

Impact assessment with proposed amendments, through a reprint, to the Swedish Board of Agriculture's Regulations (SJVFS 2006:84) on handling animal by-products and the introduction of other products, apart from foodstuffs, that can spread communicable diseases to animals.

IMPACT ASSESSMENT WITH PROPOSED AMENDMENTS, THROUGH A REPRINT, TO THE SWEDISH BOARD OF AGRICULTURE'S REGULATIONS (SJVFS 2006:84) ON HANDLING ANIMAL BY-PRODUCTS AND THE INTRODUCTION OF OTHER PRODUCTS, APART FROM FOODSTUFFS, THAT CAN SPREAD COMMUNICABLE DISEASES TO ANIMALS.....		1
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1 Background

Before an administrative authority is to decide on regulations or general advice, as a general rule, an impact assessment must be prepared and documented. Administrative authorities must also report an impact assessment when they submit proposals to the Government or the Government Offices for the Government to propose or decide on new or amended laws and regulations. When preparing the analysis, consideration should be given to the guidance provided by the Swedish National Financial Management Authority. If any part of the analysis cannot be carried out, this shall be justified.

The Swedish Board of Agriculture's Regulations (SJVFS 2006:84) on handling animal by-products and the introduction of other products, apart from foodstuffs, that can spread communicable diseases to animals (case No. K14) have undergone several changes since they were first adopted, which is why it is time to reprint these regulations.

The regulations supplement Regulation (EC) No 1069/2009¹ and its implementing regulation Regulation (EU) No 142/2011². The regulations provide possibilities for the competent authority to make decisions on a number of matters. This should be utilised in cases where it can contribute to simplification without having negative consequences for disease control. Regulation (EU) No 142/2011 has been amended several times since it became applicable in 2011 and new opportunities for simplification have emerged over the years. In order to make the best use of the possibilities offered by EU legislation, including simplifications and derogations, these should be incorporated into the regulations as far as possible. Replacing individual decisions with general exceptions in the form of regulations is an important part of the simplification process.

Many of the provisions contained in the current regulations, the Swedish Board of Agriculture's regulations (SJVFS 200:684) on handling animal by-products and the introduction of other products, apart from foodstuffs, that can spread communicable diseases to animals, are proposed to be included unchanged or are only editorially amended. Our overall assessment is that the substance of these provisions is appropriate and fulfils the purpose of the legislation on animal by-products. Therefore, we see no reason to amend these provisions further.

What is new is, among other things, that the fees are increased and that the fee for registration and record-keeping is introduced. In addition, fees will be charged for applications for permits that were previously free of charge.

¹ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

² Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempted from veterinary checks at the border under this Directive;

Furthermore, the proposal contains some new provisions which, among other things, mean that additional activities (operators) are exempt from the registration requirement. These are small-scale manufacturers of various types of products for sale on markets, among other places. These could include, for example, handicrafts made from horn or feathers from production animals, or small-scale production of dog treats. The requirement to register those who receive animal by-products directly from slaughterhouses or cutting plants for use as pet food is also being removed.

The proposal also means that operators are to be allowed to design their commercial documents themselves, provided that certain minimum requirements are met. However, the simplified documents (forms) produced by the Swedish Board of Agriculture and available on its website can still be used.

In addition to the aforementioned amendments, some minor amendments are also proposed, which are mainly mere clarifications and which do not affect the content of the regulations in substance, but only help to facilitate understanding of the provisions.

The regulations affect many different groups in society to different degrees. This includes everything from the food industry, primary producers, energy and transport companies to researchers and individual animal owners.

The regulations describe how notifications of registration and applications for approval for different activities are to be made and clarify certain aspects of EU legislation. Furthermore, the regulations contain, among other things, a large number of exemptions that have a positive impact on different activities. Most of them are already included in existing regulations. Among other things, a large number of activities are exempted from registration requirements. Certain other activities do not require individual permits, as they are permitted under the regulations. These cases concern the feeding of certain animal groups with, among other things, unprocessed slaughter by-products, the use of manufactured products for research and diagnostics, for example, as well as teaching and feeding with slaughter by-products and other animal products that have been of food quality. Some of these are also exempt from registration. Simplification for agriculture means that documentation and labelling requirements in connection with the transport of natural fertiliser are not required, that unprocessed eggshells may be spread on land under certain conditions, and that wool from Swedish farms is exempt from the requirements of the legislation. It is also permitted, under certain conditions and without special permission, to bury certain animal by-products such as dead animals and residues from slaughter. Furthermore, products which may be used for research and teaching without an individual permit, as well as for diagnostic purposes, may be disposed of as waste without further consideration being given to the legislation governing animal by-products.

Although the regulations provide for exemptions from registration, the operator must still comply with the basic requirements of EU legislation on disease control and traceability. The exemption from registration and control nevertheless entails significant simplifications overall.

1.1 Contact information

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1.2 The proposal concerns

- ☒ Companies
- ☒ Other individuals
- ☒ Municipalities
- ☒ The State (excluding county administrative boards)

1.3 The problem and the change sought and the consequences of inaction (zero option), as well as options for achieving the change and the advantages and disadvantages of these

The regulations need to be amended because:

- The fees have not changed since 2010 and do not currently cover the costs of case processing.
- Certain types of case processing have not been subject to fees.
- We should make better use of the opportunities for regulatory relief to the extent permitted by EU legislation, e.g. exemptions from registration requirements, provided that this does not adversely affect disease control.
- References to other legislation are in several cases outdated and need to be updated.

With the amendment to the regulations, we want to achieve the following objectives:

- We have new fee regulations that finance our case processing and which enter into force on 1 March 2026.
- We have provisions that reduce the administrative burden on both companies and individuals, as well as our case processing. This is because we make better use of the possibilities for exemptions provided for in EU legislation.
- The prescribed fee for approval, registration or permits shall be paid before processing begins.
- The regulations have been updated with regard to references to other legislation.
- The concept of parish has been replaced by the concept of district, in accordance with the Ordinance (2015:493) on districts, without changing the area in which the burial of animal by-products may take place.

Below is a description of each individual provision in the proposed regulations, alternatives to these, and what will happen if an individual provision is not adopted.

Chapter 1 Introductory provisions

Section 1 The proposal describes the content of the regulations in general as well as the purpose of the provisions. It must be clear what the regulations cover. If no description is given, it becomes unclear what the purpose of the legislation is.

Section 2 The proposal lays down basic provisions relating to animal by-products. The list of provisions listed in the current regulations has had to be reviewed regarding validity and relevance. New legislation has also been introduced. The legislation directly relevant to animal by-products needs to be mentioned so that it is clear to the reader what it is and that it applies in conjunction with these regulations.

Section 3 The proposal provides information that the EU Animal Health Regulation³ and its implementing acts refer to Regulation (EC) No 1069/2009 and specify when and how it is to be applied.

Section 4 The principle of mutual recognition applies as a result of the primacy of EU law. The European Commission requires that a provision on mutual recognition be included in regulatory provisions concerning technical rules. The Swedish Board of Agriculture has therefore included this provision in the regulations.

Definitions

Section 5 The proposal entails that the definitions are grouped together and adapted to the content of the regulations in order to facilitate understanding of the regulations. The alternative is to explain the terms more clearly in the sections, which increases the amount of text and reduces readability. The advantage of the proposal is that clear definitions increase readability. The disadvantage is that the reader needs to scroll back through the regulations to find the definitions. The Swedish Board of Agriculture believes that the proposed alternative is most appropriate as it contributes to increased readability while at the same time clearly defined terms facilitate understanding.

Chapter 2 Animal by-products and derived products

Notification of operator registration and establishment registration or approval

Section 1 EU legislation states that operators must notify the competent authority for registration before they start an activity. Some establishments also require approval. The provisions on how this notification is to be made for several types of establishments are currently laid down in Chapter 2, Section 1. Reference to forms has been replaced by reference to an annex specifying the information requested for different types of activities.

³ 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 ('Animal Health Law')

The provision is made clearer by specifying the information to be provided. A reference is also made to the Swedish Board of Agriculture's website in a footnote. Information on how those who wish to register or apply best do so is available on the web. If the provision is not included in the new regulations, it will be unclear how the notification should be made and what information is required. It must be clear how a notification should be made in order to facilitate the process for the individual, and the provision must be technology-neutral, which is why there is no alternative.

Section 2 The proposals concern exemptions from the operator's registration requirement. EU legislation allows the competent authority to grant exemptions in a number of cases where registration and subsequent monitoring may be considered unnecessary. However, an exemption from the registration requirement does not relieve the operator of the obligation to maintain the essential requirements of the legislation, such as, for example, the requirement for traceability and self-monitoring. This is to ensure safe processing.

