

Compliance of the Sikava and ISO 9001:2015 quality management system with the criteria for national quality schemes laid down in Regulation (EC) No 1974/2006 (Article 22(a)–(e))

Sikava activities of Animal Health ETT were most recently assessed as complying with the ISO 9001:2015 standard in spring 2021. The original ISO 9001:2008 certificate was granted in 2013.

The ISO 9001:2015 quality management system requires that Sikava activities be based on the provision of services that meet both customer requirements and legal and regulatory obligations. The ISO 9001:2015 system requires a documented and well-planned identification and analysis of Sikava's operating environment and stakeholders, including the identification of risks and opportunities. The ISO 9001:2015 standard also requires a process approach.

Sikava's quality system meets the requirements of ISO 9001:2015 and Sikava activities are systematically and actively developed in an on-going process of continuous improvement. Animal Health ETT's Sikava system has a strong and positive element of performance improvement.

Compliance of the Sikava system with the criteria for national quality schemes laid down in Commission Regulation (EC) No 1974/2006 (Article 22(a)–(e)).

Commission Regulation (EC) No 1974/2006, Article 22(2)(a)

a) the specificity of the final product under such schemes shall be derived from detailed obligations on farming methods that guarantee:

- specific characteristics including the production process, or*
- a quality of the final product that goes significantly beyond the commercial commodity standards as regards public, animal or plant health, animal welfare or environmental protection.*

According to Sikava Quality Manual (of 29 April 2021), the Sikava quality system was the first national quality scheme to be approved under the Food Act in 2013, which the consumer sees in the Quality Assurance label. The higher quality resulting from the approved quality scheme concerns live pigs that meet Sikava's national-level quality criteria and their lifetime until transport to a slaughterhouse. The criteria for approval are actions introduced to promote animal and public health that go significantly beyond the obligations laid down in legislation. These include the disease-free status of animal keeping locations within the sphere of the quality system as regards several infectious pig diseases and stricter testing requirements than those of the national salmonella control programme. Sikava has also developed and expanded its animal welfare activities. The level of animal welfare is demonstrated by a welfare index based on observations made during health visits (published on 6 February 2018). The welfare of pigs is measured using animal-based indicators, the information for which is collected during health visits, following the principles of the Welfare Quality® protocol.

All pig farms in Finland must comply with the legal requirements for keeping pigs, and compliance is supervised by the authorities. Sikava's national-level conditions are stricter than the legal requirements.

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Sikava activities go beyond the legal requirements in many respects (see the document comparing the Sikava quality system with the legal requirements of 1 December 2020).

The measures under the scheme are documented and are therefore traceable. The pig health monitoring system is continuously maintained, implemented and developed, and it is reliable. Documentation is available in a centralised web-based health classification register, which makes information collected during visits available in real time. The register will produce an alert if the entered values deviate from normal, for example, if pigs are found to have symptoms of a cough. Therefore, health monitoring is transparent and information about exceptional situations reaches the relevant parties quickly. Alerts and irregular situations can be responded to rapidly and in the extent necessary. Communication about irregular situations is also effective, with internal targeted communication, such as SMS, the Sikava website and the Sikava veterinary news service.

Specific crisis management measures that go beyond legal requirements have also been defined for acute outbreaks and situations when an acute disease outbreak is suspected. A designated crisis management team has also been appointed. The information in Sikava allows rapid response in the event of a crisis, including rapid risk assessment, tracing, planning/prioritisation of testing. The Sikava classification and the function for irregular situations is helpful for controlling animal transport logistics, and the Sikava alert and communication system enables rapid and targeted communication to producers, veterinarians and slaughterhouses, for example.

Veterinarians are given training to update their knowledge as the system evolves to ensure up-to-date and consistent actions. The continuous development of and expertise in pig health are ensured through the ETU pig expert group and the swine disease group of Animal Health ETT. The specialist expertise of Sikava employees is also maintained and developed through continuous training. Similarly, producers are trained about Sikava activities.

The Sikava health visit report has been updated (latest version 11 February 2020). In 2018, the report form was updated to include observations on behaviour that allows assessment of animal welfare:

- animal response to stimulus material
- animal response to the assessor and piglets' lying behaviour
- free-nursing in more than 50% of farrowing areas and a well-littered lying surface are further components of animal welfare monitoring.

