counted from the start of the journey and regardless of the means of transport in which they are being transported.
- 5. A manufacturer of a feeding system referred to in paragraph 2, established in the Union or, if established in a third country, represented in the Union, may submit an application to the Commission for the approval of the feeding system.
- 6. The Commission shall, by means of implementing acts in accordance with Article 49, approve the feeding system referred to in paragraph 2, provided that there is scientific and technical evidence that the feeding system allows all unweaned calves, lambs, kids, piglets and foals on board to be fed, during the journey, milk or milk replacers at body temperature and appropriate hygiene level.

### Article 30

Journeys by road to and from livestock vessels and roll-on roll-off vessels for transport of terrestrial animals other than domestic birds and rabbits

1. Journey times for transport of terrestrial animals other than domestic birds and rabbits which include a part of the journey at sea where consignments from different

places of origin are transported, shall be counted from the loading of the animals at the place of departure the farthest away in driving time from the port of loading. The counting of the journey time shall be suspended from the moment the last animal is loaded on the vessel until the moment the first animal is unloaded at the port of arrival.

2. Feeding times on board shall follow the specific rules laid down in point 1 of Chapter V of Annex I.

### Article 31

Journey times and conditions for transport of terrestrial animals other than domestic birds and rabbits by road and rail in extreme temperatures

- 1. The organiser, when submitting the journey log in TRACES, and the competent authority when approving the journey log, shall take into consideration the temperature forecast at the place of departure, the place of destination and, when relevant, the place of the control post, at the time animals are expected to be at those places. For consignments transported to third countries, the organiser shall also take into consideration the temperature forecast at the exit point or the border control post of the third country.
- 2. For transport of terrestrial animals by road, except for dogs and cats:
  - (a) when the temperature forecast indicates temperatures below 0°C, road vehicles shall be covered and air circulation in the animal compartment controlled to protect animals from exposure to windchill during the journey;
  - (b) when the temperature forecast indicates temperatures below -5°C, in addition to the measures in point (a), the journey time shall not exceed 9 hours;
  - (c) when the temperature forecast indicates temperatures between 25°C and 30°C, the journey time during the period between 10h00 and 21h00 shall not exceed 9 hours:
  - (d) when the temperature forecast indicates temperatures above 30°C, only journeys taking place fully between 21h00 and 10h00 shall be allowed.
  - (e) when the temperature forecast indicates temperatures above 30°C between 21h00 and 10h00, the space allowance for the animals shall be increased by 20%.
- 3. Dogs and cats shall be transported in a compartment with an ambient temperature ranging between 20 and 25 °C and with a humidity between 30 and 70%.
- 4. Paragraphs (1) to (3) shall not apply to animals transported in bio-secure transports for the purposes of an authorised project or breeding under Directive 2010/63/EU.
- 5. For the purposes of paragraph 1, Member States shall, by the date of application of this Regulation, include the link to their designated temperature forecast body in TRACES to share the temperature forecast to all competent authorities and operators.

For transport of animals to a third country, the expected temperatures at locations in third countries shall be determined using the designated temperature forecast body of the place of departure.

## CHAPTER VII TRANSPORT TO AND FROM THIRD COUNTRIES

#### Article 32

Obligations concerning the transport of animals to third countries

- 1. Organisers may only make arrangements for the transport of animals to third countries if they hold an authorisation granted in accordance with Article 5.
- 2. Organisers shall complete section 1 of the journey log as set out in point 1 of Annex III in accordance with Article 15 for both short and long journeys and ensure that transporters and keepers at the place of destination complete the sections of the journey log that concern them.
- 3. For journeys which include transport by livestock vessel, the organiser shall ensure that the competent authority at the third country of destination has completed, signed and stamped the attestation set out in Annex IV and transmitted it to the competent authority at the place of departure. The competent authority shall not approve the journey log if this attestation is not provided.
- 4. Consignments of animals shall only leave the customs territory of the Union through designated exit points as referred to in Article 39.

### Article 33

### Certificate for transport of animals to third countries

- 1. The organiser shall arrange for a certification body to evaluate the first journey to a place of destination in a third country arranged by the organiser.
- 2. The certification body shall evaluate whether the following conditions were met during the first journey referred to in paragraph 1:
  - (a) the vehicles and vessels comply with the relevant rules of Annex I;
  - (b) the maximum journey times, special conditions for transport in extreme temperatures, and rest periods laid down by this Regulation take place as declared in the journey log;
  - (c) the space allowances comply with Chapter VII of Annex I;
  - (d) the animals stay in the declared place of destination at least 7 days or are slaughtered;
  - (e) the purpose of the journey is in accordance with the one declared in the journey log;
  - (f) for journeys with a leg by livestock vessel, the animals arrive in good condition at the port of arrival;
  - (g) the animals are handled in accordance with this Regulation;
  - (h) if relevant, the control posts used are listed as referred to in Article 34(3);
  - (i) for transport of aquatic animals, vehicles and transport operations comply with the rules set out in Annex II.

- 3. If the conditions set out in paragraph 2 are met, the certification body shall issue a certificate for transport of animals to third countries to the organiser. The certificate shall be valid for 5 years.
- 4. The organiser shall transmit the certificate to the competent authority that granted the authorisation referred to in Article 5.
- 5. Competent authorities shall register certified organisers in TRACES.
- 6. If the conditions set out in paragraph 2 are not met, the certification body shall inform the organiser and the competent authority, who shall suspend the organiser's authorisation for transport to third countries in accordance with Article 6(4).
- 7. Certification bodies shall perform at least two unannounced evaluations of journeys carried out by the organiser within the 5 years of validity of the certificate, in order to verify compliance with the conditions listed in paragraph 2.
- 8. The certification body shall send the reports of the unannounced evaluations to the organiser and the competent authority and notify them of serious non-compliances after unannounced inspections. In such cases, the competent authority shall suspend the organiser's authorisation for transport to third countries in accordance with Article 6(4). These unannounced evaluations shall be without prejudice to official controls carried out under Regulation (EU) 2017/625.
- 9. The Commission is empowered to adopt implementing acts in accordance with Article 49 to further establish the elements to be verified by the evaluations and the frequency of evaluations.

## Article 34 Control posts in third countries

- 1. Rest periods for animals in third countries shall only take place in control posts meeting requirements at least equivalent to those laid down in Regulation (EC) No 1255/97 and that are included in the list referred to in paragraph 3.
- 2. Control posts in third countries shall only be included in the list provided for in paragraph 3 if they are certified by a certification body as having the means to comply with requirements equivalent to those laid down in Regulation (EC) No 1255/97. The certificate shall be valid for 5 years. The operator of the control post or the organiser may request the Commission to include the control post in the list referred to in paragraph 3.
- 3. The Commission shall approve, by means of implementing acts in accordance with Article 49, a list of control posts meeting standards that are equivalent to those laid down in Regulation (EC) No 1255/97. This list shall be made available in TRACES.
- 4. The Commission shall remove a control post from the list referred to in paragraph 3 when, upon evaluation by the certification body or an audit from the Commission, there is evidence that the control post no longer meets standards equivalent to those laid down in Regulation (EC) No 1255/97. The procedure referred to in Article 49 shall apply.