The provisions contained in paragraphs 1-6 of the proposal are currently found in Chapter 2, Section 1b, paragraphs a-f, and cover those who:

- a) use organic fertilisers and soil improvers but do not keep production animals;
- b) handle and distribute organic fertilisers and soil improvers in consumer packaging for use outside the feed and food chain;
- c) use the following products for the following purpose:
 - Category 3⁴ produced products in diagnostic activities or for educational or research purposes;
 - blood under certain conditions for the training of dogs in tracking;
 - certain types of animal by-products in teaching;
- d) produce hunting trophies or other preparations for non-commercial purposes;
- e) use Category 3 material from own animals for personal use;
- f) transport wool or hair under certain conditions.

These provisions are left unchanged as the assessment is that they are fit for purpose and meet the objective of the legislation on animal by-products. The application has worked well, so we see no reason to change any of this. The only change made is an update to the reference in point c, which does not, however, entail any substantive change.

EU legislation allows the competent authority to grant exemptions from the registration requirement for additional operators. Therefore, it is also proposed that the following groups be exempted from the registration requirement:

- those using small quantities of Category 3 material referred to in Article 10 of Regulation (EC) No 1069/2009 or derived products thereof and supplying processed products directly to end-users;
- those using Category 3 material for the feeding of pet animals.

⁴ Animal by-products are divided into three different categories taking into account the degree of risk to public and animal health, see further Articles 7 to 10 of Regulation (EC) No 1069/2009.

The first group mainly concerns those who carry out hobby activities, have small businesses in crafts or produce small quantities of pet food. The second group concerns pet owners who wish to give, for example, slaughter by-products to dogs or mice and rats to reptiles. It is appropriate that these small businesses, which do not pose a risk and therefore do not need to be monitored, be exempted from the registration requirement. Those who supply feed must also be registered for their feed business, which is why additional requirements may be considered superfluous. Non-implementation of the exemptions implies a registration requirement for businesses and individuals where control is not considered necessary. The registration would thus contribute to unnecessary administrative burden for both individuals and small businesses, as well as for the Swedish Board of Agriculture. With the proposed fees for registered activities, it would also mean a cost for operators, a cost that they now do not have to bear. One disadvantage of the proposal may be that it is difficult to draw a line and also to control which activities can be exempted and which, even if they are small and perhaps even smaller than those that are exempted, must register and pay an annual registration and control fee.

Categorisation

Section 3 This provision is currently contained in Chapter 2, Section 1c, and clarifies that dead experimental animals shall be classified in the highest risk class in cases where they are not covered by the exemptions mentioned in the provision. The provision is left largely unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. Some minor adjustments have been made to bring the provision more into line with current legislation on experimental animals. It has also been clarified that animal by-products from experimental animals that are not classified as Category 1 shall be classified in the usual manner, i.e. as if the animal had not been an experimental animal. This may concern, for example, animals that are slaughtered for food where certain parts also become Category 1 or 2. If the Swedish Board of Agriculture does not prescribe, all experimental animal permits must state whether the animals included in the experiment are to be categorised as Category 1 (highest risk class) or not. This information is not currently available, which is why it is necessary to clarify what applies to animal by-products arising from experimental animal activities. The provision will continue to allow for the normal classification of animal by-products resulting from experimental animal activities in one or more of the three categories.

Risk of the spread of disease

Section 4 This provision is currently contained in Chapter 2, Section 1d. Regulation (EC) No 1069/2009 states, in the three places mentioned in the provision, that certain types of animal by-products may be composted or spread directly on land if the competent authority does not consider that there is a risk of spreading infectious diseases. It clarifies when spreading may be made or digestion may be carried out by stating that it may not be done when, as a result of legislation or decisions on restrictions, there are limitations on the use or handling of the material in order to prevent and limit the spread of infection and disease. The provision has been reworded but has not been changed in substance. If the provision is not included in the new regulations, it will be unclear to individuals what is

meant by the risk of spreading disease. It is therefore left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well and we see no reason to change the provision.

Collection, transport, storage, labelling and placing on the market

Section 5 This provision is currently contained in Chapter 2, Section 2. The provision clarifies that dead animals awaiting transport must be stored in such a way that they do not pose a risk of infection and that they must be stored separately from the animal keeper's live animals so that those working to collect dead animals for transport do not come into contact with them. The term 'cadavers' is replaced by 'dead animals'. In other respects, the provision is left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to amend the provision further. If the provision is not implemented, inappropriate storage of dead animals or handling during their collection may pose a risk of infection.

Section 6 EU legislation states that operators must notify the competent authority for registration before commencing transport operations. The provision on how this notification shall be made is currently contained in Chapter 2, Section 3. There is reference to a form. The new provision similarly clarifies that the notification must be submitted to the Swedish Board of Agriculture, but refers to an annex specifying the information to be provided in connection with the notification. The provision is clearer in that, instead of referring to a form, it is made clear which information is to be provided. A reference is also made to the Swedish Board of Agriculture's website in a footnote. Information on how those who wish to register or apply best do so is available on the web. If the provision is not enacted, it will be unclear to transport operators who are required to register how to submit their notification and what information is required. It must be clear how a notification should be made in order to facilitate the process for the individual, and the provision must be technology-neutral, which is why there is no alternative.

Section 7 This provision concerns applications for approval of places for transshipment (known as 'transshipment points') to be submitted to the county administrative board, and is linked to Section 8. The county administrative board is the control authority for the collection, transshipment and transport of animal by-products and products derived therefrom that are not catering waste. As certain animal by-products are transported over long distances, often in vehicles that can only carry one container, containers must be unloaded

and collected by other vehicles for onward transport to their final destination. This shall be done at a location approved by the county administrative board, which is regarded as part of the transport route. The phenomenon does not exist in EU legislation, but this is a national provision to ensure disease control during transport. As containers are set down and sometimes left standing for several days awaiting further transport, it is important that the storage location is safe from a disease control perspective and that the traceability is maintained. Provisions on the location of transshipment are currently laid down in Chapter 2, Sections 4 and 4a. A certain editorial shift between the paragraphs has been made for the new proposal. The requirement for disease control is moved from the current Chapter 2, Section 4a to this section and the provision on on-site visits is inserted in Section 8. However, the provisions are changed very little in substance, as the assessment is that the current provisions are fit for purpose and fulfil the purpose of the legislation on animal by-products. The application has worked well, so we see no reason for further changes. If the provisions on transshipment are not included in the new regulations, the locations where containers are temporarily stored prior to vehicle replacement will be unknown to the county administrative board. The temporary storage and transshipment will then not be checked, and there may be a risk that the handling will not be safe in terms of disease control and that traceability will be lost. For example, it is important that the containers are kept closed, that there is no movement between containers and that the containers are not accessible to unauthorised persons.

Section 8 This provision supplements Section 7 and is addressed to the county administrative board. It clarifies that the county administrative board must visit a new transshipment site before approving it, and further that the decision may be time-limited and subject to conditions. This is consistent with the current provisions in Chapter 2, Sections 4 and 4a. However, the detailed requirements concerning flushing water and cleaning facilities have been removed as they can be included in the conditions that the county administrative board may impose. The application of the current provisions has worked well, which is why we do not see any reason to make any further changes. Local factors can affect the possibilities of living up to safe handling. It must therefore be ensured at the time of approval that it is safe as regards disease control. The county administrative board must therefore visit the site and also have the opportunity to set conditions. As legislation may change, as may other conditions at the location where the transshipment is to take place, it is appropriate for the county administrative board to be able to impose a time limit on the permit. If the provision does not come into effect, it will be impossible for the county administrative board to take a decision that is in line with safe handling with regard to disease control.

Section 9 Regulation (EC) No 1069/2009 stipulates that a commercial document (or health certificate) must accompany animal by-products and products derived therefrom. It is the operator⁵ who is responsible for ensuring that the document is included and that its content is correct. The document is therefore a certificate. The requirements for the document

⁵ The definition of *operator* is contained in Regulation (EC) No 1069/2009 and reads as follows: ‘the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users.’

itself are set out in Chapter III of Annex VIII to Regulation (EU) No 142/2011. There is a standardised commercial document in the form of a template and information on how to fill it in. It also states that the document must contain certain information and be issued in at least three copies (one original and two copies). The original shall be signed and shall accompany the consignment to the recipient. The sender and carrier shall each have a copy. The carrier shall ensure that the original accompanies the consignment. Originals and copies must be kept for at least two years.

For such products transported within Sweden, the Swedish Board of Agriculture may approve the transmission of the data by means of an alternative system, which may be in electronic form, provided that certain information is specified.⁶

In the current provision, the Swedish Board of Agriculture refers to a number of simplified documents for completion that can be used instead of the standard. On the basis of EU legislation, individual decisions are also made approving alternative digital systems. In this case, an assessment is made in each individual case of what information should be included. This may be a few more than the absolute minimum requirements specified in the Ordinance. The list of minimum requirements has also not been updated after the standardised commercial document received a number of additions.

The Swedish Board of Agriculture no longer sees any benefit in approving individual digital systems or preventing operators from using other types of documents, provided that the information required and referred to by EU legislation is included and certified.

