Jordbruks verket

Animal Section

9 November 2023

Ref. No 5.3.16-03528/2023

Impact assessment of draft 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 and 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

The Swedish Board of Agriculture's regulations and general advice (SJVFS 2010:58) on mandatory health monitoring of poultry, here referred to as K20 or the chicken health control, contain provisions governing the registration of and mandatory health monitoring in establishments with breeding poultry and hatcheries. The Swedish regulations need to be aligned with Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases, here referred to as the EU Animal Health Regulation[1]. Since 21 April 2021, the EU Animal Health Regulation has governed registration and record keeping requirements in all establishments as well as the conditions for the approval of establishments moving poultry (not intended for slaughter) or hatching eggs to another Member State.

In the process of adapting the K20 provisions to the EU Animal Health Regulation, consultation meetings were held with industry associations, the National Veterinary Institute (SVA) and representatives of active official veterinarians. In these consultations, it was deemed important for disease control to retain the requirements on biosecurity, animal health visits, surveillance and controls for all establishments covered by the current K20, regardless of whether or not they are subject to approval under the EU Animal Health Regulation. Regular animal health visits by veterinarians are deemed to be essential for maintaining current levels of disease control.

Detailed sampling programmes for disease surveillance in establishments that are subject to approval requirements under the EU Animal Health Regulation are set out in a Delegated Regulation[2]. In order to maintain the current level of surveillance, sampling programmes for

[1] 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')
[2] Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429

certain infectious agents and for non-approved establishments – which have until now been included in the chicken health control – need to be subject to some form of regulation.

The current system in K20 of designating a veterinarian who is attached to the establishment as their official veterinarian for the chicken health control is deemed to be incompatible with the requirements of the Official Controls Regulation[3].

The Swedish Board of Agriculture's register of establishments with breeding poultry and hatcheries contains information on the activities of the establishments, and this should be developed or updated so it can be used for selecting establishments that are covered by the provisions.

In the work on these amendments, the general requirements for simplification and a focus on a goal-oriented regulatory framework have been taken into account. The overall aim of the work has been to maintain a good animal health situation in combination with removing possible regulatory duplication with regard to the EU Animal Health Regulation. The aim has also been to maintain the possibilities for control, to enable smooth administration and a cost-effective approach, to use nomenclature adapted to the EU Animal Health Regulation and to use existing systems and processes. The intention has not been to expand the regulatory framework. The future inclusion of non-approved establishments with species other than chickens and turkeys will therefore be a later issue.

The proposed amendments to the Swedish Board of Agriculture's regulations and general advice on biosecurity measures and notification and surveillance of animal diseases and infectious agents, here referred to as K12, are considered to be the best way to maintain the current levels of biosecurity measures, surveillance and control that affected parties considered to be beneficial for the animal health situation in Sweden. This applies regardless of whether the breeding establishment or hatchery has been approved or only registered.

In addition to the amendments linked to the provisions of K20, there are four amendments relating to notification and the requirement to send certain isolates to the National Veterinary Institute. The amendments are of a simpler nature and are described in more detail in later paragraphs.

An outline of the regulations and general advice affected by the draft amendments is provided in the table below. See also the Annex which contains a table comparing the provisions of K20/the draft provisions with other legislation in force.

Table 1a. Provisions related to K20

Chapter	Section	Relates to	Remarks
2	4	General advice for establishments with breeding poultry and for hatcheries	Covers previous requirements in K20: Sections 22, 30, 35, 39, 40, 42, 43, 45 and 48

of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs.

