The Swedish Board of Agriculture

Animal Department

Impact assessment

Reference number
5.3.16-03528/2023

Complementary impact assessment of proposed amendments to the Swedish Board of Agriculture's regulations and general advice (SJVFS 2021:10) on biosecurity measures and notification and surveillance of animal diseases and infectious agents as well as repealing the Swedish Board of Agriculture's regulations (SJVFS 2010:58) on mandatory health monitoring of poultry

In accordance with the Ordinance (2007:1244) on regulatory impact assessments, an authority that is considering new or amended rules shall investigate the economic and other impacts of the rules to the extent needed for the particular case and document the investigation procedure in an impact assessment.

Introduction

This is a complementary impact assessment to Impact assessment on proposed amendments to the Swedish Board of Agriculture's regulations and general advice (SJVFS 2021:10) on biosecurity measures and notification and surveillance of animal diseases and infectious agents as well as repealing the Swedish Board of Agriculture's regulations (SJVFS 2010:58) on mandatory health monitoring of poultry.[1]

The previous draft regulations referred to the fact that sampling and analysis would be carried out in accordance with an EU Delegated Regulation[2] and to the Swedish

[1] Impact assessment of proposed amendments to the Swedish Board of Agriculture's regulations and general advice (SJVFS 202110) on biosecurity measures and notification and surveillance of animal diseases and infectious agents as well as repealing the Swedish Board of Agriculture's regulations (SJVFS 2010:58) on mandatory health monitoring of poultry. Registry No. 5.3.16-03528/2023 Dated 9 November 2023.
[2] Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for

Board of Agriculture's decision on a national monitoring plan. Regulating sampling by means of a national monitoring plan has now been abandoned because the provisions impose requirements on the individual and must therefore be in the form of regulations.

We have now, in revised draft regulations, included provisions on the sampling to be carried out to monitor animal health in certain types of poultry establishments. The provisions have been inserted as three new sections in Chapter 4 and a new Annex 7 to the Regulations. This complementary impact assessment concerns these provisions on sampling.

During the preparations of the new Annex to the regulations amending SJVFS 2021:20, the Swedish Veterinary Agency (SVA) and representatives of the poultry sector have been consulted at an early stage.

For those establishments that are subject to approval requirements under the EU Animal Health Regulation, detailed sampling requirements for surveillance of diseases are laid down in EU legislation.[3] In order to maintain the level of disease surveillance currently regulated in the Swedish Board of Agriculture's regulations and general advice (SJVFS 2010:58) on mandatory health monitoring of poultry, here referred to as SJVFS 2010:58 or the hen health control, complementary national rules on sampling for the disease agent *Egg Drop Syndrome* (EDS) are necessary. EDS is not regulated by the EU Regulation. Similarly, in order to maintain the level of surveillance, a national regulation is needed for sampling in non-approved establishments which have until now been sampled in accordance with the requirements of SJVFS 2010:58.

The proposed changes to the Swedish Board of Agriculture's regulations and general advice on biosecurity measures and notification and surveillance of animal diseases and infectious agents (SJVFS 2021:10) are considered to be the most optimal way to maintain current levels of disease surveillance. Sweden has a good status, both national and international, as regards salmonella and other communicable diseases. The aim of the regulations is to ensure maintained disease surveillance, a maintained good animal health situation, and high quality in Swedish poultry production.

For more information on which sampling is to be carried out and which should be subject to the sampling requirements, reference is made to the original impact assessment.

establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs.

[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')

Our ambition is to change as little as possible compared to today, while complying with the requirements of EU legislation.

Some minor adjustments concerning the time of sampling have nevertheless been made regarding sampling taking place in non-approved establishments, in order to make things more similar to the requirements for approved establishments. This is considered to make it easier for operators, trade organisations, veterinarians and the Swedish Board of Agriculture as the control authority.

A. General information

1. Description of the problem and desired outcome

The current regulation, SJVFS 2010:58, contains provisions on the conditions for registration and mandatory health monitoring in breeding poultry establishments and hatcheries. The Swedish regulations need to be aligned with the EU Animal Health Regulation. [4]

SJVFS 2010:58 does not comply with EU legislation. The regulations partially duplicate the provisions of the EU Animal Health Regulation. National regulations are required to ensure continued monitoring of agents not covered by EU legislation, as well as continued monitoring in establishments not subject to approval.