## Article 35 Animals entering into the Union

- 1. Transporters who transport animals to the Union shall:
  - (a) ensure that the animals are transported in compliance with this Regulation, or under conditions recognised by the Union to be equivalent to those set out in this Regulation, from the place of departure in the third country until the place of destination in the Union:
  - (b) complete the journey log in TRACES, as set out in point 1 of Annex III, specifying in particular the place, date and time of departure in the third country.
- 2. The official health certificate accompanying animals entering into the Union from third countries and territories shall contain an attestation from the competent authority at the place of departure certifying that the planning of the journey complies with requirements at least equivalent to those of this Regulation.
- 3. For long journeys, the competent authority at the place of departure in the third country shall review and approve the journey log prior to departure, in TRACES.

## Article 36 Animals transiting through the Union territory

When animals are transported from a place of origin in a third country to a place of destination in the same or another third country and transit through the Union territory, operators shall ensure that the rules of this Regulation are complied with during the part of the journey taking place on the Union territory, except for the provisions on maximum journey times set out in Article 27 paragraphs (1), (2) and (3), Article 28, Article 29 paragraphs (1) and (2), and point 2.2 of Chapter V of Annex I.

## CHAPTER VIII OBLIGATIONS OF COMPETENT AUTHORITIES

### Article 37 Trainings

- 1. For the purposes of Article 10, Member States shall designate the competent authority responsible for:
  - (a) ensuring that training courses are available for drivers, attendants and animal welfare officers involved in the transport of animals relevant to species and the categories of animals concerned;
  - (b) keeping a list of approved training courses available to drivers, attendants and animal welfare officers responsible for animal welfare during transport;
  - (c) organising an independent final examination to test the drivers', attendants' and animal welfare officers' knowledge, the content of which shall be relevant for the categories of animal concerned and shall correspond to the stage of transport concerned;
  - (d) delivering certificates of competence attesting the passing of the independent final examination;

- (e) determining the content of the training courses referred to in point (a) and the modalities of the examination referred in point (b).
- 2. The training courses referred to in paragraph 1 shall cover at least the following competences, knowledge and skills:
  - (a) the animal welfare obligations, in particular those set out in Annexes I and II;
  - (b) the species-specific behaviour of animals and their physiological and ethological needs during a journey;
  - (c) ways to minimise animal welfare risks during a journey;
  - (d) recognition of expressions of animals' positive and negative emotions, including any sign of suffering during a journey;
  - (e) use and maintenance of equipment used for animals accommodated in the means of transport;
  - (f) methods for monitoring indicators in accordance with Article 26; and
  - (g) contingency plans in Article 8.

## Article 38 Certificate of competence

- 1. The competent authority shall grant a certificate of competence in TRACES provided that the following conditions are fulfilled:
  - (a) the applicant has successfully passed the final examination referred to in Article 37(1), point (c);
  - (b) the applicant has provided a written declaration stating that he/she has not committed a serious infringement as provided for in Article 44 in the 3 years preceding the date of the application for that certificate.
- 2. The competent authority shall not grant the certificate of competence if another competent authority has prohibited the applicant from handling animals.
- 3. The certificate of competence shall include the information set out in Section 4 of Annex V. It shall be valid for a period of not more than 5 years from the date of issue.
- 4. Member States shall recognise valid certificates of competence granted in another Member State.
- 5. Member States may recognise qualifications obtained for other purposes as equivalent to certificates of competence for the purposes of this Regulation, provided they have been obtained under conditions equivalent to those laid down in this Article. The competent authorities shall make publicly available and keep up to date, via the Internet, a list of qualifications recognised as equivalent to the certificate of competence.
- 6. Competent authorities shall withdraw in TRACES a certificate of competence granted under this Regulation where the person holding that certificate no longer shows sufficient competence, knowledge or awareness of his/her tasks.

### Article 39 Designation of exit points

### Member States shall:

- (a) designate the exit points through which transport of animals to third countries may take place;
- (b) record the designated exit points on their territory in TRACES and regularly update this information.

This information shall be publicly available in TRACES.

### Article 40

### Livestock vessel inspection on loading and unloading

- 1. Before animals are loaded onto a livestock vessel, the competent authority shall inspect the vessel in order to verify in particular that:
  - (a) the livestock vessel is built and equipped for the number and the type of animals to be transported;
  - (b) compartments where animals are to be accommodated remain in a good state of repair;
  - (c) the equipment referred to in Chapter IV of Annex I remains in good working order:
  - (d) the livestock vessel's ship risk profile rating is standard risk or low risk according to the Paris Memorandum of Understanding on port State control.
- 2. Before animals are loaded onto or unloaded from a livestock vessel, the competent authority shall inspect the vessel to verify that:
  - (a) the animals are fit to continue their journey;
  - (b) loading/unloading operations are being carried out in compliance with point 2 of Chapter III of Annex I;
  - (c) feed and water arrangements are in accordance with point 2 of Chapter IV of Annex I.

### Article 41

### Liaison Bodies on protection of animals during transport

- 1. Liaison bodies on protection of animals during transport, designated in accordance with Article 103(1) of Regulation (EU) 2017/625, shall, in addition to the tasks and responsibilities provided for in Regulation (EU) 2017/625, have the following tasks:
  - (a) the provision of mutual assistance to facilitate a smooth application of this Regulation, including delays in the transport or rejections of consignments by third countries of animals transported by road, rail or vessel;
  - (b) the exchange of advice and best practices regarding compliance with this Regulation.

2. The Commission shall organise regular meetings of the network of liaison bodies referred to in paragraph 1, for the purpose of facilitating a uniform enforcement of this Regulation within the Union.

## CHAPTER IX SANCTIONS

### Article 42

### Measures and sanctions to ensure compliance

Without prejudice to the application of Regulation (EU) 2017/625, Member States shall lay down the rules on measures and sanctions against the natural person having committed, or the legal person held liable for, an infringement of this Regulation. In particular, Member States shall systematically:

- (a) investigate suspected infringements in order to confirm or eliminate the suspicion;
- (b) take appropriate measures, when an infringement is detected, including to bring the infringement to an end; and
- (c) apply sanctions in accordance with this Chapter and with Regulation (EU) 2017/625 against the natural person having committed or legal person held liable for the infringement of this Regulation.