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

4	4	Requirements for animal health visits	Requirement for regular veterinary visits transferred from K20 Section 11, with some adjustments
4	5-7	Requirements concerning frequency, content and reporting for animal health visits	Requirements transferred from K20 Sections 11-12, with some adjustments
6	2-3	Surveillance of avian influenza in poultry	Linguistic adjustment and reference to K20 deleted, footnote added

Table 1b. Provisions on notification, not linked to K20

Chapter	Section	Relates to	Remarks
3	7	Notification of suspected fish diseases BKD and IPN genotype 2	Correction
3	14	Requirement to send bacterial isolates to the SVA	Amendment of provision
3	23	Notification of diagnosis of ESBL$_{CARBA}$ in Enterobacterales, MRSA or MRSP to the county administrative board	Amendment of provision
Anne x 1		Notification obligation for leptospirosis	Correction

A General

1. Description of the problem and desired outcome

The current K20 from 2010 contains provisions governing the registration of and mandatory health monitoring in establishments with breeding poultry and hatcheries. The Swedish regulations need to be aligned with the EU Animal Health Regulation. The high degree of detail in K20 regarding biosecurity should be seen in the light of the fact that the regulations were introduced during a period when the voluntary salmonella control for poultry was governed by the Swedish Board of Agriculture's regulations and general advice (SJVFS 1993:179) on prevention and special hygiene measures, etc. to prevent the spread of zoonoses and other infectious agents (K103). The reason for the hygiene requirements in K20 was that they were needed to maintain Swedish control over salmonella and to maintain the Swedish additional guarantees. The hygiene requirements from K20 are now part of the industry's control programme with plans and guidelines approved by the Swedish Board of Agriculture and are mandatory for the members of the organisations. Requirements for operators, where appropriate and as needed, to take biosecurity measures in the form of physical or management measures are set out in Article 10 of the EU Animal Health Regulation. The requirement applies to all operators. More specific requirements for biosecurity measures for approved establishments can be found in a Delegated Regulation[4].

[4] Commission Delegated Regulation (EU) 2019/2035.

Some of the provisions in K20, in particular regarding biosecurity measures, are more detailed than the requirements of the EU Animal Health Regulation. This is also the case for the specific requirements imposed on approved establishments. Furthermore, K20 contains relatively detailed requirements for the design of buildings where the basis for the Swedish Board of Agriculture's authorisation can now be called into question to some extent.

General hygiene rules for all establishments with animals have also been laid down since 2013 in the Swedish Board of Agriculture's regulations and general advice (SJVFS 2013:14) on prevention and special hygiene measures, etc. to prevent the spread of zoonoses and other infectious agents.

The EU Animal Health Regulation governs the registration of all establishments and the approval of establishments moving poultry or hatching eggs to another Member State. The EU Animal Health Regulation also lays down rules on record keeping requirements in registered establishments. Commission Delegated Regulation (EU) 2019/2035 supplements the provisions on the approval of establishments under the EU Animal Health Regulation. Establishments that have previously been approved are still approved by means of transitional provisions of the EU Animal Health Regulation. Before new approvals of establishments are granted, an examination is carried out against the requirements of the EU Animal Health Regulation.

Data on approved establishments is recorded in the context of approval decisions. According to the information available, approximately 90 breading poultry and hatchery establishments in Sweden have approved status under the EU Animal Health Regulation.

K20 specifies no limits as regards the size of breeding poultry establishments covered by the regulations. The Swedish Board of Agriculture's control guidance for mandatory health monitoring of poultry, adopted on 18 May 2016 (Ref. No 5.3.18-4762/16) deals with three types of control subjects: all breeding poultry establishments with chickens or turkeys, hatcheries producing more than 50 000 day-old chicks per year, and all breeding poultry establishments with a species other than chickens and turkeys which export eggs or poultry to another country. In practice, however, K20 has only been applied to breeding poultry and hatchery establishments, regardless of size, which are part of the breeding chains of the country's major breeding companies.

Our intention is to make a searchable selection of control subjects consisting of the breeding and hatchery establishments that are covered by the currently proposed provisions. At the same time, the intention is that the new provisions will cover the same sizes and types of establishments as today. For the selection, it should be possible to use data in the Swedish Board of Agriculture's holding register, provided that the register is further developed or quality assured. The register information is provided by operators in accordance with the requirements of the EU Animal Health Regulation. The Swedish Board of Agriculture's register of breeding poultry and hatchery establishments contains information on the activity of the establishment, the number of animals the operator intends to keep on the establishment and the maximum capacity.