A clear account of the regulations and general advice affected by the proposed amendments covered by the additional consultation is given in Table 1.

Table 1. Provisions related to SJVFS 2010:58 covered by this consultation.

Chapter	Section	Relates to	Amendment compared to previous draft regulations
4	Section 6(5)	Animal health visits shall include an examination of sampling in accordance with Annex 7.	The sampling requirements are those set out in Annex 7.
4	Section 8	Operators shall ensure that samples are taken in accordance with Annex 7.	Requirement transferred from Section 13 of SJVFS 2010:58, with certain adjustments

[4] 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’)

		Requirements for samples to be sent to the laboratory designated by the Swedish Board of Agriculture for analysis	
4	Section 9	Microbiological hygiene control requirements for hatcheries with hens and turkeys with a simultaneous maximum incubation capacity of more than 1,000 eggs	Requirement transferred from Section 47 of SJVFS 2010:58, with certain adjustments
4	Section 10	Microbiological hygiene control requirements for approved hatcheries in accordance with Article 94(1)(c) of Regulation (EU) 2016/429	Requirement transferred from Section 47 of SJVFS 2010:58, with certain adjustments
6	Section 2	Surveillance of avian influenza in poultry	Return to the wording in the regulations currently in force.
6	Section 3	Surveillance of avian influenza in poultry	Return to the wording in the regulations currently in force, but with amended reference to samples in accordance with Annex 7 instead of SJVFS 2010:58
Appendix 7		Sampling	New Annex, which largely corresponds to the previous Annex to SJVFS 2010:58

Surveillance of diseases

The Swedish Board of Agriculture has assessed that it is important from the point of view of disease control to retain the requirements for surveillance. This applies to all the establishments covered by the current regulation SJVFS 2010:58, i.e. also

those establishments that do not apply for approval under the EU Animal Health Regulation.

At present, sampling for the disease *Egg Drop Syndrome* (EDS) is regulated only by SJVFS 2010:58. The disease is also subject to a notification obligation under SJVFS 2021:10 (Annex 1). EDS is not included in the listed diseases of the EU Animal Health Regulation, but continued surveillance is deemed important by both the industry and the expert authority, the SVA. We choose to keep the sampling requirement for EDS. We adjust the exact age in weeks at the start of lay for sampling to ‘at the start of lay’ only, in order to be consistent with other sampling at this time. Acccording to Article 269 of Regulation (EU) 2016/429 of the European Parliament and of the Council, Member States may apply additional or stricter measures than those laid down in that Regulation as regards surveillance for the purpose of detecting the presence of disease. Disease surveillance programmes in establishments subject to approval under Article 97 of the EU Animal Health Regulation and Articles 7 and 8 of Commission Delegated Regulation (EU) 2019/2035 are set out in Annex II to the latter Regulation.

The disease agents *Salmonella pullorum, Salmonella gallinarum, Mycoplasma gallisepticum* and *Mycoplasma meleagridis* that are now subject to surveillance under SJVFS 2010:58 will continue to be subject to surveillance at a similar interval as before. Some minor adjustments concerning the time of sampling have nevertheless been made for sampling in accordance with Annex 7, in order to make things more similar to the requirements for approved establishments. For example, sampling of *Mycoplasma gallisepticum* and *Mycoplasma meleagridis* ‘during rearing two weeks before moving to laying houses’ has been adjusted to 16 weeks (for hens) and 20 weeks of age (for turkeys), respectively, as defined in EU legislation. For the same reason, every twelve weeks have been adjusted to every 90 days, which in practice is irrelevant as there is only a difference of 6 days. Sampling every 90 days means that no more than 90 days should pass between the sampling procedures. It is permitted to take samples at a shorter interval, for example in order to avoid sampling during public holidays.

For *Salmonella pullorum* and *Salmonella gallinarum* as well as *Mycoplasma gallisepticum* and *Mycoplasma meleagridis,* the exact age in weeks at the start of lay for sampling has been changed to ‘at the start of lay’ only, since the week in which the lay phase starts is different for different breeds. Here, however, we deviate from the Swedish translation in EU law, where the time of sampling is stated as ‘at laying’. Questions have arisen about what it means. What is meant by ‘at laying’ can be misinterpreted as meaning the entire period of laying. The English version of EU legislation reads “at the point of lay”. We choose to translate this into “at the start of lay” as the meaning of “at the point of lay” is when hens have matured to the stage when they start laying eggs.