## Article 43 Sanctions for infringements of this Regulation

- 1. Without prejudice to the application of Regulation (EU) 2017/625, Member States shall ensure that a natural person having committed or a legal person held liable for an infringement of this Regulation is subject to administrative sanctions in accordance with this Regulation, and national law. Alternatively, Member States may apply criminal sanctions.
- 2. Member States shall ensure that sanctions applied in accordance with this Regulation and the relevant provisions of national law are proportionate to the seriousness of infringements and adequate in severity to effectively punish and deter further infringements.
- 3. When determining sanctions, including when fixing the amount of financial penalties in accordance with paragraph 5, Member States shall take into account the nature, gravity and extent of the infringement, including the harm to the welfare of the animals concerned, their number, type, age or vulnerability, the duration of the infringement, its repetition, and the accumulation of simultaneous infringements and if the infringement was committed deliberately or by negligence.
- 4. The following shall be considered aggravating circumstances:
  - (a) infringements perpetrated though fraudulent or deceptive practices, or using documents/certificates that are falsified or known to be invalid;
  - (b) deliberately making false or misleading declarations in journey logs.
- 5. In the case of a serious infringement, Member States shall ensure that the serious infringement is punishable by administrative financial penalty of which the minimum shall be at least the value of the consignment. In the case of a repeated

serious infringement within a three-year period, Member States shall ensure that the serious infringement is punishable by administrative financial penalties, of which the minimum shall be at least twice the value of the consignment.

Member States may take into account the economic situation of the natural person having committed or legal person held liable for the infringement to ensure the deterrence of sanctions. For that purpose, Member States may, in accordance with national law, apply a system whereby a financial penalty is imposed which is calculated as a percentage of the turnover of the operator being held liable for the infringement.

## Article 44 Serious infringements

The following infringements shall be considered serious when committed deliberately or negligently:

- (a) animals with severe open wounds, prolapses and broken limbs are transported;
- (b) animals are transported before the minimum age for transport;
- (c) the vertical height provided to animals transported is less than 80% of the requirements for vertical height set out in point 6 of Chapter III of Annex I;
- (d) the space allowance for animals transported is less than 80% of the requirements for space allowances set out in Chapter VII of Annex I;
- (e) the journey time exceeds the maximum journey time by 30%, excluding rest periods;
- (f) aquatic animals are transported without monitoring of water parameters in accordance with Annex II;
- (g) animals are transported for long journeys without an organiser authorisation, a transporter authorisation, a certificate of approval for a means of transport, or a certificate of competence of driver or attendant;
- (h) animals are transported for long journeys without an approval by the competent authority of the journey log;
- (i) animals are transported with a destination in a third country without a valid certificate for transport of animals to third countries in accordance with Article 33.

### Article 45 Other sanctions

- 1. The sanctions provided for in this Chapter are without prejudice to other sanctions that may be taken by competent authorities in the event of an established infringement, in particular:
  - (a) the immobilisation of the vehicle or livestock vessel involved in the infringement;
  - (b) the confiscation of the vehicle or livestock vessel or the animals transported;
  - (c) the suspension or withdrawal of the organiser or transporter authorisation;
  - (d) the suspension or cessation of all or part of the economic activities of the operator related to the transport of animals.

2. Member States shall determine the duration of the sanctions referred to in paragraph 1.

## CHAPTER X PROCEDURAL PROVISIONS

### Article 46

Report on the state of animal welfare in transport

- 1. Based on the data recorded in TRACES in accordance with Article 26 and any other relevant data, the Commission shall publish by [5 years after the date of entry into force of this Regulation] and thereafter every 5 years, a monitoring report on the state of animal welfare with regard to transport in the Union.
- 2. For the purpose of the reporting referred to in paragraph 1, Member States shall provide the Commission with the information necessary for the preparation of this report.

## Article 47 Amendment of Annexes

- 1. The Commission is empowered to adopt delegated acts in accordance with Article 48 to update the technical rules contained in Annex I, Chapters I, II, V and VII, and Annex II in order to take into account technical progress and scientific developments when available, including scientific opinions of the EFSA, and of social, economic and environmental impacts, with regards to:
  - (a) the design and maintenance of means of transport;
  - (b) the handling equipment;
  - (c) the water requirements, including maximum levels for water parameters, and water monitoring requirements;
  - (d) feeding requirements;
  - (e) fitness for transport;
  - (f) loading and unloading practices;
  - (g) handling during and after transport activities;
  - (h) conditions on board roll-on roll-off vessels and transport by air;
  - (i) transport practices;
  - (j) space allowance and stocking density requirements.
- 2. The Commission is empowered to adopt implementing acts in accordance with Article 49 to update the templates for journey logs in Annex III and the model of attestation in Annex IV.

## Article 48 Exercise of delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

- 2. The power to adopt delegated acts shall be conferred on the Commission for a period of 5 years from the date of entry into force of this Regulation. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.
- 3. The delegation of power referred to in paragraph 2 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
- 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
- 5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
- 6. A delegated act adopted pursuant to paragraph 2 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

### Article 49 Committee procedure

- 1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011.
- 3. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and of Article 5(4), third subparagraph of Regulation (EU) No 182/2011 shall apply.

## Article 50 Implementing powers concerning documents

The Commission may, by means of implementing acts in accordance with Article 49, lay down rules for the uniform application of Articles 6, 9, 12, 13 and 38 concerning rules for the issuance of electronic authorisations, certificates and journey logs and for the use of electronic signature.

### CHAPTER XI OTHER PROVISIONS

#### Article 51

Data protection in the context of authorisations, journey logs, real-time tracking positioning systems and certificates

- 1. For the authorisations referred to in Chapter II, the journey logs referred to in Chapter IV and the certificates referred to in Chapter VIII, the Commission and Member States shall be joint controllers in the meaning of Article 28 of Regulation (EU) 2018/1725 and Article 26 of Regulation (EU) 2016/679, pursuant to Article 11 of Implementing Regulation (EU) 2019/1715.
- 2. For the purposes of the real-time tracking positioning systems referred to in Article 24, the Commission shall be the controller in the meaning of Article 3(8) of Regulation (EU) 2018/1725.
- 3. The data recorded in the information system referred to in Article 24(3) shall only be accessible to the Commission, for the purpose of retrieving the information referred to Article 24(5) in TRACES.
- 4. In addition to the categories of data processed pursuant to Article 10 of Implementing Regulation (EU) 2019/1715, the data gathered by means of the real-time positioning system referred to in Article 24 and the data in the journey log related to the name and telephone number of the driver shall also be processed for the only purpose of performing official controls and other official activities as defined in Article 2 of Regulation (EU) 2017/625.
- 5. The recording of positioning data on short period intervals shall be retained in the information system referred to in Article 24(3) for a period of 6 years.
- 6. The personal data related to the authorisations referred to in Chapter II and the certificates referred to in Chapter VIII shall be retained by TRACES throughout the validity of those authorisations and certificates and for a period of 6 years after their expiry or withdrawal.

### Article 52 Stricter national measures

This Regulation shall not prevent Member States from adopting stricter national measures aimed at improving the protection of animals during transport that takes place entirely within the territory of a Member State, or during transport that takes place exclusively between a place of departure in the territory of a Member State and a place of destination in a third country, provided those measures do not interfere with the proper functioning of the internal market.

Member States shall inform the Commission about such national rules before their adoption. The Commission shall bring them to the attention of the other Member States.