On the basis of the required register information, the amended regulations propose that the number of animals intended to be kept and the maximum incubation capacity shall be applied in order to determine whether a non-approved establishment shall be covered by the provisions. For simplification purposes, the same scope for hatcheries as in SJVFS 2007:19[5] (K104) is being proposed; hatcheries with simultaneous incubation capacity of more than 1 000 eggs.

The original plan was to set the limit as a maximum capacity for the keeping of chicken and turkey breeding poultry. However, according to the information in our register, for a significant number of establishments, the number of animals the operator intends to keep and

[5] Swedish Board of Agriculture's regulations (SJVFS 2007:19) on mandatory salmonella controls in poultry.

the maximum capacity of animals that can be kept on the establishment differs greatly. So instead, we opted for the number of animals the operator intends to keep on the establishment. The information in the holding register is not reliable enough to be able to provide a figure for the number of establishments that will be covered by the draft provisions, compared with those currently covered by K20. Random checks of a number of establishments of different types showed that the difference is small between those who have previously been subject to a chicken health control compared to the provisions currently being proposed.

In light of our intention that the same flocks that have been covered by the chicken health control to date will be covered by the new provisions, the proposal means that the threshold for chicken and turkey establishments to be covered by the requirements will be 1 000 breeding poultry.

In the process of adapting the K20 provisions to the EU Animal Health Regulation, private consultation meetings have taken place with industry associations, the National Veterinary Institute (SVA) and representatives of active official veterinarians. The industry associations expressed their wish to maintain regulation with a high degree of detail. It was deemed important for disease control to retain the requirements on biosecurity, animal health visits, surveillance and control for all entities covered by the current K20, that is to say also for those that do not apply for approval under the EU Animal Health Regulation. Regular animal health visits by veterinarians are considered essential for maintaining current levels of disease control. The wishes expressed, for animal health visits of operators keeping breeding poultry for restocking supplies of game birds to be better included in the new provisions, have not been taken into account here. However, to some extent the requirements for this sector have increased, as more establishments are subject to the approval requirement due to the introduction of the EU Animal Health Regulation.

K20 contains provisions on regular veterinary visits. Animal health visits are part of the surveillance to be carried out in accordance with the EU Animal Health Regulation, which allows for continued requirements for regular veterinary visits. The details on the frequency and elements of animal health visits laid down in Chapter 4, Sections 4-7 allow for risk-based surveillance in accordance with Articles 25-27 of the EU Animal Health Regulation. For animal health visits, the veterinarian does not have to be officially appointed, which simplifies matters for operators.

Operators shall ensure that the establishments under their responsibility receive animal health visits by a veterinarian, taking into account the risk posed by the establishment concerned. This is set out in Article 25 of the EU Animal Health Regulation. It may be advantageous to combine these visits with animal health visits for other purposes.

The prescribed time intervals in Chapter 4, Section 5, lay down a minimum requirement for the establishments covered under Chapter 4, Section 4. The time intervals correspond to those in K20, except that animal health visits shall be carried out at least annually instead of every six months in poultry establishments for the restocking of supplies of game birds. This change is justified by the fact that operations normally only last part of the year and should therefore not fall within the category of ‘other establishment’, as has previously been the case.

The Swedish Board of Agriculture’s regulations and general advice (SJVFS 2021:13) on registration, etc. with regard to animal health[6] (here referred to as JK3) and K12 are applicable to areas which are now also governed by K20.

[6] The Swedish Board of Agriculture’s regulations and general advice (SJVFS 2021:13) on registration, approval, traceability, movement, entry and export with regard to animal health.

Chapter 4, Section 2 of K12 stipulates that sampling to map the presence of animal diseases or infectious agents shall be carried out in accordance with the Swedish Board of Agriculture's decision establishing the national surveillance plan (hereinafter NSP). It should be possible to apply this procedure in order to maintain the level of sampling currently governed by K20, which is considered essential for maintaining a good animal health situation. The fact that sampling in such a way is regulated in decisions facilitates more flexible and, above all, faster adaptation to the current animal health situation. Therefore, in order to maintain the current level of surveillance, sampling programmes in non-approved establishments need to be covered by the Swedish Board of Agriculture's decision establishing the NSP. At present, sampling for the disease *Egg Drop Syndrome (EDS)* is only regulated in K20 and is subject to a notification obligation under K12 (Annex 1). EDS is not included in the EU Animal Health Regulation's listed diseases, but continued surveillance is deemed important by both the industry and the expert authority, the SVA.