One observation is that these samples currently consist of blood samples for serological testing, but that the sampling matrix in the surveillance programme of Commission Delegated Regulation (EU) 2019/2035 for approved establishments also leaves room for, inter alia, tissue and environmental samples “as appropriate” (Annex II, Part 2, Paragraphs 2.4 and 3.4). What is appropriate is up to the operator to decide, but the SVA recommends blood samples for serological testing for the agents mentioned above. We have therefore chosen to provide for blood samples to be taken in non-approved establishments.

The SVA has been consulted on the number of birds to be sampled, as there is some scope in the EU regulations to adapt this. The SVA considers that 60 birds is the number that should continue to apply. No change is therefore proposed to the number.

The requirement for annual sampling of *Salmonella pullorum* and *Salmonella gallinarum* in establishments for breeding poultry other than hens and turkeys will be removed. This requirement applies to those establishments for breeding poultry other than hens and turkeys that move hatching eggs or poultry to another Member State or to a third country. These establishments are subject to approval requirements. According to Commission Delegated Regulation (EU) 2019/2035, samples are to be taken from each flock at poultry establishments subject to approval. The species covered, except hens and turkeys, are guinea fowl *(Numida meleagris)*, quail *(Coturnix coturnix),* pheasants *(Phasianus colchicus),* partridges *(Perdix perdix)* and ducks *(Anas spp.)*. Breeding poultry shall be sampled at laying and productive poultry at least once a year during production. Transferring the requirement to SJVFS 2021:10 would therefore lead to double regulation.

Paragraph 3.6 of Part 2 of Annex II to Commission Delegated Regulation (EU) 2019/2035 describes that tests for the presence of infection with *Mycoplasma gallisepticum* and *Mycoplasma meleagridis* shall be carried out using validated methods approved by the competent authority. The way in which the methods are to be approved is not clear from EU legislation. The SVA uses common serological surveillance methods that are validated at the SVA. The methods or analyses used may be changed depending on the test supplier. Prescribing specific suppliers or tests may lead to problems as there is no guarantee that they remain or continue to be of the same quality. Prescribing validated methodology with one or more specific technologies would require their continued presence on the market. Therefore, the proposal does not require validated methods.

Microbiological hygiene control requirements for hatcheries

Microbiological hygiene control requirements in the hatcheries covered by SJVFS 2010:58 are transferred to the new provisions with some adjustments. The requirements that samples should be taken, by what means and how often, are

retained. The requirements that the arrangements for the hygiene control are to be drawn up in consultation with the veterinarian is retained for the non-approved hatcheries. We introduce a change from the requirement that samples are to be taken from cleaned and disinfected incubators and hatchers to a requirement that these locations should at least be covered by sampling. Consultations with representatives of the industry have shown that samples are taken from several places in hatcheries, including incubators and hatchers.

EU rules for approved hatcheries lay down requirements to the number of samples (60 samples) for microbiological hygiene control. We see no justification for introducing an equivalent number for the non-approved hatcheries. On the other hand, it is justified to impose requirements on where samples are to be taken also in approved hatcheries, to include at least incubators and hatchers. We also consider it justified to require that sampling be documented in order for it to be covered by official controls.

Bacteriological testing in approved hatcheries

The EU Regulation lays down requirements on bacteriological testing for salmonella in approved hatcheries. For approved hatcheries, there is no room for waiving these requirements. However, there is room for manoeuvre with regard to the sampling requirements for the non-approved hatcheries which are covered by national regulations. As the requirements are deemed to be unjustifiably high in relation to the current situation in Sweden, we will not introduce similar requirements for bacteriological testing for non-approved hatcheries as in the EU regulations.

Provisions on surveillance of avian influenza in poultry

The provisions on surveillance of avian influenza will be reviewed in full in future regulatory updates. In order not to give the impression that the provision has been changed in substance, we choose not to implement previously proposed linguistic adjustments at this stage. The only change compared to the current regulations is that the reference to samples taken in accordance with the Swedish Board of Agriculture’s regulations (SJVFS 2010:58) on mandatory health monitoring of poultry is replaced by a reference to samples taken in accordance with Annex 7.