### Article 53 Mobile application

- 1. By [5 years from the date of entry into force of this Regulation], the Commission shall develop and make available to operators and competent authorities a mobile application allowing the performance of administrative tasks in relation to the transport of animals. The application shall have at least the following functionalities connected to TRACES:
- (a) creation and update of sections of a journey log by registered TRACES users;
- (b) submission of a journey log for approval;
- (c) calculation of required space allowance;
- (d) tools to check of fitness for transport;
- (e) tools to check the weather forecast.
- 2. By [5 years after the date of entry into force of this Regulation] the Commission shall, by means of implementing acts in accordance with Article 49, lay down detailed specifications for the development of the application referred to in paragraph 1.

## Article 54 Reporting and evaluation

- 1. By [10 years after the date of entry into force of this Regulation], the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.
- 2. For the purpose of the reporting referred to in paragraph 1, Member States shall provide the Commission with the information necessary for the preparation of this report.

## Article 55 Derogation

By way of derogation to this Regulation, Member States may continue to apply the current national provisions concerning transport of animals within their outermost regions, originating from or arriving at those regions. They shall inform the Commission thereof.

## CHAPTER XII TRANSITIONAL AND FINAL PROVISIONS

### Article 56 Repeals

- 1. Council Regulation (EC) No 1/2005 is repealed.
- 2. References to the repealed Regulation shall be construed as references to this Regulation and read in accordance with the correlation table in Annex VI.

## Article 57 Amendments to Council Regulation (EC) No 1255/97

Council Regulation (EC) No 1255/97 is amended as follows:

In Article 3, the following point is added:

- '(e) be equipped for the species and categories of animals they accommodate;
- (f) be of a size sufficient to accommodate at least a truck load of animals while respecting the space allowances laid down in Council Directives 2008/119/EC<sup>60</sup> and 2008/120/EC<sup>61</sup>.

In Article 5, the following point is added:

'(j) to keep a booking system in TRACES allowing organisers to see and book slots available.'

### Article 58 Transitional provision

Point (2)(e) of Chapter I of Annex I, Chapter V of Annex I, point 3.1. of Chapter VI of Annex I and Chapter VII of Annex I to Council Regulation (EC) No 1/2005 shall continue to apply until the date of application of point 1 (h) of Chapter I of Annex I, Articles 27 to 30 and Chapter VII of Annex I to this Regulation.

## Article 59 Entry into force and application

- 1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
- 2. It shall apply as from 2 years from the date of entry into force of this Regulation, unless otherwise provided for in paragraphs 3 and 4.
- 3. Article 13(2), point (d), Article 44(5), Article 44, point 10 of Chapter I of Annex I, point 2.5. of Chapter II of Annex I and point 3.3 of Chapter V of Annex I shall apply from 3 years from the date of entry into force of this Regulation.
- 4. Article 24, paragraphs 1 to 4, Article 51, Articles 27 to 30, Chapter VII, Point 1(h) of Chapter I of Annex I, and Chapter VII of Annex I shall apply from 5 years from the date of entry into force of this Regulation.

Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves, OJ L 10, 15.1.2009, p. 7.

Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs, OJ L 47, 18.2.2009, p. 5.

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

For the European Parliament The President For the Council The President

### LEGISLATIVE FINANCIAL STATEMENT

- 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE
- 1.1. Title of the proposal/initiative
- 1.2. Policy area(s) concerned
- 1.3. The proposal/initiative relates to:
- 1.4. Objective(s)
- 1.4.1. General objective(s)
- 1.4.2. Specific objective(s)
- 1.4.3. Expected result(s) and impact
- 1.4.4. Indicators of performance
- 1.5. Grounds for the proposal/initiative
- 1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative
- 1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention, which is additional to the value that would have been otherwise created by Member States alone.
- 1.5.3. Lessons learned from similar experiences in the past
- 1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments
- 1.5.5. Assessment of the different available financing options, including scope for redeployment
- 1.6. Duration and financial impact of the proposal/initiative
- 1.7. Method(s) of budget implementation planned
- 2. MANAGEMENT MEASURES
- 2.1. Monitoring and reporting rules
- 2.2. Management and control system(s)
- 2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed
- 2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them
- 2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)
- 2.3. Measures to prevent fraud and irregularities
- 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

## 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- 3.2. Estimated financial impact of the proposal on appropriations
- 3.2.1. Summary of estimated impact on operational appropriations
- 3.2.2. Estimated output funded with operational appropriations
- 3.2.3. Summary of estimated impact on administrative appropriations
- 3.2.3.1. Estimated requirements of human resources
- 3.2.4. Compatibility with the current multiannual financial framework
- 3.2.5. Third-party contributions
- 3.3. Estimated impact on revenue

### 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

### 1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council on the protection of animals during transport and related operations, amending Council Regulation (EC) No 1255/97 repealing Regulation (EC) No 1/2005

### 1.2. Policy area(s) concerned

Heading 1: Single Market, Innovation and Digital

### 1.3. The proposal/initiative relates to:

 $\square$  a new action

□ a new action following a pilot project/preparatory action<sup>62</sup>

√ the extension of an existing action

 $\Box$  a merger or redirection of one or more actions towards another/a new action

### 1.4. Objective(s)

### 1.4.1. General objective(s)

The proposal aims to improve the protection of animals during transport, contributing both to higher welfare and to more sustainable food production.

### 1.4.2. Specific objective(s)

### Specific objective No

To update the current conditions for transporting animals in light of the latest scientific and technological progress in order to ensure higher level of welfare and better quility of the food from animal origin.

Contribute to a better and harmonised enforcement of the animal transport rules at EU level, strengthening the official controls related to the protection of animals during transport and digitalising the whole process for transporting animals in order to reduce the administrative burden for the operators and the competent authorties.

### 1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

### Specific objective 1

- -Reduced journey times
- -Better harmonised and unified approach for the calculation of journey times for animals for slaughter and the five main farmed animal species
- -Increased space allowance
- -Clearer and more specific conditions for different species and categories of animals
- -Improved conditions for transporting of vulnerable categories of animals such as pregnant animals, unweaned calves or end of carer laying hens

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As referred to in Article 58(2)(a) or (b) of the Financial Regulation.

- -Improvement of the conditions of livestock vessels
- -External certification on compliance beyond Union borders
- -Stricter conditions for exporting animals from EU to third countries
- New and more specific requirements for the transport of dogs and cats and aquatic animals
- Clearer rules for reducing the exposure of animals during transport to extreme temperatures (i.e. very low or extremely high)

Specific objective 2

- -Reduce internal market distortions
- -Modernising the information-sharing tools
- -Digitalising the whole process and reduce the paperwork and administrative burden
- -Harmonised approach for sanctioning system and common understanding of the level of severity of non-compliances
- -Live time tracking system ensuring better response in case of incidents during transport

### 1.4.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

### Specific objective 1:

- -Duration of journey times
- -Number and percentage of animals injured during transport
- -Number and percentage of animals with health-related and physical state-related issues (heat or cold stress, prolonged thirst and hunger)
- Number and percentage of animals dead on arrival
- Number of transports of animals
- -Less non-compliances

Specific objective 2:

-Use of a digital app based on TRACES to be developed.