The current NSP does not contain detailed sampling programmes but is based on the sampling provisions in Annex 2 of K20 plus additions for monitoring *Mycoplasma synoviae*.

Sampling programmes for monitoring establishments that are subject to approval in accordance with 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. K20 prescribes sampling for *Paramyxovirus type 1* in breeding poultry for laying hens, chickens for fattening and turkeys. K12 contains provisions with a corresponding purpose, i.e. serological examination of breeding poultry of species in the order Galliformes in order for Sweden to maintain its status as being free from the Newcastle disease virus without vaccination.

The diseases *Salmonella pullorum, Salmonella gallinarum, Mycoplasma gallisepticum* and *Mycoplasma meleagridis* that are now monitored under K20 will continue to be monitored at an interval similar to that which applies to establishments approved under the EU Animal Health Regulation. However, one observation is that these samples today consist of blood samples for serological examination but that the sampling matrix in the surveillance programme of Commission Delegated Regulation (EU) 2019/2035 for approved establishments also leaves room for environmental samples for bacteriological examination 'as appropriate' (Annex II, Part 2, points 2.4 and 3.4). Some form of guidance on the type of sampling/analysis method that can be 'appropriate' should therefore be included in the NSP.

The current system – where a veterinarian attached to the establishment carries out official controls to check compliance with the requirements of K20 – is outdated due to the fact that, inter alia, the Official Controls Regulation requires inspectors carrying out official controls to be free from conflicts of interest[7].

Pursuant to Commission Implementing Regulation (EU) 2022/160[8] and Commission Delegated Regulation (EU) 2022/671[9] an official veterinarian shall carry out an annual control of approved establishments. Article 14 of the Official Controls Regulation states that the choice of control method can be made as appropriate. The control shall include inspection of, inter alia, equipment, premises, animals and traceability.

[7] Article 5(2) of the Official Controls Regulation.
[8] Commission Implementing Regulation (EU) 2022/160 of 4 February 2022 laying down uniform minimum frequencies of certain official controls to verify compliance with Union animal health requirements in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and repealing Regulations (EC) No 1082/2003 and (EC) No 1505/2006.
[9] Commission Delegated Regulation (EU) 2022/671 of 4 February 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards specific rules on official controls performed by competent authorities on animals, products of animal origin and germinal products, follow-up action to be taken by the competent authorities in case of non-compliance with identification and registration rules for bovine, ovine and caprine animals or of non-compliance during transit through the Union of certain bovine animals, and repealing Commission Regulation (EC) No 494/98.

For establishments that are registered but not approved, there is no minimum frequency for official controls in the legislation. The Swedish Board of Agriculture intends to establish, after a risk evaluation, an appropriate interval for such controls.

According to K20, the official veterinarian attached to the establishment is required to report annually on the flocks for which control visits have been carried out. The report shall be submitted to the county administrative board of the county where the establishment is located. The county administrative board shall then forward the report to the Swedish Board of Agriculture. The requirement that reports be sent to the county administrative boards is not deemed appropriate and has been removed from the draft. Instead, the veterinarian conducting the animal health visit is to report the results of the visit to the operator. Whether or not animal health visits have taken place is checked during official controls.

Through an agreement between the Swedish Board of Agriculture and the SVA, the SVA is responsible for, inter alia, handling referrals for samples that are to be submitted in accordance with K20, monitoring that sampling takes place in accordance with the programme and taking certain measures in cases where samples have not been received.