The advantage of allowing operators to freely use other types of paper-based documentation means that they are no longer bound by the documentation produced by the Swedish Board of Agriculture, but can produce their own documentation with a different appearance and perhaps combine it with other documents accompanying the transport. It is true that operators who wish to use a digital system can currently obtain a permit free of charge. However, the advantage of no longer having to apply to the Swedish Board of Agriculture is that the administrative burden is reduced.

The fact that operators themselves may choose the appearance of commercial documents in paper and digital form may lead to difficulties in the control by allowing a longer

⁶ According to Article 21.3 of Regulation (EC) No 1069/2009 and further in Chapter III points 4 and 6(f) of Annex VIII to Regulation (EU) No 142/2011.

period of time to understand how the document or system is structured and to conclude that it complies with the requirements. The advantage is that the acceptance of using commercial documents is likely to increase.

Existing documentation for commercial documents in paper form will remain on the Swedish Board of Agriculture's website and continue to be usable for those who wish to do so. They can also, after some adjustment, be incorporated as templates in the companies' own digital systems. Using these makes it easy for operators to do the right thing and for the control authorities to ensure compliance with the legislation.

If the provision is not enacted, there will continue to be restrictions on which documents may be used, and anyone wishing to obtain a digital system must apply to the Swedish Board of Agriculture. Such an application procedure would also entail a cost under the new rules.

Section 10 This provision is currently contained in Chapter 2, Section 9. The provision concerns simplifications for primary producers, meaning that the requirement for commercial documents for most transports of natural fertilisers has been removed. Some editorial adjustment has been made, but the provision is left unchanged in substance as the assessment is that it is appropriate and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change it. If the provision is not included in the new regulations, all shipments of natural fertiliser will have to be accompanied by commercial documents, which would place a significant administrative burden on primary producers engaged in animal husbandry.

Section 11 This provision is currently contained in Chapter 2, Section 9a. The provision concerns simplifications for primary producers, meaning that the labelling requirement in connection with certain transports of natural fertilisers has been removed. The current provision is amended so that vehicles in the form of motorised equipment and tractors travelling faster than 30 kilometres per hour are also covered by the exemption. In other respects, the provision is left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason for further changes. If the provision is not adopted, all transport of natural manure, regardless of the type of vehicle, must be labelled in accordance with the basic requirements of the legislation, which would place an unnecessary burden on primary producers with livestock who transport natural manure over short distances.

Section 12 This provision is currently contained in Chapter 2, Section 9b. The provision concerns simplifications for primary producers, among others, which means that wool and

hair are exempt from the requirements of the legislation if they come from Swedish herds. The provision is left largely unchanged in substance as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. A technical adjustment has been made to the effect that wool and hair from animals other than pigs may also be taken from registered or approved establishments provided that the wool or hair originates from farms that could have delivered wool directly from the farm. Since the application of the current provision has worked well, we see no reason to amend this provision further.

Particular requirements for approved establishments

Section 13 This provision is currently contained in Chapter 2, Section 12b. The provision contains a reference to Annex 4 which specifies which national methods can be applied for the anaerobic digestion and composting of Category 3 catering waste. In the proposed provision, the part concerning composting of the type carried out by private individuals has been removed, as this activity is covered by environmental legislation as long as the compost is not distributed or made available to farm animals. In other respects, the provision is left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, which is why we do not see any reason to change the provision or the annex to which it refers.

Section 14 This provision is new. It clarifies the requirements for temperature measurement in incineration plants approved by the Swedish Board of Agriculture. These are plants that incinerate whole animal carcasses, which are ‘incineration plants’ mainly for pet animals and so-called ‘farm boilers’ in primary production. These establishments are exempted from the legislation regulating the incineration of waste⁷ and are instead regulated by Regulation (EC) No 1069/2009. The temperature measurement requirements shall be laid down in the approval decision of the competent authority. At present, the requirements are included as conditions in each individual approval decision. By adding the requirements to the regulations, the same requirements will instead be imposed on all boilers that are approved after the regulations have entered into force. If the provision is not included in the new regulations, the conditions will have to continue to be included in each individual decision. The proposed conditions are the same as those included in approval decisions in recent years. There may be older decisions that apply until further notice and that have different conditions. These may be both stricter and less strict than those proposed here.

⁷ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions from animal husbandry (integrated pollution prevention and control)

Anyone who wishes to do so may apply for an updated decision in order to comply with the updated terms and conditions instead.

Use of organic fertilisers and soil improvers

Section 15 This provision on the spreading of eggshells is currently contained in Chapter 2, Section 15a. The provision concerns simplifications for egg packing centres, which means that eggshells produced there can be handled locally and spread on land. The provision is left unchanged in substance as the assessment is that it is fit for purpose and meets the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change this provision. Since it is important to help the individual to do the right thing, an addition has been made with a clarification that means that environmental legislation must be complied with. This may entail limitations on how much shells may be spread on a certain surface, but this does not entail a change compared to what currently applies under environmental legislation.

Section 16 This provision is currently contained in Chapter 2, Section 15b. The provision concerns simplifications for those who manufacture products from molluscs and echinoderms where the skin with attached soft tissue becomes a by-product in the handling process. The provision is left unchanged in substance as the assessment is that it is fit for purpose and meets the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change this provision. Since it is important to help the individual to do the right thing, an addition has been made with a clarification that means that environmental legislation must be complied with. This may entail limitations on how much shells may be spread on a certain surface, but this does not entail a change compared to what currently applies under environmental legislation.

Use of animal by-products for feeding animals

Section 17 This provision is currently contained in Chapter 2, Section 18. The provision describes what information must be sent to the Swedish Board of Agriculture for primary producers who wish to use milk and milk products as feed and where the milk does not come from their own farm. In the proposal, the reference to the form has been replaced by a reference to an annex specifying the information requested. The provision is made clearer by specifying the information to be provided. A reference is also made to the Swedish Board of Agriculture's website in a footnote. Information on how to apply is available online. If the provision is not included in the new regulations, it will be unclear how an application should be submitted and what information is required. It must be clear how an application should be submitted in order to make things easier for the individual. If it is not clear how to submit an application, it becomes more difficult for individuals to do so correctly. It may also increase the administrative burden and delay the process for both the applicant and the Swedish Board of Agriculture, as the required information will need to be submitted in the form of supplementary documents.

Section 18 This provision is currently contained in Chapter 2, Section 19. The provision describes the information to be submitted to the Board of Agriculture in the event of an

application or notification concerning the feeding of animal by-products to animals other than wild animals. In the proposal, the reference to the form has been replaced by a reference to an annex specifying the information requested. The provision is made clearer by specifying the information to be provided. A reference is also made in a footnote to the Swedish Board of Agriculture's website where there is information on how best to notify or apply. If the provision is not included in the new regulations, it will be unclear how a notification or application should be made and what information is requested. It must be clear how an application or notification should be made in order to make things easier for the individual. If it is not clear how the individual should apply or notify their activities to the Swedish Board of Agriculture, this makes it more difficult for the individual to do so correctly. It may also increase the administrative burden and delay the process for both the applicant and the Swedish Board of Agriculture, as the required information will need to be obtained in the form of supplementary information.

Section 19 This provision is currently contained in Chapter 2, Section 19 a. The provision describes what information must be submitted to the Swedish Board of Agriculture in order to feed wild animals with animal by-products. In the proposal, the reference to the form has been replaced by a reference to an annex specifying the information requested. The provision is made clearer by specifying the information to be provided. A reference is also made in a footnote to the Swedish Board of Agriculture's website where there is information on how best to notify or apply. If the provision is not included in the new regulations, it will be unclear how a notification or application should be made and what information is requested. It must be clear how an application or notification should be made in order to make things easier for the individual. If it is not clear how the individual should apply or notify their activities to the Swedish Board of Agriculture, this makes it more difficult for the individual to do so correctly. This may also increase the administrative burden and delay the process for both the applicant and the Swedish Board of Agriculture, as the required information will need to be obtained in the form of supplementary information.

Section 20 This provision is currently contained in Chapter 2, Section 21. This provision provides that whole bodies or parts of wild terrestrial animals not covered by Regulation (EC) No 1069/2009 may, without prior slaughter and veterinary inspection, be used for the feeding of predators.

Section 7 of the Act (2006:805) on feed and animal by-products states that the Government or the authority designated by the Government may issue regulations on exemptions from the

requirement that wild animals may only be used as feed if the animals have been killed, slaughtered and subsequently inspected by a veterinarian. The Swedish Board of Agriculture is given the opportunity to prescribe exemptions by means of Section 4 of the Ordinance (2016:814) on feed and animal by-products.

Current regulations stipulate that feeding with whole or parts of terrestrial wild mammals may take place within the municipality where the material originated or was found, as well as in the immediately adjacent municipalities. The demarcation with the same municipality and neighbouring municipalities is done to reduce the spread of possible infection from wild animals to areas where the animals do not normally move in the wild.