### 1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

The proposal aims at improving animal welfare and facilitate a harmonised level of enforcement and compliance. The proposal updates rules on the welfare of animals during transport in accordance with the latest scientific and technological progress with the aim to improve welfare of animals and ensure fair competition for business operators. TRACES would be further developed to address all certifications, authorisations and approvals electronically, allowing all comeptent authorities in the EU to access the relevant data for the transport of animals. In addition, live tracking of road vehicles will be available in TRACES to better monitor that journey times are respected.

The need for financial resources starts in 2024 with a study on modalities for the use of new technologies and digitalization to facilitate the implementation and enforcement of rules on animal welfare during transport. The following years would be dedicated to the design of these tools and their maintenance.

1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention, which is additional to the value that would have been otherwise created by Member States alone.

Since the adoption of the Transport Regulation, science has evolved, technology allows for a more efficient implementation of rules and EU citizens are paying increasing attention to animal welfare. Member States often have challenges with the interpretations of the same provisions, often leading to an different level of enforcement of the transport rules across Members States. In addition, Member States have adopted their own rules on welfare matching their new requirements to the latest science avialable. This implies distortions on the internal market and the level playing field for all actors involved.

This proposal brings to the transport the most recent scientific advice, contributes to both the trade of animals and food of animal origin respecting a level playing field and to improve across the EU the welfare of the livestock. The internal market would be improved, and the EU high values on animal welfare would be easier promoted at global level.

1.5.3. Lessons learned from similar experiences in the past

The fitness check (evaluation) carried out on the EU animal welfare legislation shows that significant developments in science and technology, new societal trends and sustainability challenges are not fully reflected in the current regulation. Member States have addressed these disparities in science through national legislation, contributing to an uneven level playing field across the Union.

In addition, the current transport rules have proven to be difficult to implement and enforce, leading to a fragmented level of animal welfare and an uneven playing field on the EU market.

Exchanges with competent authorities form Member States, different stakeholders, results from Commission audits and better practices identified by national experts show that clearer rules and responsibilities are needed to facilitate a harmonised implementation and enforcement across the Union.

1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments

The Regulation is to be part of the Food Strand of the Single Market Programme and will work in synergy with the Common Agriculture Policy. While this proposal will tend to promote animal welfare through consumers' demand, the CAP possesses various instruments to improve animal welfare of food producing animals through subsidies to producers (ecoschemes, rural development measures on animal welfare, investments, training, advisory services, quality schemes, etc.).

1.5.5. Assessment of the different available financing options, including scope for redeployment

The costs will be supported from Single Market Programme - Food Strand given that the objectives of this regulation contribute to one of the key objectives of the programme, i.e. Sustainable and resilient production of food and to the EU 'Farm to Fork' targets.

| 1.6.  | Duration and financial impact of the proposal/initiative  |
|-------|---|
|       | ☐ limited duration  |
|       | <ul> <li>□ in effect from [DD/MM]YYYY to [DD/MM]YYYY</li> </ul>   |
|       | <ul> <li>         — □ Financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.     </li> </ul>  |
|       | ✓ unlimited duration  |
|       | <ul> <li>Implementation with a start-up period from 2024 to 2027,</li> </ul>  |
|       | <ul> <li>followed by full-scale operation.</li> </ul>   |
| 1.7.  | Method(s) of budget implementation planned <sup>63</sup>  |
|       | ✓ Direct management by the Commission   |
|       | <ul> <li>         — ✓ by its departments, including by its staff in the Union delegations;     </li> </ul>  |
|       | <ul> <li>         — ✓ by the executive agencies     </li> </ul>   |
|       | ☐ Shared management with the Member States  |
|       | ☐ <b>Indirect management</b> by entrusting budget implementation tasks to:  |
|       | <ul> <li>         — □ third countries or the bodies they have designated;     </li> </ul>   |
|       | <ul> <li>         — □ international organisations and their agencies (to be specified);     </li> </ul>   |
|       | <ul> <li>         — □ the EIB and the European Investment Fund;     </li> </ul>   |
|       | <ul> <li>         — □ bodies referred to in Articles 70 and 71 of the Financial Regulation;     </li> </ul>   |
|       | <ul> <li>         — public law bodies;     </li> </ul>  |
|       | <ul> <li>         — □ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees;     </li> </ul>   |
|       | <ul> <li>         — □ bodies governed by the private law of a Member State that are entrusted with         the implementation of a public-private partnership and that are provided with         adequate financial guarantees;     </li> </ul> |
|       | <ul> <li>         — □ bodies or persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.     </li> </ul>   |
|       | - If more than one management mode is indicated, please provide details in the 'Comments' section.  |
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Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: <a href="https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx">https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx</a>

### 2. MANAGEMENT MEASURES

### 2.1. Monitoring and reporting rules

Specify frequency and conditions.

The Regulation includes provisions to collect data and yearly indicators of animal welfare.

The Regulation requires the Member Statest and operators to enter all information in TRACES and the competent authorities of the Member States to report yearly to the Commission data for monitoring and evaluation purposes.

### 2.2. Management and control system(s)

2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

In accordance with the governance statement of the European Commission, DG Health and Food Safety (SANTE) conducts its operations in compliance with the applicable laws and regulations, working in an open and transparent manner and meeting the expected high level of professional and ethical standards.

The actions aiming to improve the protection of animals during transport will be implemented through direct management, using the implementation modes offered by the Financial Regulation: direct management allows to establish grant agreements/contracts with beneficiaries/contractors directly engaged in activities that serve Union policies. The Commission ensures direct monitoring over the outcome of the actions financed. The payment modalities of the actions funded will be adapted to the risks pertaining to the financial transactions.

In order to ensure the effectiveness, efficiency and economy of the Commission controls, the control strategy will be oriented towards a balance of ex-ante and expost checks and focus on three key stages of grant/contract implementation, in accordance with the Financial Regulation:

- Selection of proposals/tenders that fit the policy objectives of the Regulation;
- Operational, monitoring and ex-ante controls that cover project implementation, public procurement, pre-financing, interim and final payments;
- Ex-post controls at the beneficiaries' sites will also be carried out, typically on a risk-based sample of transactions due to efficiency considerations.

The Directorate General for Health and Food Safety (DG SANTE) is subject to administrative controls including budgetary control, annual reports by the European Court of Auditors and the Commission's Internal Audit Service, the annual discharge for the execution of the EU budget and possible investigations conducted by OLAF to ensure that the resources allocated are put to proper use.

In accordance with the Commission's Internal Control Framework<sup>64</sup>, DG SANTE has elaborated an internal control strategy which focusses on financial management and its compliance with the Financial Regulation, especially with regard to the five

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<sup>&</sup>lt;sup>64</sup> C(2017) 2373 of 19/04/2017

control objectives<sup>65</sup> and the main principles of cost-efficient and effective controls and anti-fraud measures. The strategy is an evolving document which is regularly updated and it is adopted by DG SANTE's Management Board.

The Director in charge of Risk Management and Internal Control (RMIC) of DG SANTE is responsible for co-ordinating the drafting, updating and communication of the control strategy to all staff concerned. To this end, the Director launches each year an annual assessment of the internal control system that feeds into the Annual Activity Report of DG SANTE.