The SVA has developed a digital analysis management service that replaces previous referral management and test results. The service is aimed at breeders of breeding poultry and simplifies ordering and provides a better overview of both upcoming and completed testing. The operator themself provides the information on their own establishments and flocks. Each sample taker has their own login. The service is currently adapted to the sampling programmes under K20, but can be adapted to modified sampling programmes.

The requirement for coordinated sampling for avian influenza in Chapter 6, Section 3 will no longer be included in the regulations. This requirement meant that examination as part of surveillance for avian influenza should be carried out at the same time as breeding poultry flocks were examined under K20.

With respect to the provisions not linked to K20, which concern the notification and the requirement to send certain isolates to the SVA:

- Chapter 3, Section 7: Regarding the fish disease BKD, in connection with K12 replacing earlier legislation, the requirement for notification of suspected cases of BKD was removed. This requirement is now being reinstated in Chapter 3, Section 7 of the draft. The same applies to the fish disease IPN genotype 2. Since BKD and IPN are diseases for which Sweden has national measures, it is important to take measures even if cases are merely suspected. A notification requirement when there is reason to suspect the presence of BKD or IPN genotype 2 is therefore needed. By virtue of the Epizootic Diseases Act (1999:657), IPN other than genotype 2 is to be controlled in accordance with Chapter 1, Section 2 of the Swedish Board of Agriculture's regulations (SJVFS 2023:15) on the prevention and control of certain animal diseases. A notification requirement for suspected cases of these diseases was previously laid down in Chapter 3, Section 5 of the Swedish Board of Agriculture's regulations (SJVFS 2014:4) on animal health requirements for aquaculture animals and products, and was worded as follows: *Where a contagious disease is suspected in the farm or during transport, as a result of, for example, abnormal mortality, abnormal behaviour or abnormal appearance of the animals, the owner or operator of an aquaculture establishment or transporter shall immediately notify the veterinarian.*
- Chapter 3, Section 14: As an adaptation to future analytical methodology, it is necessary to require that bacterial isolates be sent to the SVA in cases where ESBL$_{CARBA}$ in Enterobacterales, MRSA and MRSP are detected by molecular biological methods without prior phenotypic examination. The reason such a requirement has not existed before is that it was not relevant based on analytical methodology that has existed. However, the legislation should be adapted to future

methodology.

- Chapter 3, Section 23: Notification of preliminary diagnosis of ESBL$_{CARBA}$ in Enterobacterales, MRSA or MRSP shall also be made, according to the draft, to other county administrative boards affected, i.e. county administrative boards other than in the county where the animal is located. The reason for the proposed amendment is that an animal is often tested in a county other than the one in which it lives. A positive sample could indicate that the spread of infection is also ongoing, for example in the clinic in the county where the animal was tested. Since a case of ESBLcarba, MRSA and MRSP may therefore concern more than one county administrative board, the current provision needs to be supplemented in order for the county administrative boards concerned to be informed.
- Annex I: A correction to the notification obligation for leptospirosis is made by adding:
  ** in the left column, which was inadvertently removed when K12 was drawn up. Leptospirosis is a zoonosis with hundreds of different serovars with different pathogenicity for different species and humans as well as possible reservoir species such as rodents. Notification where antibodies are detected in a single sample is important as it is extremely significant for monitoring the disease in relation to its presence and possible spread.

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

A solution involving only a decision to repeal K20 without any additional requirements beyond those applicable under the EU Animal Health Regulation and the existing K12 has been discussed. However, as can be seen from the problem description above, regular animal health visits by veterinarians are now deemed to be a central part of our ability to maintain current levels of disease control. Without continued requirements concerning the frequency and content of animal health visits, we risk having a lower level of animal health. The industry's desire to maintain certain biosafety requirements was also considered relevant.

An alternative solution could have been to specify, in detail, in K12 the sampling to be carried out, instead of having a provision for sampling to be carried out in accordance with the adopted national surveillance plan. However, this would mean a lower degree of flexibility, which negatively affects the possibilities to make rapid changes to surveillance if necessary. A flexible solution is desirable and is also in line with the existing wording of K12.

In light of the above, the option to make the proposed regulatory changes to K12 was chosen.