Since even aquatic animals are sometimes fed and municipal boundaries in those cases are not relevant, an addition has been made to the effect that for aquatic animals, instead, feeding of aquatic animals to aquatic animals may only take place within the water area where the material originated or was found. This is to prevent any infection from spreading to other water areas.

The provision is otherwise left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to amend the provision further. The alternative is that if those who wish to feed animals are not exempted in this way, they must comply with the requirements set out in the law, which means requirements for slaughter and veterinary inspection. This would make it difficult to use, for example, roadkill for supplementary feeding of endangered species and would make it impossible to use smaller animals that do not normally undergo veterinary inspection.

Section 21 This provision is currently contained in Chapter 2, Section 21a. The provision means that, except as provided for in Chapter 2, Section 25, unprocessed Category 3 material may be used for the feeding of pet animals, dogs in established kennels or groups of such dogs, such as hunting or sled dogs, and for the feeding of fur animals, zoo animals and circus animals.

The provision is left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change the provision.

If the provision is not included in the new regulations, anyone wishing to feed these animals with unprocessed Category 3 material will have to apply for a permit. Not introducing the

provision would increase the administrative burden for the individual and for the Swedish Board of Agriculture, which is why this is not a desirable option.

Pets are proposed to be exempted from the registration requirement under Chapter 2, Section 2.

Section 22 This provision is currently found in Chapter 2, Section 21b, and means that wild animals may be fed Category 3 material in the form of slaughter by-products in accordance with Article 10(a)-(b) of Regulation (EC) No 1069/2009, provided that the animals in question need this feed for conservation purposes or are to be attracted to a specific location in connection with hunting or fishing. We have chosen to extend the provision to include additional activities such as tourism, photography, filming and other artistic activities, as these activities may also require the feeding of Category 3 animal by-products to wild animals.

One condition that has been changed is that the by-products may be used no earlier than 21 days after slaughter compared to the previous two weeks. The reason for the change is that the provision should be compatible with the EU legislation regulating listed diseases⁸. It requires that products during outbreaks of diseases listed as Category A be traced and withdrawn if there is a risk of spreading the disease through them. Here, you have to go back 21 days in time. The assessment is therefore that by-products to be used for feeding in the wild may be used no earlier than 21 days after slaughter. In addition, we have added a condition stipulating that animal by-products must not be handled in kitchens where food is handled, as there is a risk that they may come into contact with food, which could pose a risk of infection to animals. The risk of this is small, but the assessment is still that this condition is necessary because a spread of infection could have major consequences for Sweden's animal health situation. One example of a disease that could spread in this way is African swine fever.

For those parts that remain unchanged, the assessment is that they are fit for purpose and fulfil the purpose of the legislation on animal by-products. The application has worked well, so we see no reason for further changes.

If the provision is not included in the new regulations, the individual will have to apply for a permit. Not introducing the provision would increase the administrative burden for the individual and for the Swedish Board of Agriculture, which is why this is not a desirable option.

Section 23 This provision is currently found in Chapter 2, Section 21c, and means that colostrum delivered from another production site may be used as feed provided that it does not pose a risk of infection and that the colostrum is needed for animal health reasons for a specific animal.

⁸ Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as amended, as regards rules for the prevention and control of certain listed diseases

The provision is left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change it.

The alternative to including this provision is that the individual will have to apply for a permit in each individual case. Colostrum is important for, among other things, calves during the first hours of life as it contains necessary antibodies that are important for the immune system. If the animal keeper does not have access to their own colostrum, it may need to be obtained from another farm. In that case, there is no time to apply for a permit from the Swedish Board of Agriculture. Not introducing the provision would delay the process and increase the administrative burden for both the applicant and the Swedish Board of Agriculture.

Section 24 This provision is currently contained in Chapter 2, Section 21d. The provision means that unprocessed eggshells may be used as feed for animals within the same epidemiological unit. We do not see any risk of spreading the infection because we delimit the feeding of eggshells to animals in this way. Eggshells contain calcium carbonate and phosphorus, both of which are important minerals for shell formation during egg production in hens. A deficit of calcium carbonate and phosphorus can cause the shells of the eggs to become thin.

The provision is left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change the provision. The alternative is that if the individual is not granted permission under the regulations, they will have to apply for permission to use the shells. Not introducing the provision would increase the administrative burden for the individual and for the Swedish Board of Agriculture, which is why this is not a desirable option.

Section 25 This provision is currently contained in Chapter 2, Section 22. Under the provision, pigs and birds which are pet animals, zoo animals or circus animals may not be fed with catering waste or animal by-products covered by Article 10(f) of Regulation (EC) No 1069/2009 (referred to as 'former foodstuffs'). Article 10(f) also covers certain processed products from food establishments which, under certain conditions, may be fed to production animals that are part of the food chain, which is why this type of feed is permitted. The provision therefore contains a reference to what applies to these products.

The provision is left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change it.

It is not permitted to feed production animals with catering waste or former foodstuffs (with certain exceptions). It is reasonable to also include pigs and birds that are kept as pets, as well as animals in zoos and circuses, in the ban. This is because there is a risk that this feed may contain contamination that can be passed on to animals. One example of such an infection is African swine fever, which could have major consequences for animal health in Sweden if it were to spread.

Burial or other disposal

Section 26 This provision is currently contained in Chapter 2, Section 23. The provision specifies the different types of animal by-products that may be buried and where this may take place. For dead horses and pet animals and for animal by-products from slaughter in game-handling establishments, burial may take place throughout the country. For dead production animals, as well as for residues from domestic slaughter and animal by-products from reindeer slaughter, burial may take place within the areas defined in Annex 2. The proposal means that slaughter residues from other species than reindeer within the defined area may also be buried without special permission from the Swedish Board of Agriculture. In other respects, the provision is left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change the provision.

Section 27 This provision is currently contained in Chapter 2, Section 24. The provision states that bees and by-products from beekeeping may be disposed of by burning or burying on site. The provision is left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change this provision.

Section 28 This provision is currently contained in Chapter 2, Section 26. The provision states that entire bodies of wild game in enclosures and animal by-products arising from the hunting of these animals that are not taken to a game-handling establishment may be buried. The provision is left unchanged in substance, since the assessment is that the provision is fit for purpose and serves the purpose of the legislation on animal by-products. However, a simplified wording has been made for better understanding. Game-handling establishments and wild game in enclosures are defined in Chapter 1, Section 5. The application has worked well, so we see no reason to change the provision.

Section 29 This provision states that, in addition to complying with the requirements of the legislation governing animal by-products, the burial referred to in Chapter 2, Sections 26-28, must also comply with environmental legislation. Contact may therefore need to be made with the municipality. The corresponding provision currently in force stipulates that burial 'shall be carried out in accordance with instructions from the municipality'. We believe that the municipality does not need to issue instructions, but that it is important that environmental legislation is complied with. It is the municipality that must be contacted in

the first instance in case of questions and that has the responsibility to verify that the burial complies with the requirements of the legislation.

Section 30 This provision is currently contained in Chapter 2, Section 28, which states that milk and colostrum produced on a farm may be disposed of there as waste in accordance with instructions from the municipality. The provision is now being amended so that milk and colostrum, as well as Category 2 and 3 material arising from surgical procedures or childbirth, may be disposed of at the establishment on the farm where the material arose. It is highly likely that this type of material is already being disposed of at agricultural establishments by spreading it on the ground or adding it to manure, depending on the type of material. The Swedish Board of Agriculture is empowered by EU legislation to decide to allow this, and it would not be reasonable to require the material to be collected and sent to a disposal facility. The material does not pose a greater risk of infection than the animals present on the establishment or their faeces. Not allowing this by regulation would mean that primary producers would have to apply for a permit and is therefore not an option. Restricting the term to 'establishment' from 'farm' is justified for reasons of disease control, as the material should not be moved between a company's establishments.

Section 31 This provision is currently contained in Chapter 2, Section 30. The provision specifies how packaging that has contained animal by-products and products derived therefrom shall be handled. Packaging that has contained unprocessed Category 1 or 2 material, with the exception of natural manure that cannot be suspected of containing any infection that can be transmitted to animals or humans, shall be incinerated in the same way as the contents. Other packaging may be handled in accordance with waste legislation, and can therefore be recycled. The provision is left unchanged as the assessment is that the provision is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change the provision.

Use for research, diagnostics, educational and artistic purposes

Section 32 EU legislation provides that operators must notify the competent authority before commencing an activity involving animal by-products or derived products in research, diagnostics or teaching or for use for exhibition or artistic purposes. Activities of this kind also require a permit if they are not specifically exempted. This provision is currently contained in Chapter 2, Section 31 and describes how notifications and applications for the use, disposal or transport of products other than those covered by Chapter 2, Sections 31a to 31c are to be made. There is reference to a form. The proposal clarifies, in the same way as in the current provision, that the application must be made to the Swedish Board of Agriculture, but refers to an annex setting out the information to be provided in connection with the notification and application. The provision is clearer in that, instead of referring to a form, it is already clarified in the regulations which information is to be provided. A reference is also made to the Swedish Board of Agriculture's website in a footnote. That contains information on how to best apply. If the provision is not included in the new regulation, it will be unclear how the application should be made and what information is requested.