## 2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

Risk management is fully integrated into DG SANTE's planning and control cycle. The most important risks are identified in the annual risk assessment exercise. The focus is on the residual risk exposure taking into account all measures already taken to mitigate the risk. The exercise closes with discussions at senior management level chaired by the Director General. The so-called "critical risks" are reported to the Commissioner together with an action plan to reduce them to an acceptable level. To monitor the implementation of the action plans, a progress report is prepared and communicated to the Commissioner in the context of the mid-term report.

DG SANTE integrated risk management into its budget implementation processes. Potential risks, issues or problems are identified in each step of the financial management process.

The implementation of the new Regulation focuses on the attribution of public procurement contracts as well as a number of grants for specific activities and organisations.

The public procurement contracts will mainly be concluded in areas such as IT product development and support and studies.

The main risks are the following:

• Risk of not fully achievening the objectives of the Regulation due to insufficient uptake or quality/delays in the implementation of the selected projects or contracts;

Risk of inefficient or non-economic use of funds awarded, both for grants (complexity of funding rules) and for procurement (limited number of economic providers with the required specialist knowledge entailing insufficient possibilities to compare price offers in some sectors);

• Reputational risk for the Commission, if fraud or criminal activities are discovered; only partial assurance can be drawn from the third parties' internal control systems as contractors and beneficiaries are each operating their own control system.

The Commission put in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the Financial Regulation and include anti-fraud measures and cost-benefit considerations. Within this framework, the Commission continues to explore possibilities to enhance the

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According to the COSO model adopted by the Commission Internal Control Framework in its latest version: C(2017) 2373 of 19/04/2017 3 Communication to the Commission on the revision of the Internal Control Framework (C(2017) 2373 of 19/04/2017) which replaces the Internal Control Standards laid down in SEC(2001)2037 and revised by SEC(2007)1341.

management and to realise efficiency gains. Main features of the control framework are the following:

Controls before and during the implementation of the projects:

- An appropriate project management system will be put in place focusing on the contributions of projects and contracts to the policy objectives, ensuring a systematic involvement of all actors, establishing a regular project management reporting complemented by on-site-visits on a case by case basis, including risk reports to senior management, as well as maintaining appropriate budgetary flexibility.
- Model grant agreements and service contracts used are developed within the Commission. They provide for a number of control provisions such as audit certificates, financial guarantees, on-site audits as well as inspections by OLAF. The rules governing the eligibility of costs are being simplified, for example, by using unit costs, lump sums, contributions not linked to costs and other possibilities offered by the Financial Regulation. This will reduce the cost of controls and put the focus on checks and controls in high risk areas.
- All staff sign up to the code of good administrative behaviour. Staff who are involved in the selection procedure or in the management of the grant agreements/contracts (also) sign a declaration of absence of a conflict of interest. Staff is regularly trained and uses networks to exchange best practices.
- Technical implementation of a project is checked at regular intervals at the desk on the basis of technical progress reports of the contractors and beneficiaries; in addition contractors'/beneficiaries' meetings and on-site-visits are foreseen on a case by case basis.

Controls at the end of the project: Ex-post audits are performed on a sample of transactions to verify on-the-spot the eligibility of cost claims. The aim of these controls is to prevent, detect and correct material errors related to the legality and regularity of financial transactions. With a view to achieving a high control impact, the selection of beneficiaries to be audited may combine a risk based selection with a random sampling. Attention to operational aspects will be paid whenever possible during the on-site audit.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)

The Commission's and DG SANTE's internal control strategies take into consideration the main cost drivers, and the efforts already taken over several years to reduce the cost of controls, without compromising the effectiveness of controls. The existing control systems proved to be able to prevent and/or to detect errors and/or irregularities, and in case of errors or irregularities, to correct them.

#### 2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the Anti-Fraud Strategy.

Article 325 of the Treaty on the functioning of the European Union (TFEU) requires the EU and its Member States to combat fraud and any other illegal activities that may affect the EU's financial interests. According to Article 317 of the TFEU and

Article 36 of the Financial Regulation<sup>66</sup>, the EU Commission implements the EU budget, in compliance with sound financial management principles, applying effective and efficient internal control<sup>67</sup>, which includes preventing, detecting, correcting, and following up on fraud and irregularities.

As for its activities in direct management, the Commission shall take appropriate measures ensuring that the financial interests of the European Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportional and deterrent penalties. To this effect, the Commission adopted an anti-fraud strategy, latest update of April 2019 (COM(2019) 196) with the revised Action Plan of July 2023 (COM(2023) 405). DGs and executive agencies have developed and implemented their own anti-fraud strategies on the basis of the methodology provided by OLAF. In general, these are updated every three years and their implementation is monitored and reported to the management on a regular basis.

For budget implementation under direct management, the Commission also implements a series of measures such as:

- decisions, agreements and contracts resulting from the implementation of the Regulation will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections and to recover amounts unduly paid and, where appropriate, impose administrative sanctions;
- during the evaluation phase of a call for proposals/tender, the applicants and tenderers are checked against the published exclusion criteria based on declarations and the Early Detection and Exclusion System (EDES);
- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;
- regular training and awareness raising on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

The assurance building process of the Authorising Officer by Delegation (AOD) is based on the capacity of the control systems in place to detect significant and/or repetitive deficiencies. The control systems are composed of different elements: supervision and verification of operations, ex-ante verifications, ex-post controls, and audits of the Internal Audit Service and the European Court of Auditors, as well as the health and food audits performed by DG SANTE in EU Member States and third countries. All actors involved play an essential role in fraud prevention and detection.

Communication to the Commission on the Revision of the Internal Control Framework C(2017)2373 adopted on 19/04/2017 (Principle 8, Characteristic 8.2).

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Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, O.J. L 193, 30.7.2018, 1.

### 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

# 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

• Existing budget lines

<u>In order</u> of multiannual financial framework headings and budget lines.

|   | Budget line  | Type of expenditure               |                           |  |                                 |                        |  |
|---|--|-----------------------------------|---------------------------|--|---------------------------------|------------------------|--|
| Heading of<br>multiannual<br>financial<br>framework | Number   | Diff./Non-<br>diff. <sup>68</sup> | from<br>EFTA<br>countries | from<br>candidate<br>countries<br>and<br>potential<br>candidates | fromother<br>third<br>countries | other assigned revenue |  |
|   | 03.02.06 - Contributing to a high level of health and welfare for humans, animals and plants | Diff                              | NO                        | NO   | NO                              | NO                     |  |

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Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

<sup>69</sup> EFTA: European Free Trade Association.

Candidate countries and, where applicable, potential candidates from the Western Balkans.