With respect to the provisions not linked to K20, which concern the notification and the requirement to send certain isolates to the SVA:

- Chapter 3, Section 7: As regards the fish disease BKD and IPN genotype 2, the effect of no change would, in practice, be small. The SVA, which carries out the analyses in question, already reports suspected cases, despite the fact that doing so is not required by the legislation.
- Chapter 3, Section 14: If different laboratories in Sweden in the future have the possibility to use a methodology that will allow them to confirm ESBL$_{CARBA}$ in Enterobacterales, MRSA and MRSP by molecular biological methodology without prior phenotypic examination, the SVA will not have access to these isolates unless the proposed change is implemented. These isolates form an important part of Sweden's monitoring of resistant bacteria.
- Chapter 3, Section 23: Today, more and more animal keepers are seeking veterinary care in a different county than where the animal is normally kept. The county administrative boards are designated to exercise official controls over the activities of

keepers and veterinarians in accordance with the Swedish Board of Agriculture's regulations and general advice (SJVFS 2013:14) on prevention and special hygiene measures, etc. to prevent the spread of zoonoses and other infectious agents. This means that an animal that is tested, admitted or treated at a clinic/animal hospital in one county can actually be from another county. In case of an outbreak of ESBLcarba, MRSA or MRSP for example at the clinic/animal hospital, the county veterinarian in that county may not know that such a case is ongoing and the laboratory or, in some cases, the sample-taking veterinarian cannot share the necessary information with the county administrative board that exercises supervision over the clinic/animal hospital, for confidentially reasons (under Chapter 3, Section 8 and Section 23 of the current K12, they shall only share this information with the county administrative board in the county where the animal is located). This problem has become increasingly common in recent years and the proposed wording would allow a laboratory or, in some cases, the sample-taking veterinarian to share information with other county administrative boards concerned if there is a need to do so. If the proposed amendment is not implemented, the county administrative boards concerned will not always receive the information they need.

- Annex I: The impact if no change is made is that the quality of surveillance of the presence and spread of leptospirosis will be reduced. The Swedish Board of Agriculture's statistics will then give an incorrect picture of the prevalence of leptospirosis.

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, Swedish Board of Agriculture.

4. The veterinarians carrying out animal health visits.

5. The National Veterinary Institute (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. It is mainly larger operators that are covered, because of the size threshold described above.

With respect to the provisions not linked to K20, which concern the notification and the

requirement to send certain isolates to SVA, the following operators will be affected by the regulation:

- Chapter 3, Section 7: As regards the fish disease BKD and IPN genotype 2, the SVA is affected, as it is the laboratory that makes the notification in question.
- Chapter 3, Section 14: Laboratories using new methodology in the future, as described above. There are currently about ten laboratories that carry out relevant analyses and may be affected by the requirement to send isolates to the SVA. Most likely, not all laboratories will use this methodology. The size of the companies varies from those that are part of larger groups to smaller companies with a few employees. At just over half of the companies, analysis is not the company's main activity. These are primarily larger animal hospitals that have their own laboratory. All laboratories concerned also carry out other types of analysis and the analyses that are relevant for this regulatory amendment are only a small part of the total activity.
- Chapter 3, Section 23: Laboratories, or in some cases sample-taking veterinarians, who send a notification of a preliminary diagnosis must also send the notification to another county administrative board in cases where it is apparent from the medical history and referral that the animal has been sampled in one county but lives in another county.
- Annex I: Veterinary clinics and laboratories that diagnose leptospirosis with rapid antibody tests in blood (single sample).

4. Information about the authorisations on which the Swedish Board of Agriculture's decision-making power is based

The provisions are based on Sections 3-5, 6 and 9 of the Ordinance (2006:815) on animal testing, etc.

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

The current K20 specifies no thresholds as regards the size of breeding poultry establishments covered by the regulations. If the draft is compared with the actual wording of K20, the draft means that fewer establishments will be covered, due to the size thresholds introduced for the scope of the provisions. However, compared to how K20 has been applied in practice, the draft means that a few more establishments may be covered by the requirement for a defined minimum frequency for such animal health visits.