Welfare indices are calculated every six months as averages over the past year. For comparison, an index is also always calculated for the most recent health visit. The index shows the level of animal welfare on each farm as compared to the index average for all Sikava pig-keeping units. In Sikava, the result of the index is illustrated using the traffic light colours. Deviations in welfare also trigger alerts in the Sikava system and are within the sphere of alert notifications and responses. The use and analysis of the animal welfare index exceeds legal requirements and shows that animal welfare monitoring goes beyond the level required by legislation (based on an assessment of the Sikava quality system on 1 December 2020). The health plan and the functionality, scope and issues addressed by the animal welfare index will be further developed in the Sikava system.

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Result: Based on the documentation and other evidence reviewed during the ISO 9001:2015 assessment, the Sikava system provides reliable and responsible information on the overall health and welfare of animals. The Sikava system is structured in a way that goes beyond the obligations of legislation, and the development of the system to promote animal health and welfare is significant and continuous.

Commission Regulation (EC) No 1974/2006, Article 22(2)(b)

b) the schemes involve binding product specifications and compliance with those specifications shall be verified by an independent inspection body;

From 1 May 2021, the Sikava health classifications are the following:

- Basic-level conditions from 1 June 2019
- Register-level conditions in addition to the basic-level conditions from 1 May 2021
- National-level conditions for all types of production in addition to the basic-level conditions from 1 May 2021

Sikava member companies operating in the slaughtering business require that their contract producers meet at least Sikava's national-level conditions. ([Sikava](#) see website, Sikava conditions for the health classification of pigs, as of 1 May 2021).

Internal audits of health care visits by Sikava veterinarians are carried out by EnviroVet Ltd. The auditors are veterinarians qualified as principal auditors for ISO 9001.

The compliance of the ISO 9001:2015 quality system with requirements is monitored by the accredited certification body Inspecta Sertifointi Oy (Kiwa Finland). The ISO 9001:2015 quality system's certification/monitoring assessment is carried out annually.

Result: Compliance with product specifications is monitored by independent bodies.

Commission Regulation (EC) No 1974/2006, Article 22(2)(c)

c) the schemes shall be open to all producers;

According to Sikava Quality Manual (of 29 April 2021), joining the scheme is voluntary for pig farms and Sikava is open to all pork producers. Sikava slaughterhouses require their contracted farms to be members of the Sikava system. Pig farms join Sikava by signing a health contract. When joining Sikava, pig farms are required to comply not only with official regulations but also with the guidelines issued by Animal Health ETT and Sikava.

Result: All producers of pork may join the Sikava system if they wish.

Commission Regulation (EC) No 1974/2006, Article 22(2)(d)

d) the schemes shall be transparent and assure complete traceability of the products;

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Access rights to the systems are described in detail in Sikava Quality Manual (of 29 April 2021). Sikava users are granted access rights on the basis of an application and each user group has its own user profile. Each user is only allowed to process the data which their user group is entitled to process. The addition of a new user group to Sikava is subject to the approval of the management group.

Health classification officer's rights are granted to Sikava or ETT personnel. Such rights can be granted to others only by the Sikava management group. The producer authorises veterinarians, Sikava employees, slaughterhouses and collaborating organisations to view the farm's information in the health classification register as part of the health contract. Upon request, the Sikava management group may also provide researchers with anonymously collected data from the Sikava system for research purposes. In the Sikava system, farms have an Authorisations section where they can check who is authorised to view the Sikava data for their farm. Public documents related to the Sikava quality system are available on the Sikava website www.sikava.fi.

The data in the Sikava system is fully traceable as regards animal health and welfare data for the lifetime of the animals.

Result: The system is transparent, taking into account the different user profiles, full traceability is possible for the lifetime of the animals

Commission Regulation (EC) No 1974/2006, Article 22(2)(e)

e) the schemes shall respond to current and foreseeable market opportunities.

The information in the Sikava system can be used for marketing purposes. Member companies can use Sikava data in their own marketing activities. For example. The Quality Assurance logo is used for the marketing of meat products. According to Sikava Quality Manual (of 29 April 2021), the Sikava management group decides at its meetings on issues related to data use, such as requests for the use of data for research and for Sikava interface cooperation or measures related to Quality Assurance rules. The Quality Assurance label shows that the opportunities provided by the certified, national Sikava quality system are being used.

Result: Current and foreseeable marketing opportunities are being taken into account in the activities

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