### 3.2. Estimated financial impact of the proposal on appropriations

- 3.2.1. Summary of estimated impact on operational appropriations
  - □ The proposal/initiative does not require the use of operational appropriations
  - ✓ The proposal/initiative requires the use of operational appropriations, as explained below:

EUR million (to three decimal places)

| Heading of multiannual financial framework | Number 1 | Single Market, Innovation and Digital |
|--|----------|---------------------------------------|
|--|----------|---------------------------------------|

| DG SANTE   |                 |           | Year<br>2024 | Year <b>2025</b> | Year<br>2026 | Year 2027 et seqq | TOTAL |
|--|-----------------|-----------|--------------|------------------|--------------|-------------------|-------|
| O Operational appropriations   | •               |           |              |                  |              |                   |       |
| 03.02 06 Contributing to a high level                                      | Commitments     | (1a)      | 0,250        | 0,850            | 0,800        | 0,500             | 2,400 |
| of health and welfare for humans, animals and plants                       | Payments        | (1b)      | 0,050        | 0,245            | 0,490        | 1,615             | 2,400 |
| Appropriations of an administrative nature envelope of specific programmes | re financed fro | m the     |              |                  |              |                   |       |
| Budget line  |                 | (3)       | 0            | 0                | 0            | 0                 | 0     |
| TOTAL appropriations   | Commitments     | =1a+3     | 0,250        | 0,850            | 0,800        | 0,500             | 2,400 |
| for DG SANTE   | Payments        | =1b<br>+3 | 0,050        | 0,245            | 0,490        | 1,615             | 2,400 |

| O TOTAL operational appropriations | Commitments | -4 | 0,250 | 0,850 | 0,800 | 0,500 | 2,400 |
|------------------------------------|-------------|----|-------|-------|-------|-------|-------|
|                                    | Payments    | -5 | 0,050 | 0,245 | 0,490 | 1,615 | 2,400 |

| O TOTAL appropriations of an admin financed from the envelope for specific progr   | -6          |       |       |       |       |       |       |
|--|-------------|-------|-------|-------|-------|-------|-------|
| TOTAL appropriations   | Commitments | =4+ 6 | 0,250 | 0,850 | 0,800 | 0,500 | 2,400 |
| under HEADING 1 of the multiannual financial framework   | Payments    | =5+6  | 0,050 | 0,850 | 0,490 | 1,615 | 2,400 |
|  |             |       |       |       |       |       |       |
| TOTAL operational appropriations (all  | Commitments | (4)   | 0,250 | 0,850 | 0,800 | 0,500 | 2,400 |
| operational headings)  | Payments    | (5)   | 0,050 | 0,245 | 0,490 | 1,615 | 2,400 |
| TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings) |             |       |       |       |       |       |       |

| TOTAL operational appropriations (an  | ( )         | 0,250 | 0,050 | 0,000 | 0,500 | 2,100 |       |
|---|-------------|-------|-------|-------|-------|-------|-------|
| operational headings) Payments  |             | (5)   | 0,050 | 0,245 | 0,490 | 1,615 | 2,400 |
| TOTAL appropriations of an administrative from the envelope for specific programmes headings) |             |       |       |       |       |       |       |
| TOTAL appropriations  | Commitments | =4+ 6 | 0,250 | 0,850 | 0,800 | 0,500 | 2,400 |
| under HEADINGS 1 to 6 of the multiannual financial framework (Reference amount)               | Payments    | =5+6  | 0,050 | 0,245 | 0,490 | 1,615 | 2,400 |

| Heading of multiannual financial framework | 7 | 'Administrative expenditure' |
|--|---|------------------------------|
|--|---|------------------------------|

This section should be filled in using the 'budget data of an administrative nature' to be firstly introduced in the <u>Annex to the Legislative</u> <u>Financial Statement</u> (Annex V to the internal rules) which is uploaded to DECIDE for interservice consultation purposes.

EUR million (to three decimal places)

|   | _                                    |              |              |              |                         |       |       |
|---|--------------------------------------|--------------|--------------|--------------|-------------------------|-------|-------|
|   |                                      | Year<br>2024 | Year<br>2025 | Year<br>2026 | Year<br>2027 et<br>seqq | ТО    | ΓAL   |
| DG SANTE  |                                      |              |              |              |                         |       |       |
| O Human resources   |                                      | 0,599        | 0,610        | 1,180        | 1,252                   |       | 3,640 |
| O Other administrative expenditure  |                                      |              | 0,000        | 0,000        | 0,000                   |       | 0,000 |
| TOTAL DG SANTE  | Appropriations                       | 0,599        | 0,610        | 1,180        | 1,252                   |       | 3,640 |
|   |                                      |              |              |              |                         |       |       |
| TOTAL appropriations under HEADING 7 of the multiannual financial framework | (Total commitments = Total payments) | 0,599        | 0,610        | 1,180        | 1,252                   | 3,640 |       |

EUR million (to three decimal places)

|  |             | Year<br>2024 | Year<br>2025 | Year<br>2026 | Year<br>2027 et<br>seqq | TOTAL |
|--|-------------|--------------|--------------|--------------|-------------------------|-------|
| TOTAL appropriations                               | Commitments | 0,849        | 1,460        | 1,980        | 1,752                   | 6,040 |
| under HEADINGS 1 to 7 of the multiannual financial | Payments    | 0,649        | 0,855        | 1,670        | 2,867                   | 6,040 |

| framework |  |  |  |
|-----------|--|--|--|
|           |  |  |  |

## 3.2.2. Estimated output funded with operational appropriations

Commitment appropriations in EUR million (to three decimal places)

| Indicate objectives and outputs |  |                 | Ye | ear   | Ye | ear     | Ye | ear   | Year   |         | то       | ΓAL        |
|---------------------------------|--|-----------------|----|-------|----|---------|----|-------|--------|---------|----------|------------|
|                                 |  |                 | 20 | 24    | 20 | )25     | 20 | 26    | 2027 e | et seqq |          |            |
| Û                               |  |                 |    |       |    | OUTPUTS |    |       |        |         |          |            |
|                                 | <u>Type[1]</u>   | Average<br>cost | No | Cost  | No | Cost    | °Z | Cost  | No     | Cost    | Total No | Total cost |
| SPECI                           | FIC OBJECTIVE No 2   |                 |    |       |    |         |    |       |        |         |          |            |
| - Output                        | Study on modalities for<br>the use of new<br>technologies and<br>digitalization to<br>facilitate the<br>implementation and<br>enforcement of rules on<br>animal welfare during<br>transport. |                 |    | 0,250 |    |         |    |       |        |         |          | 0,250      |
| - Output                        | Development of the system in TRACES  |                 |    |       |    | 0,800   |    | 0,600 |        |         |          | 1,400      |
| - Output                        | Maintenance of TRACES  |                 |    |       |    | 0,050   |    | 0,200 |        | 0,200   |          | 0,450      |
| - Output                        | Development of digital app   |                 |    |       |    |         |    |       |        | 0,300   |          | 0,300      |
| Subtotal                        | for specific objective No2   |                 |    | 0,250 |    | 0,850   |    | 0,800 |        | 0,500   |          | 2,400      |
| Totals                          |  |                 |    | 0,250 |    | 0,850   |    | 0,800 |        | 0,500   |          | 2,400      |

| 3.2 | .3. | Summary of | of estimated | ' impact on | administrative  | appropriations   |
|-----|-----|------------|--------------|-------------|-----------------|------------------|
| ·   |     | Devinion y | , countered  | uniperer on | COCCITION COLOR | uppi opi verrois |