If it is not clear how the individual should apply to the Swedish Board of Agriculture, it makes it more difficult for the individual to do it correctly and can increase the administrative burden and delay the process both for the applicant and for the Board, since the information required will need to be included in the form of supplements.

It must be clear how an application should be made in order to facilitate the process for the individual, and the provision must be technology-neutral, which is why there is no alternative.

Section 33 This provision is currently contained in Chapter 2, Section 31 a. The provision means that those who wish to use products derived from Category 3 material for diagnostic purposes, teaching and research, as well as for exhibition and artistic purposes, do not need to apply for a permit. We consider that the current provision is reasonable because derived products have undergone some form of processing and do not pose any risk of possible spread of infection. An addition has been made, which means that we include in the same provision that the material may be transported, as in most cases it is the person who will use the material who carries out the transport themselves. The permit for transport is currently covered by a separate provision. The provision is otherwise left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change it.

If the provision is not included in the new regulations, the individual will have to apply for a permit. This would increase the administrative burden for the individual and for the Swedish Board of Agriculture, which is why this is not a desirable option.

Section 34 This provision is currently contained in Chapter 2, Section 31b. The provision constitutes an exception to the requirement for individual authorisation for anyone who wishes to use blood that was foodstuffs at the time of release for training and assessment of dogs intended for searching for injured game. One condition is that the blood must come from animals that were slaughtered at least two weeks prior to use. The proposal involves a change to the current provision, which stipulates that the blood must come from animals slaughtered at least 21 days prior to use. The reason for the change is that the provision should be compatible with the EU legislation regulating listed diseases⁹. It requires that products during outbreaks of diseases listed as Category A be traced and withdrawn if there

⁹ Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as amended, as regards rules for the prevention and control of certain listed diseases

is a risk of spreading the disease through them. Here, you have to go back 21 days in time. The assessment is therefore that by-products to be used in nature may be used no earlier than 21 days after slaughter. This type of blood is often purchased frozen in grocery stores, which in practice means that the animal was slaughtered significantly longer ago than 21 days.

An addition has also been made, which means that we include in the same provision that the transport of blood may be carried out, as in most cases it is the person who will use the material who carries out the transport themselves. The permit for transport is currently covered by a separate provision. The provision is otherwise left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well. We see no reason to change this.

If the provision is not included in the new regulations, the individual will have to apply for a permit to use and transport the blood. This would increase the administrative burden for the individual and for the Swedish Board of Agriculture, which is why this is not a desirable option.

Section 35 This provision is currently contained in Chapter 2, Section 31c. The provision means that by-products from slaughter and other animal products that were foodstuffs until the time of release may be used for educational purposes and that those affected by the provision therefore do not need to apply for an individual authorisation for use.

An addition has been made, which means that we include in the same provision that the material may be transported, as in most cases it is the person who will use the material who carries out the transport themselves. The permit for transport is currently covered by a separate provision. The provision is otherwise left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well, so we see no reason to change it.

If the provision is not included in the new regulations, the individual will have to apply for an individual permit. This would increase the administrative burden for the individual and for the Swedish Board of Agriculture, which is why this is not a desirable option.

Section 36 This provision is currently contained in Chapter 2, Section 31d. The provision means that products covered by Chapter 2, Sections 31a-c of the current regulations may be transported before and after use and that after use they shall be handled as waste in accordance with environmental legislation.

The fact that transport may be carried out for the products covered by Chapter 2, Sections 33-35, has been moved to these provisions. The provision is otherwise left

unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well. We therefore see no reason to change this.

Entry

Section 37 This provision is currently contained in Chapter 2, Section 43. The provision describes what information must be submitted to the Swedish Board of Agriculture when applying for introduction of products that require entry authorisation under Regulation (EU) No 142/2011. There is reference to a form. The new provision similarly clarifies that the application must be made to the Swedish Board of Agriculture but instead of referring to a form, refers to an annex in which it is stated which information is to be provided in connection with the notification. The provision is made clearer by specifying in the regulations what information is to be provided. A reference is also made in a footnote to the Swedish Board of Agriculture's website where there is information on how best to apply. If the provision is not included in the new regulation, it will be unclear how the application should be made and what information is requested. If it is not clear how the individual should apply to the Swedish Board of Agriculture, it makes it more difficult for the individual to do it correctly and can increase the administrative burden and delay the process both for the applicant and for the Board, since the information required will need to be included in the form of supplements. It must be clear how an application should be made in order to facilitate the process for the individual, and the provision must be technology-neutral, which is why there is no alternative.

Section 38 This provision is currently contained in Chapter 2, Section 43 a. The provision entails informing individuals about the health certificate that must accompany products covered by Chapter IV, Section 2, point 2 of Annex XIV to Regulation (EU) No 142/2011. Very few shipments of this type of product covered by the provision are imported. The provision is left unchanged as the assessment is that it is fit for purpose and fulfils the purpose of the legislation on animal by-products. The application has worked well. We see no reason to change this.

As stated in Chapter IV, Section 2, point 2 of Annex XIV to Regulation (EU) No 142/2011, the certificate must comply with the requirements of national provisions. What should be requested in a certificate may vary depending on the type of product to be imported, which is

why it is appropriate that detailed requirements for the certificate are instead included as a condition in the decision.

Chapter 3 Requirements for entry permits for other products (other than foodstuffs) which may spread infectious diseases to animals.

Section 1 This provision is currently contained in Chapter 3, Section 1. The provision describes an application for a permit to introduce products other than animal by-products and derived products, other than foodstuffs, which may spread infectious diseases to animals. These may include, for example, infectious agents in the form of viruses, bacteria, fungi, parasites and protozoa. However, these may also be materials suspected of conveying infectious agents. The Ordinance (1994:1830) on the entry of live animals, etc. stipulates that the Swedish Board of Agriculture shall prescribe requirements for special permits and other conditions for the entry of, among other things, animal products and disease-causing organisms. The assessment is that the provision should essentially be included in the new regulations, as those who import this type of material must identify themselves and the entry may need to be subject to conditions.

In the proposal, the reference to the application form has been replaced by a reference to an annex specifying the information required from the applicant. The provision is made clearer by specifying in the regulations what information is to be provided. A reference is also made in a footnote to the Swedish Board of Agriculture's website where there is information on how best to apply. If the provision is not included in the new regulations, it will be unclear how the notification should be made and what information is required.

If it is not made clear how individuals should apply or register their activities with the Swedish Board of Agriculture, this will make it more difficult for them to do so and may increase the administrative burden on both individuals and the Swedish Board of Agriculture, as the required information will need to be requested in the form of supplementary information.

Section 2 This provision is currently contained in Chapter 3, Section 2. The provision describes the health certificate that shall accompany the material in Chapter 3, Section 1. It must be made clear to anyone wishing to import this type of product that it must be accompanied by health certificates and that there are requirements regarding what such certificates must contain. The provision contains only certain basic requirements. What

should be further requested in a certificate may vary depending on the type of product to be imported, which is why it has been considered appropriate that detailed requirements for the certificate are instead included as a condition in the decision.

The provision is left unchanged as the assessment is that it is fit for purpose. The application has worked well, which is why we do not see any reason to change the provision.

Chapter 4 Fees for the approval of establishments and permits, etc., for animal by-products

Chapter 4 contains fees for case types. Most of the fees are fees that already exist today. If current fees are kept unchanged, cost recovery is not provided for those cases that are required to be fee-financed under the legislation. For certain types of cases, the fee is too low in relation to the costs incurred by the authority. For other types of cases, fee collection has not been regulated in regulations. This should also be seen in the light of the fact that the fee amounts were last changed in 2010, which means that they have remained unchanged for 15 years.

If we do not have regulations on fees, we cannot charge a fee. Then we do not live up to the requirement of full cost recovery for these cases. There are no alternatives to the introduction of cost-recovery fees for case processing. In accordance with Ordinance (2006:1165) on fees for official controls of feed and animal by-products, the processing is to be financed by fees.

The amount of the fees is calculated on the basis of the cost of case processing.

Fees are proposed for:

- record keeping of operator data (new annual fee);
- registration (new one-off fee, free of charge for e-forms);
- the Swedish Board of Agriculture's approval assessment (increased one-off fee);
- the county administrative boards' approval assessment of the point of transshipment (increased one-off fee);
- permit fee (increased one-time fee).

The one-off registration fee is laid down in a separate decision and not in the regulations. This is in accordance with the provisions of Sections 14-15 of the Ordinance (2006:1165) on fees for official controls of feed and animal by-products.

Chapter 4, Section 1 refers to the annual fee for maintaining a register of operator data. The proposal means that a new annual fee for maintaining a register of operator data will cover

register development, maintenance and administration. This annual fee applies to all operators for whom information is kept in the Swedish Board of Agriculture's animal by-product register. Approved establishments and operators with different permits are also subject to this fee. The annual fee is proposed to be 200 Swedish kronor, calculated based on the Swedish Board of Agriculture's costs.