Measures to ensure that the proposal does not entail more far-reaching costs or restrictions than necessary

In the regulatory work, we have assumed that the proposal should not entail more far-reaching costs or restrictions than what is deemed necessary to achieve its objective. The purpose of the provisions is to maintain the monitoring that exists today. Therefore, the proposal does not provide for raising the requirements for

non-approved establishments in order to match the requirements laid down in EU legislation for approved establishments. Nor have we introduced new requirements, which, according to Article 269 of Regulation (EU) 2016/429 of the European Parliament and of the Council, would have been possible. In order to avoid unnecessary restrictions, we have refrained from prescribing a validated method, as explained above.

Summary

The draft regulations are considered appropriate to maintain the level of sampling currently regulated in SJVFS 2010:58 and are considered to be of significant importance for maintaining a good animal health situation.

2. Description of alternative solutions for the stated objectives and effects if no regulation is put in place

A solution involving only a decision repealing SJVFS 2010:58 without any additional requirements to those being in force under the EU Animal Health Regulation and the existing SJVFS 2021:10 has been discussed. This would lead to a deterioration of animal health surveillance, in particular with regard to EDS and for establishments which have until now been subject to animal health surveillance where approval is not required. Such a solution is therefore deemed inappropriate.

One alternative is that we impose the same requirements on large establishments not subject to approval as on approved establishments. This means that we do not make a distinction between establishments that are part of the chain of trade with other countries and those that are not. This is not considered relevant, as it would lead to unnecessary costs for businesses.

We have concluded that if sampling requirements are to apply in addition to the sampling requirements laid down in the EU Regulation, these must be specified in the form of regulations. This also applies to the possibility of designating the person responsible for ensuring that samples are taken. In this case, there are no alternative solutions for retained sampling.

Not repealing SJVFS 2010:58 would mean double regulation and, to some extent, national legislation that is in conflict with EU legislation. Maintaining SJVFS 2010:58 is therefore not relevant.

3. Information on those affected by the regulation

The following operators will be affected by the regulation:

1. Operators of establishments approved under the EU Animal Health Regulation for:

a. the keeping of poultry from which poultry (not intended for slaughter) or hatching eggs are moved to another Member State; or

b. hatcheries from which hatching eggs or poultry are moved to another Member State; and

c. establishments supplying poultry and hatching eggs to establishments referred to in points (a) and (b).

The EU Animal Health Regulation exempts certain operators from the requirement to apply for approval. This applies to hatcheries from which consignments of fewer than 20 hatching eggs or consignments of fewer than 20 poultry birds are moved to another Member State. It also applies to establishments keeping poultry from which consignments of fewer than 20 poultry birds not intended for slaughter or consignments of fewer than 20 hatching eggs are moved to another Member State.

2. Operators of establishments keeping chickens and turkeys whose intention is to maintain at the same time more than 1 000 breeding poultry birds and hatcheries for chickens and turkeys with a simultaneous maximum incubation capacity of more than 1 000 eggs. Establishments for restocking supplies of game birds, if they are to be approved in accordance with paragraph 1, are therefore included.

3. Competent authority, the Swedish Board of Agriculture.

4. The veterinarians carrying out animal health visits.

5. The Swedish Veterinary Agency (SVA).

Based on the information we have at our disposal, we estimate that around 90 establishments will be affected, based on the number of establishments included in the chicken health control today. These establishments belong to approximately ten different companies of varying sizes. It is mainly large companies active in breeding that are covered. According to the figures available for the number of employees and turnover of the various companies, about half are classified as micro and small enterprises and half as medium-sized enterprises (SMEs) according to the European Commission’s definition of small and medium sized enterprises.

4. Information regarding the authorisations on which the Board’s decision-making power is based

The provisions on sampling covered by this impact assessment are based on Sections 3 and 5 of the Regulation (2006:815) on sampling of animals and related matters.

5. Information on the cost and other impacts of the regulation and an impact comparison of the considered regulatory alternatives

The inclusion of sampling requirements as an annex to the regulations does not have any cost implications in terms of costs or revenues for municipalities, regions, businesses, or other individuals. This is because the sampling required under the proposal already takes place and is regulated in the regulations (SJVFS 2010:58) to be repealed.