- — □ The proposal/initiative does not require the use of appropriations of an administrative nature
- — ✓ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

|   | Year  | Year  | Year  | Year         | TOTAL |  |
|---|-------|-------|-------|--------------|-------|--|
|   | 2024  | 2025  | 2026  | 2027 et seqq | TOTAL |  |
| ·   | -     |       |       |              |       |  |
| HEADING 7   |       |       |       |              |       |  |
| of the multiannual financial<br>framework         |       |       |       |              |       |  |
| Human resources 71                                | 0,599 | 0,610 | 1,180 | 1,252        | 3,640 |  |
| Other administrative expenditure                  | 0     | 0,000 | 0,000 | 0,000        | (     |  |
| Subtotal HEADING 7                                |       |       |       |              |       |  |
| of the multiannual financial<br>framework         | 0,599 | 0,610 | 1,180 | 1,252        | 3,640 |  |
|   |       |       |       |              |       |  |
| Outside HEADING 7[2] of the multiannual financial |       |       |       |              |       |  |
| framework   |       |       |       |              |       |  |
| Human resources                                   |       |       |       |              |       |  |
| Other expenditure                                 |       |       |       |              |       |  |
| of an administrative nature                       |       |       |       |              |       |  |
| Subtotal  |       |       |       |              |       |  |
| outside HEADING 7                                 |       |       |       |              |       |  |
| of the multiannual financial<br>framework         |       |       |       |              |       |  |
|   |       |       |       |              |       |  |
| TOTAL   | 0,599 | 0,610 | 1,180 | 1,252        | 3,64  |  |

The appropriations required for human resources and other expenditure of an administrative nature will be partially met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

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### 3.2.3.1. Estimated requirements of human resources

- □ The proposal/initiative does not require the use of human resources.
- ✓ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full time equivalent units

|                                |                                      | Estimate to be expressed in juit time equivalent units             |                  |                  |                  |                         |  |
|--------------------------------|--------------------------------------|--|------------------|------------------|------------------|-------------------------|--|
|                                |                                      |  | Year <b>2024</b> | Year <b>2025</b> | Year <b>2026</b> | Year<br>2027 et<br>seqq |  |
| O Establishment plan posts (of | fficials and temporary staff)        |  |                  |                  |                  |                         |  |
|                                | 20 01 02 01 (Headquarters a Offices) | 20 01 02 01 (Headquarters and Commission's Representation Offices) |                  |                  | 6,5              | 6,5                     |  |
|                                | 20 01 02 03 (Delegations)            | 20 01 02 03 (Delegations)  |                  |                  |                  |                         |  |
|                                | 01 01 01 01 (Indirect resear         | 01 01 01 01 (Indirect research)                                    |                  |                  |                  |                         |  |
|                                | 01 01 01 11 (Direct research         | 01 01 01 11 (Direct research)                                      |                  |                  |                  |                         |  |
|                                | Other budget lines (specify)         | Other budget lines (specify)                                       |                  |                  |                  |                         |  |
| O External staff (in Full Time | Equivalent unit: FTE) <sup>72</sup>  |  | •                | •                |                  | •                       |  |
|                                | 20 02 01 (AC, END, INT fro           | 20 02 01 (AC, END, INT from the 'global envelope')                 |                  |                  |                  |                         |  |
|                                | 20 02 03 (AC, AL, END, IN            | 20 02 03 (AC, AL, END, INT and JPD in the delegations)             |                  |                  |                  |                         |  |
|                                | XX 01 xx yy zz <sup>73</sup>         | - at Headquarters  |                  |                  |                  |                         |  |
|                                |                                      | - in Delegations   |                  |                  |                  |                         |  |
|                                | 01 01 01 02 (AC, END, INT            | 01 01 01 02 (AC, END, INT - Indirect research)                     |                  |                  |                  |                         |  |
|                                | 01 01 01 12 (AC, END, INT            | 01 01 01 12 (AC, END, INT - Direct research)                       |                  |                  |                  |                         |  |
|                                | Other budget lines (specify)         | Other budget lines (specify)                                       |                  |                  |                  |                         |  |
|                                | TOTAL                                | TOTAL  |                  |                  | 6,5              | 6,5                     |  |

**XX** is the policy area or budget title concerned.

The human resources required will be partially met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

| Officials and temporary staff | AD will perform all the tasks that involve relationship with Member States, reference centres, stakeholders as well as any preparation of legislation. |
|-------------------------------|--|
| External staff                |  |

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AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JPD= Junior Professionals in Delegations.

Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

## 3.2.4. Compatibility with the current multiannual financial framework The proposal/initiative: $-\checkmark$ can be fully financed through redeployment within the relevant heading of the Multiannual Financial Framework (MFF). EUR 2,400 million of operational expenses under budget line 03.02.06 in years 2024 to 2027 will be covered by internal redeployment within the budget line. - □ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation. Explain what is required, specifying the headings and budget lines concerned, the corresponding amounts, and the instruments proposed to be used. □ requires a revision of the MFF. Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts. 3.2.5. Third-party contributions The proposal/initiative: ✓ does not provide for co-financing by third parties - □ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

|                                  | Year<br>N <sup>74</sup> | Year<br>N+1 | Year<br>N+2 | Year<br>N+3 | Enter as many years as necessary<br>to show the duration of the<br>impact (see point 1.6) |  | Total |  |
|----------------------------------|-------------------------|-------------|-------------|-------------|---|--|-------|--|
| Specify the co-financing body    |                         |             |             |             |   |  |       |  |
| TOTAL appropriations co-financed |                         |             |             |             |   |  |       |  |

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Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

|                      | _ 🗆                           | on other  | revenue     |               |             |   |    |  |  |
|----------------------|-------------------------------|---|-------------|---------------|-------------|---|----|--|--|
|                      | – please                      | indicate, it                                    | f the rever | nue is assi   | gned to ex  | xpenditure lines □  |    |  |  |
|                      |                               |   | ]           | EUR milli     | on (to thre | ee decimal places)  |    |  |  |
| Budget revenue line: | Appropriations available for  | Impact of the proposal/initiative <sup>75</sup> |             |               |             |   |    |  |  |
|                      | the current financial year    | Year<br><b>N</b>                                | Year<br>N+1 | Year<br>N+2   | Year<br>N+3 | Enter as many years as necessary to s the duration of the impact (see point |    |  |  |
| Article              |                               |   |             |               |             |   |    |  |  |
| For a                | assigned revenue, sp          | pecify the bu                                   | dget expend | diture line(s | ) affected. |   |    |  |  |
| []                   |                               |   |             |               |             |   |    |  |  |
|                      | r remarks (e.g. n<br>mation). | nethod/formu                                    | ıla used fo | or calculatin | ng the imp  | act on revenue or any other   | er |  |  |
| [ -                  |                               |   |             |               |             |   |    |  |  |

The proposal/initiative has no financial impact on revenue.

□ The proposal/initiative has the following financial impact:

on own resources

**Estimated impact on revenue** 

3.3.

As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20 % for collection costs.