Chapter 4, Section 2 concerns fees for registration. The proposal means that a new fee for registration is charged in accordance with a separate decision. This decision will mean that a fee will be charged if the notification is made on paper form, but not if the notification is made via e-service. The e-service is not currently available but will be developed. The advantage of this solution is that operators are motivated to use the e-service, which results in lower costs when manual entry into the system does not need to be done. One option could be to charge a separate fee for new registrations, even when the application is submitted via an electronic form, as well as for changes to registrations or deregistrations. If a fee is charged for new registration or deregistration, this is considered to discourage companies' motivation to register or deregister establishments.

Chapter 4, Section 3 refers to the fee for the Swedish Board of Agriculture's approval assessment. The proposal entails an increase in the fee for the Swedish Board of Agriculture's approval assessment. The approval fee may either reflect the actual costs of the individual case or the same fee may be charged regardless of the location of the establishment and the degree of complexity of the approval assessment. We believe that the fee should reflect the complexity of the case, i.e. cases that require more processing, including more time for on-site visits, should be charged a higher fee based on the time required. We consider it fairest that the same fee is charged irrespective of travel costs, which reflect whether the installation is close to or far from the Swedish Board of Agriculture. In cases where more than one visit is required for the approval assessment, an additional fee shall be paid. This additional fee is the same regardless of the actual travel costs, which depend on where the establishment is located in relation to the Swedish Board of Agriculture. For assessment, including an on-site visit, the fee is 13 000 Swedish kronor, according to the proposal. According to the proposal, in cases where more than one on-site visit is required during the examination, the applicant shall pay a cost of 5 000 Swedish kronor to the Swedish Board of Agriculture for each visit additional to the first one. In cases where handling the matter, including on-site visits (but excluding travel time), takes more than 12 hours, the applicant shall, according to the proposal, pay 900 Swedish kronor for each additional hour commenced. This means that cost recovery can be achieved even when

an individual case is particularly complex. The proposal implies that the cost of the approval case is the same regardless of whether it is a new approval or an extended approval. A lower cost applies if the assessment can be carried out without an on-site visit. The normal thing is that on-site visits are required. An example of when an assessment can be carried out without a visit could be if an approval is to be written for a new legal entity, while the establishment and operations remain unchanged.

Chapter 4, Section 4 concerns fees for approval assessment of transshipment points by the county administrative board. The proposal means that the fee for the county administrative boards' approval assessment will be increased. The fee can be set either as a lump sum amount that is the same for all approval cases or adapted according to the time needed for processing and travel in the individual case. It is considered appropriate that the same fee is charged for the approval of transshipment points, regardless of where they are located and the actual differences in travel costs that this may entail. The proposal specifies a fixed sum for the approval assessment, including an on-site visit, in the same way as in the current regulations. We believe that the fee should reflect the complexity of the case, i.e. cases that require more processing, including more time for on-site visits, should be charged a higher fee based on the time required. According to the proposal, the fee for an assessment, including an on-site visit, is 10 000 Swedish kronor. In cases where more than one on-site visit is required during the assessment, the applicant shall, according to the proposal, pay a fee of 800 Swedish kronor to the county administrative board for each visit in addition to the first. The fee is calculated based on an average time consumption of 10 hours. In cases where handling of the matter, including on-site visits (but excluding travel time), takes more than 12 hours, the applicant shall, according to the proposal, pay 900 Swedish kronor for each additional hour. This means that cost recovery can be achieved even when an individual case is particularly complex.

Chapter 4, Section 5 concerns a fee for a permit for the entry and use of animal by-products. The proposal is to increase the fee for a permit to 3 000 Swedish kronor. The same fee amount shall apply to different permits, such as permits for the entry or use of animal by-products for different purposes. The alternative would have been that the fees differ between different permits. This has not been deemed appropriate. The calculations made on the costs of permits show that the fee should be the same regardless of the type of permit. Visits are not required in the case of a permit for the use of animal by-products.

Chapter 4, Section 6 concerns fees for certain permits. This provision on hourly fees refers to fees for decisions on permits or approvals that the Swedish Board of Agriculture may need to

make in cases not specifically mentioned in these regulations, but which follow from EU legal provisions on animal by-products. The proposal provides for a new fee to be charged for cases where a fee is not levied under the current rules. These are cases that the Swedish Board of Agriculture has rarely or never dealt with, and is unlikely to encounter in the future. It is estimated that, on average, there is a maximum of one case per year.

Chapter 4, Section 7 concerns fees for sampling and analysis costs. The provision stipulates that any costs for sampling and analysis in connection with the assessment of approval or permits shall be borne by the applicant. The proposal means that the provision will be transferred to the new regulations without any substantive changes.

Chapter 4, Section 8 refers to the time of payment of the fee for registration and permit. The proposal means that registration and permit cases must be paid for before they are accepted for assessment.

Chapter 4, Section 9 refers to the date of payment of fees in connection with the Swedish Board of Agriculture's approval assessment. The proposal provides for a fee for approval cases to be paid at the time of sending or submitting the application. The exception is if a fee in hourly rates is charged, or if several on-site visits are required. If the fee is not paid, the case will not be assessed. An alternative could be that the fee for approval cases is divided so that an administrative fee is paid when the application is submitted, while the fee for an on-site visit must be paid before the visit is booked. This means that operators do not risk paying fees in cases where approval is not required, while ensuring that the Swedish Board of Agriculture receives the fees for the costs incurred in processing the case.

Chapter 4, Section 10 refers to the time of payment of the fee in connection with the county administrative board's approval assessment. The proposal provides for a fee for approval cases to be paid at the time of sending or submitting the application. The exception is if a fee in hourly rates is charged, or if several on-site visits are required. If the fee is not paid, the case will not be assessed. An alternative could be that the fee for approval cases is divided so that an administrative fee is paid when the application is submitted, while the fee for an on-site visit must be paid before the visit is booked. This means that operators do not risk paying fees in cases where approval is not required, while ensuring that the Swedish Board of Agriculture receives the fees for the costs incurred in processing the case.

Chapter 5 Other provisions

It is not possible for the county administrative boards to grant exemptions from the provisions of the regulations, as the Swedish Board of Agriculture does not have the authority to stipulate that the county administrative boards may decide on exemptions from the regulations.

It is necessary to specify in the regulations the provisions from which it is possible to derogate if there are special reasons.

According to the draft regulation, exemptions may be granted from the following provisions:

1. Chapter 2, Section 3
2. Chapter 2, Section 14
3. Chapter 2, Section 20
4. Chapter 2, Section 22
5. Chapter 3, Section 2

2 Authorisations, etc.

2.1 Information about the authorisations on which the authority's decision-making power is based

The powers to make regulations are found in:

- Sections 2, 4, 8, 9 and 23 of the Ordinance (2006: 814) on feed and animal by-products;
- Sections 18-19 of the Ordinance (2006:1165) on fees for official controls of feed and animal by-products; and
- Section 3 of the Ordinance (1994:1830) on the entry of live animals, etc.

The fundamental provisions in this area are found in:

EU legislation:

- European Parliament and Council Regulation (EC) No 1069/2009;
- Commission Regulation (EU) No 142/2011).

National legislation:

- Act (2006:805) on feed and animal by-products;
- Ordinance (2006:814) on feed and animal by-products;
- Ordinance (2006:1165) on fees for official controls of feed and animal by-products;
- Ordinance (1994: 1830) on the entry of live animals, etc.

2.2 Assessment of whether the regulation is in line with or exceeds Sweden's obligations as a Member State of the European Union

The assessment is that the draft regulation complies with the obligations arising from Sweden's accession to the EU.

2.3 Please state the reasons if the proposal aims at transposing EU directives into national law that go beyond the minimum level of the directive

None of the proposals aims to implement EU directives into national law.

3 Companies

A company herein refers to a legal or natural person engaged in business activities, i.e. the sale of goods and/or services professionally and independently. Professional activities should be interpreted broadly.

3.1 Description of the number of companies affected, the sectors in which the companies operate and the size of the companies

The companies directly affected by the regulations are those that in some way handle animal by-products or products derived from them. These are a very large number of companies, see Table 1. The size of the companies, the number of employees and the annual turnover varies from individual small companies to large companies. The Swedish Board of Agriculture does not have information on the detailed distribution and size of these companies, nor on the exact number in many cases. Most of the companies have small operations with animal by-products and are therefore marginally affected.

In point 1.3 above, we describe how the various provisions affect companies.