The proposal introduces a new requirement for companies to document and keep hygiene control results. Such checks shall be carried out every six weeks. This means that hygiene control measures take place 9 times in one year. Entering the results into an Excel file is estimated for an establishment to take 3 minutes per occasion, a total of 27 minutes in one year. On the basis of the estimate that 90 establishments distributed on 10 companies are concerned, the cost for a company is on average 27 minutes times 9, which works out to about 4 hours per company per year. With a cost of SEK 700 per hour, the total cost of the administrative burden per year is SEK 28,000 for all ten companies. This administrative burden is estimated as marginal for the companies, as it amounts to an average of SEK 2,800 per company per year. See specific impact assessment attached.

Aligning sampling times with the requirements of the EU regulatory framework has consequences for the SVA, which must review its procedures for the follow-up to ensure that sampling is carried out in accordance with the requirements of the legislation.

There is no impact on municipalities, as they neither have establishments of the type covered by the proposal nor do they have control responsibilities or carry out other official activities in the field of animal health in this type of establishments. The proposal does not change municipal powers or obligations, or the basis for the organisation or operation of municipalities or regions.

Currently applicable regulations specify no thresholds as regards the size of breeding poultry establishments covered by the regulations. Compared to the actual wording of SJVFS 2010:58, the proposal means that fewer establishments are covered due to the introduced size limit for the scope of the provisions.

In conclusion, the regulation is not deemed to significantly impact the working conditions, competitiveness or other conditions of companies.

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

The regulation goes beyond Sweden’s obligations arising from its accession to the EU but does not violate EU law. Article 269 of Regulation (EU) 2016/429 of the European Parliament and of the Council allows Member States to apply additional or stricter measures than those laid down in that Regulation in a number of areas,

including surveillance for the purpose of detecting the presence of disease and documentation in the form of journal entries.

7. Assessment as to whether special consideration needs to be given to the time of entry into force and whether special information initiatives are required

The time of entry into force should be at a year-end, given that official controls and animal health monitoring can then be carried out for the whole year on the basis of the same legislation.

Information needs to be provided online and to affected operators, control staff, animal health veterinarians, the SVA and county administrative boards. A communication plan has been drawn up to support this work. This is important as the regulations must be read as part of a whole together with EU legislation.

8. Evaluation of the impact of the proposal

Evaluation of the impact of the proposal will be carried out through dialogue with all interested parties, businesses, and trade associations as well as the Swedish Board of Agriculture as the control authority.

The evaluation is planned to take place just over a year after the entry into force of the regulations, i.e.in the spring of 2026. This will occur in the context of the annual evaluation of the control of the food chain.

B. Municipalities and regions

Mark X:

☒ The regulation is not deemed to have an impact on municipalities or regions. For this reason, the impact assessment does not contain any description of the point in Section B.

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1. Description of impact on municipalities or regions

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C. Enterprises

An enterprise herein refers to a legal or natural person engaged in business activities, i.e. the sale of goods and/or services professionally and independently. To professionally carry on business activity is something that should be interpreted broadly.

Mark X:

☒ The regulation is not deemed to have to significantly impact the working conditions, competitiveness or other conditions of companies. For this reason, the impact assessment does not contain any description of the points in Section C.

☐ The regulation is deemed to significantly impact the working conditions, competitiveness or other conditions of companies. For this reason, the impact assessment contains a description of the points in Section C.

Our assessment is that the draft regulations will not have a *significant* impact on the working conditions, competitiveness, or other conditions of enterprises.

The intention has been to change as little as possible, while aligning national legislation with EU law.

The draft regulations do not place enterprises with approved establishments at a disadvantage compared to European operators.

The industry has expressed its support for maintaining the national rules on sampling contained in the current regulations and has not deemed this to be negative from the point of view of competition.

Nor is the proposal considered to have a significant impact on the working conditions, competitiveness, or other conditions of small enterprises. The additional documentation requirement is not of such a scope or nature as to place small enterprises at a disadvantage.

D. Impact on rural areas

Description of how the draft regulations will affect rural areas

The draft regulations are not expected to have any impact on rural areas.

E. Consultation

1. Description of any early consultation

During the process of including the sampling requirements in the draft regulations, the Swedish Board of Agriculture has had both early and compulsory consultation with SVA. There has also been consultation with representatives of the poultry sector.

F. Contact person

1. Specify who can be contacted in the event of any questions

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