Animal health visits are a requirement laid down in the EU Animal Health Regulation, but without a regulated minimum frequency. The frequency shall be adjusted according to the risks at the establishments. If animal health visits have been conducted to date at lower intervals than those currently proposed, there will be an increased cost for businesses. According to the information we have been able to obtain, a few establishments may be affected by the more regular minimum frequency for animal health visits under the draft than they currently have in practice. This is because the K20 requirements have not been complied with, rather than because the actual requirements have been changed. Shortcomings in the current holding register limit the possibility of compiling reliable data on which establishments will have a changed minimum frequency for animal health visits.

Prior to the entry into force of the EU Animal Health Regulation, establishments which exported poultry more than 72 hours old and intended for restocking supplies of game birds were not subject to the requirement for approval under the EU Animal Health Regulation. As a result of the expanded approval requirement, these operators will also be covered by the draft provisions on animal health visits. In the absence of information on the current frequency of animal health visits to these establishments, we cannot estimate whether there will be any change as a result of the draft regulations.

Any increase in documentation or other administrative work that may arise in connection with animal health visits is considered to be very limited and affects primarily the animal health veterinarian and not the operator; such is part of the service provided by the veterinarian and should not be considered as an administrative burden. The draft amendments largely transfer the previous provisions into a new regulation.

With respect to the provisions that are not linked to K20, the draft contains some changes that can be seen as corrections:

- Chapter 3, Section 7: As regards the fish disease BKD and IPN genotype 2, no impact from the regulation is expected in practice. The notification is made through a short telephone call from the SVA to the Swedish Board of Agriculture. The requirement existed until 21 April 2021 and is now being reinstated.
- Chapter 3, Section 14: The cost impact of the provision is the cost of sending a confirmed isolate to the SVA. Corresponding provisions already exist for preliminary diagnosis in Section 8. At the moment, the draft regulations are not expected to have any impact on Swedish laboratories, but this is something that may become relevant in the future.
- Chapter 3, Section 23: The cost and other impacts are deemed to be marginal. Affected laboratories that need to send the notification to an additional county administrative board may need to spend some time identifying the county in which the sample-taking veterinarian operates. However, it is the same notification that must be sent to the affected county administrative boards. The increased time needed for laboratories, and in some cases sample-taking veterinarians, as a result of the regulation is deemed to be marginal.
- Annex I: The cost and other impacts are marginal. The requirement existed until 21 April 2021 and is now being reinstated.

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.

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

Entry into force should be synchronised with the update/revision of the national surveillance plan (NSP).

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 because the regulations need to be read as part of a whole, together with EU legislation and decisions on the national surveillance plan.

B Municipalities and county councils

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☒ The regulation is not deemed to impact municipalities or county councils.
The impact assessment therefore does not contain a description in point 8.

☐ The regulation is deemed to impact municipalities or county councils.

8. Description of impact on municipalities or county councils

Click or tap here to enter text.

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. Being engaged in business activities professionally should be interpreted broadly.

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☒ The regulation is not deemed to significantly impact the working conditions, competitiveness or other conditions of enterprises. 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 enterprises.

Our assessment is that the draft regulations should 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.

Enterprises with approved establishments are not placed at a significant disadvantage compared to European operators by the draft regulations.

The size thresholds are set to reflect the application of the provisions in force today. The industry has expressed its support for maintaining the national rules contained in the current regulations and has not deemed this to be negative from the point of view of competition.

Nor are the draft regulations deemed to entail any competitive disadvantage for small enterprises. On the contrary, small enterprises benefit because they can be exempted from rules on size thresholds.

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

Description of any early consultation

While preparing the amendments to the regulations, the Swedish Board of Agriculture held private consultation meetings with the industry associations Svenska Ägg, Svensk Fågel, Föreningen för smittskyddskontroll av fjäderfä, SweHatch and the SVA.

The Swedish Board of Agriculture held consultations with the SVA regarding the adaptation of sampling programmes and the future design of the NSP.

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