Table 1 Number of companies¹⁰

Type of company/industry	Number
Establishments requiring approval (e.g. facilities for storage, cremation, processing, biogas, composting and the manufacture of pet food)	337
Registered establishments handling animal by-products or derived products	68
Registered users	
Companies engaged in research and/or diagnostics	139
Feeding of animals with unprocessed animal by-products (e.g. zoos, fur breeders and wild animals)	90
Other registered activities	
Carriers	608
Other registered parties, such as conservators, waste incineration plants and manufacturers of pharmaceuticals and medical devices	169
Primary producers	
Incineration plants (farm boilers)	267
Total number	approx. 75 000
With animal husbandry (including 4 000 sheep keepers)	approx. 25 000
Beekeepers	490 ¹¹

¹⁰ The number of companies is taken from the Swedish Board of Agriculture's register dated 2 May 2025. The section concerning activities described under primary producers (not farm boilers), where the numbers are taken from the county administrative board's register "primör" (early produce) dated 8 May 2025, and the number of food establishments taken from the Swedish Board of Agriculture's report on the control of feed and animal by-products in 2024 (diary number 5.4.17-08483/2024).

¹¹ County administrative board's register "primör", 8 May 2025

Type of company/industry	Number
Establishments with horses ¹²	See footnote
Food establishments	
Establishments controlled by municipalities (warehouses, shops and restaurants)	approximately 50 000 to 75 000
Establishments controlled by the Swedish Food Agency (slaughterhouses, dairies and manufacturers) ¹³	1 130

3.2 Description of the time required for companies to comply with the regulation and what the regulation means for companies' administrative costs, as well as other costs that the proposed regulation entails for companies and what changes in activities companies may need to make as a result of the proposed regulation

The sections where the proposal constitutes a substantive change compared to the current regulations and which have an impact on companies in terms of time required, cost and change in activities are described below.

The vast majority of companies are affected only marginally in relation to today's provisions.

In addition to what is proposed on fees, the regulations will largely only lead to positive effects such as the simplification of commercial documents and clarifications of the information to be included in connection with an application for the companies.

The administrative burden imposed by the proposed regulation is described in the attached impact assessment.

Notification of registration of operator and registration or approval of establishment handling animal by-products and derived products

The proposals in Chapter 2, Section 2 concern exemptions from the requirement for registration of certain operators. Compared with the current provisions, it is proposed that additional activities be exempted. This means that they do not have to spend time on reporting their activities to the Swedish Board of Agriculture. They also do not need to pay any registration fee, annual registration fee or annual inspection fee. This means reduced

¹² In 2016, a report from the Swedish Board of Agriculture estimated that there were approximately 61 700 properties/establishments with horses. The report did not show how many of the estimated establishments are operated by individuals or as companies. We have no information on how many of the animal keepers living in the areas listed in Annex 7 are in need of burying animal bodies. Official Swedish statistics – Horses and horse facilities 2016, JO 24 SM, corrected version 22 February 2017, Series JO – Agriculture, forestry and fishing, published 2 February 2017, Swedish Board of Agriculture

¹³ Of these, 13 are reindeer slaughterhouses and about 200 game-handling establishments. Currently, three livestock slaughterhouses and five fish farms have permission from the Swedish Board of Agriculture to bury animal by-products from their operations in areas covered by Annex 7.

administrative and financial burdens. In practice, however, this is likely to be of less importance because many of the new companies that are now exempted have not been aware of the registration requirement and consequently have not been in the register.

One consequence of the proposal will therefore be that fewer companies will operate without being registered.

Those who are registered, but where this is no longer required, can deregister to avoid annual registration fees and inspection fees. The need for such deregistration in itself is a consequence of the proposal.

Collection, transport, storage, labelling and placing on the market

Chapter 2, Section 9 of the proposal means that the operator can use an own developed document or a system for commercial documents for transports within the country as long as it meets certain requirements. In other words, the operator no longer needs to use the standardised commercial document, which is a template of EU legislation, the simplified commercial documents published by the Swedish Board of Agriculture on the web or an alternative digital system approved by the Swedish Board of Agriculture. The templates developed by the Swedish Board of Agriculture can still be used as an aid and already approved systems can continue to be used. Producing your own documents in paper form or a digital system can take time and cost money, but at the same time it can be easier for the company to manage. However, recipients of consignments containing these proprietary 'documents' may find that it takes longer to understand the information, as its format can vary between different providers.

Particular requirements for approved establishments

Chapter 2, Section 14 of the proposal means that the requirements imposed on temperature measurement in incineration plants that the Swedish Board of Agriculture will approve in the future now fall under the regulations, which means that they do not need to be included as a condition in the decisions made in the future. Most existing approval decisions already contain these requirements as conditions. There are favourable decisions that apply until further notice and have requirements that may be perceived as stricter. Companies with such decisions may apply to the Swedish Board of Agriculture to renew the decision against a cost.

If, instead, we were to continue with conditions in each individual decision, the operator could appeal against the decision. If the conditions are specified in the regulation, the operator must instead apply for an exemption from the provision.

Use for feeding of animals

Chapter 2, Section 22. The proposal introduces minor changes as regards the conditions relating to those wishing to feed wild animals with Category 3 material. The proposal means that the material must be stored seven days longer than before and that it must not be handled in kitchens where food is handled. Any companies that handle by-products in kitchens must

therefore change their handling procedures, and additional costs may be incurred for storing the material during the waiting period. See Chapter 1.3 for details.

Burial or other disposal

Chapter 2, Section 26. The proposal provides that different types of animal by-products may be buried and concern both primary producers, food establishments and private individuals. What is new is that by-products of Categories 2 and 3 from the slaughter and cutting of farmed animals other than reindeer may also be buried without an individual permit in the areas listed in Annex 7. Thus, companies that start up a slaughter or cutting operation in any of these areas do not need to apply for a permit from the Swedish Board of Agriculture in order to bury, which reduces the administrative burden and reduces the uncertainty during the start-up of activity as to whether the Swedish Board of Agriculture will grant a permit.

Chapter 2, Section 30. This provision is currently found in Chapter 2, Section 28 and states that milk and colostrum may be disposed of at the original farm. It is now proposed that Category 2 and 3 material arising from surgical procedures or childbirth may also be disposed of on the farm. The addition is made so that it is clear to the individual what applies, and that it is possible to handle these animal by-products on the farm where the animals are kept. It is common practice for this type of material to be handled in this way, which is why no primary producers are affected by the provision.

Fees for the approval of establishments and permits, etc.

The provisions in Chapter 4, Sections 1-10, concern fees for different types of cases. The provisions on amended fees in Chapter 4 apply to all those who register their establishment or activity or who apply for approval or a permit in accordance with the requirements of the Ordinance on animal by-products, see Table 1 above.

The proposed fee increases in Chapter 4, Sections 3, 4 and 5 will not affect the time required by companies or their administrative costs. The fact that a fee must be paid before a case is taken up for consideration is not considered to have such an impact either.

The proposed new annual fee in Chapter 4, Section 1, which is introduced for the purposes of record-keeping, constitutes an additional task, since a fee of 200 Swedish kronor is to be paid each year. The time this is expected to take for companies is estimated at 6 minutes, i.e. 0.1 hours. The number of companies affected by the annual fee is estimated at 1 075. The total time spent by companies will then be 107.5 hours per year (0.1 hours per

year x 1 075 operators). At an estimated hourly cost for these companies of 600 Swedish kronor, the invoicing costs will be 64 500 Swedish kronor (107.5 x 600).

The new fee in Chapter 4, Section 6 has been introduced so that fees can also be charged for other types of cases than those regulated by the other fee provisions. In practice, it is expected that there will be no or up to two such cases per year. The overall cost for the companies is therefore considered to be marginal.

The fees will be higher. For small enterprises, this may affect profitability and lead to it not being appropriate to run this type of business. This could lead to certain smaller operators engaging in unauthorised activities without applying for approval or permits.

The fees for approval cases are designed to be higher for those operators where the case processing is more extensive, which makes this fee more fair than it is today.

Other costs for the companies beyond administrative costs

The proposed amendment to the regulation does not entail any costs for companies other than those mentioned above. Most of the proposed provisions are based on authorisations in EU legislation that allows the competent authority or the Member State to decide on exemptions or grant permits for different types of activities. The proposals therefore do not entail any costs for companies, but instead clarify, for example, how a permit should be applied for, or they inform that there is a permit through the regulations so that no application for an individual permit must be made.

3.3 Outline of the measures taken to ensure that the draft regulations do not entail costs or restrictions that go beyond what is deemed necessary to achieve the objective

One of the starting points for the regulatory work has been that the proposal should not entail costs or restrictions beyond what is necessary to achieve its objectives. Possibilities for derogations that have not already been used in current regulations have been identified and introduced to the extent that it has been assessed that they do not adversely affect disease control.

There are plans to develop an e-service for registration, which would make registration free of charge.

3.4 Description of the extent to which the regulation may affect companies' competitive environment

The proposal in Chapter 2, Section 2 favours those who are exempted from the registration requirement. Small companies that need to be registered are at a competitive disadvantage in relation to smaller companies that are exempt from the registration requirement and only sell domestically directly to final recipients.

In general, small companies are disadvantaged in relation to larger companies, for which the tax represents a smaller part of the turnover.

The proposed changes lead to the following competitive relationships with other companies in Sweden:

- Increased fees for approvals and permits may affect competitive conditions between different Swedish companies, since the size of the fee affects the profitability of small operators to a greater extent than larger companies.

The proposed changes lead to the following competitive relationships with companies in other countries:

- Increased fees for approvals and permits may, to some extent, adversely affect the competitive conditions for small operators, as their profitability may be affected.

3.5 Description of how the regulation may impact companies in other respects

Smaller companies can be expected to deregister their activities due to the introduction of annual registration fees.

The companies whose activities no longer need to be registered are also not subject to public control.

4 Other individuals

4.1 Description of who is affected by the regulation and how many they are

The individuals directly affected by the provisions are those who in some way handle animal by-products or products derived therefrom. We describe in point 1.3 how the different provisions affect individuals. For several types of activities, we do not have data on the number of individuals. We have data on the number of a few businesses such as those that wish to feed wild animals with animal by-products and registered businesses, see Table 2.

Table 2. Number of individuals.

Type of other individual	Number
Person handling or producing game trophies or other preparations referred to in Chapter VI of Annex XIII to Regulation (EU) No 142/2011 for personal or non-commercial purposes	Unknown number
Anyone using Category 3 material from their own animals for personal use	Unknown number
Anyone who wants to buy untreated wool	Unknown number
Anyone wishing to use Category 3 material for the	Approx. 470 ¹⁴

feeding of pet animals	
Anyone who wishes to feed wild animals with animal by-products	Approx. 200 ¹⁵
Anyone who wishes to bury dead pets or horses	Unknown number
Anyone keeping bees	Approx. 21 000 ¹⁶
Anyone who imports products other than animal by-products, except foodstuffs, that may spread infectious diseases to animals	2
Other registered entities that are not companies, e.g. universities and schools	16
Establishments with horses ¹⁷	See footnote

4.2 Description and calculation of the costs and revenue of the proposal

Individuals will have increased costs for permits, approvals and registrations.

4.3 Description and, if possible, a calculation of other relevant impacts

In practice, it is likely that many of those who are exempt from registration under the proposed regulation were unaware of the registration requirement. Fewer instances of non-compliance will be a consequence of the proposal as individuals now do not need to be registered to deal with what they previously dealt with without the required registration.

Those who are registered, but where this is no longer required, can deregister to avoid the annual registration fee. The need for such deregistration in itself is a consequence of the proposal.

Individuals are expected to further deregister activities or establishments that no longer exist as a result of the introduction of a registration fee.

Due to the registration fee, several of the individuals who collect animal by-products from slaughterhouses to feed wild animals can switch to using alternative products for feeding, such as cat food or food from shops.

¹⁴ The Swedish Board of Agriculture's register, 3 May 2025

¹⁵ The Swedish Board of Agriculture's register, 3 May 2025

¹⁶ Adolfsson J. 2023. Report by the Swedish Association of Beekeepers in the project "Describing the Swedish apiculture sector"

¹⁷ In 2016, a report from the Swedish Board of Agriculture estimated that there were approximately 61 700 properties/establishments with horses. The report did not show how many of the estimated establishments are operated by individuals or as companies. We have no information on how many of the animal keepers living in the areas listed in Annex 7 are in need of burying animal bodies. Official Swedish statistics – Horses and horse facilities 2016, JO 24 SM, corrected version 22 February 2017, Series JO – Agriculture, forestry and fishing, published 2 February 2017, Swedish Board of Agriculture

4.4 Outline of the measures taken to ensure that the draft regulations do not entail costs or restrictions that go beyond what is deemed necessary to achieve the objective

One of the starting points for the regulatory work has been that the proposal should not entail costs or restrictions beyond what is necessary to achieve its objectives. Possibilities for derogations that have not already been used in current regulations have been identified and introduced to the extent that it has been assessed that they do not adversely affect disease control.

There are plans to develop the e-service for registration, which would make registration free of charge. The amount of the registration fee is regulated in a separate decision.

5 Municipalities and regions

5.1 Description of who is affected by the regulation and how many they are

The municipalities are responsible for the control of animal by-products in primary production and at food establishments. They need to be familiar with the legislation and also know which primary producers with animals are registered to receive and use organic fertilisers other than natural manure.

All municipalities can be affected by the fact that schools can use animal by-products in education.

Regions with hospitals carrying out research with animal by-products are marginally affected.

5.2 Description and calculation of the costs and revenue of the proposal

This proposal does not involve any substantive change.

5.3 Description and, if possible, a calculation of other relevant impacts

There will be no other relevant consequences.

5.4 Outline of the measures taken to ensure that the draft regulations do not entail costs or restrictions that go beyond what is deemed necessary to achieve the objective

Not relevant.

5.5 Does the proposal restrict municipal self-government?

No.

5.6 Does the proposal entail changes to municipal powers or obligations, or to the basis for the organisation or forms of operation of municipalities or regions?

No.

6 The Central Government

6.1 Description of who is affected by the regulation and how many they are

The Swedish Board of Agriculture will be affected by the regulation.

The county administrative boards have control responsibility over collection and transport and are affected by the regulation by approving points for transshipment. They need to be aware of the legislation and know which transporters are registered for the transport of animal by-products and products derived therefrom.

The National Veterinary Institute is affected by the regulation in that it conducts research and diagnostics and has a registered waste incineration plant. The Institute also imports animal by-products from other countries.

The National Food Agency has control responsibility at food establishments and carries out research and diagnostics and needs to be aware of the legislation.

The Public Health Agency of Sweden and the Swedish Defence Research Agency carry out research and diagnostics and need to be aware of the legislation. Individual other government authorities may be affected to a marginal extent where they handle animal by-products.

6.2 Description and calculation of the costs and revenue of the proposal

The Swedish Board of Agriculture has an estimated cost of 200 working days for the preparation of the regulations.

Costs may be incurred for approvals and deregistrations resulting from the amended regulations. This is described in the previous section.

The Swedish Board of Agriculture will receive revenue from the changed or new fees. The fees have been calculated to cover the full costs. The fees shall not generate a profit.

The county administrative boards receive revenue from the amended fees. The fees have been calculated to cover the full costs. The fees shall not generate a profit.

Other government authorities may incur marginally increased costs in cases where they need new permits or renew existing permits for the use of animal by-products.

6.3 Description and, if possible, a calculation of other relevant impacts

One consequence of the proposed changes is that the Swedish Board of Agriculture's register can be expected to be kept more up-to-date as there are incentives for operators to deregister activities or establishments that no longer exist by levying an annual registration fee.

The staffing situation at the Swedish Board of Agriculture must initially be adapted for the work on registration fees before e-services are in place. It is estimated that handling the new fees will require an additional 100 hours of work per year. Since the registration fee will be waived if e-services are used, according to the proposed decision, it is important that such e-services be developed as soon as possible. Work on such an e-service should commence immediately.

6.4 Outline of the measures taken to ensure that the draft regulations do not entail costs or restrictions that go beyond what is deemed necessary to achieve the objective

In the Swedish Board of Agriculture's regulatory work, one of the starting points has been that the proposal should not entail costs or restrictions beyond what is necessary to achieve its objectives. This also applies to costs for the Government. Possibilities for derogations that have not already been used in current regulations have been identified and introduced to the extent that it has been assessed that they do not adversely affect disease control.

Those who are registered, but where this is no longer required, can deregister to avoid the annual registration fee. The Swedish Board of Agriculture is planning communication efforts to provide information to those concerned so that they can deregister the activity in cases where this has ceased before invoices for annual registration fees are sent out.

There are plans to develop an e-service for registration for all types of activities, which would make registration less resource-intensive.

7 Consultation

7.1 Description of early consultation

Dialogue has been conducted with the Swedish Environmental Protection Agency regarding activities that have a bearing on environmental legislation.

Consultations have been held with the county administrative boards regarding the fee for approval of the point of transshipment.

8 Entry into force and evaluation

8.1 **Assessment as to whether special consideration must be given to the date of entry into force and whether special information initiatives are required**

The fees need to be increased as soon as possible in order to cover the costs of case processing. For this reason, the date of entry into force of the draft regulation is set at 1 March 2026, which is the earliest date on which the regulations can enter into force.

There is a need for information campaigns regarding the possibility of deregistration for those operators where this is relevant, so that annual fees are not sent out to them.

8.2 **Description of how and when the impact of the draft regulations can be evaluated**

Monitoring of whether the fees provide the intended cost recovery will be done annually. The follow-up is carried out by means of financial monitoring of the costs and revenue of the case processing. Follow-up is also done in the form that we take note of the animal control unit's views on how the regulatory framework functions during control, e.g. whether it is sufficiently clear what the requirements are for exemption from registration and what applies to commercial documents.

Evaluation of the other parts of the proposal will be carried out once the regulations have been applied for a two-year period. It will be done in relation to impacts on companies, individuals and authorities.