Commission Regulation (EU) 2017/894 of 24 May 2017 amending Annexes III and VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the genotyping of ovine animals (Text with EEA relevance)

COMMISSION REGULATION (EU) 2017/894

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[(1)], and in particular the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine and caprine animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

(2) Regulation (EC) No 999/2001 provides that each Member State is to carry out an annual monitoring programme for TSEs in accordance with Annex III thereto, which lays down rules for a monitoring system. Part II of Chapter A of that Annex lays down rules for monitoring in ovine and caprine animals and point 8.2 of Part II of that Chapter provides that all Member States are to determine the prion protein genotype for the codons 136, 141, 154 and 171 of a minimum sample of ovine animals, representative of the entire ovine population of the Member State, of at least 600 animals for Member States with an adult sheep population of more than 750 000 animals and of at least 100 animals for other Member States.

(3) Since the introduction of the random genotyping requirement set out point 8.2 of Part II of Chapter A of Annex III to Regulation (EC) No 999/2001, the original objectives of mapping scrapie susceptible sheep genotypes and identifying resistant sheep genotypes per country have been achieved. However, random genotyping of sheep remains useful in Member States which, in accordance with Article 6a of Regulation (EC) No 999/2001 and Chapter C of Annex VII thereto, carry out a breeding programme to select for resistance to TSEs in their ovine populations, and whose breeding programme aims at having an impact on the genetic profile of their overall ovine population. For those Member States, genotyping randomly a fraction of their entire ovine population allows them to assess whether the breeding programme in place has the desired impact, which

is to increase the frequency of the ARR allele while reducing the prevalence of those alleles which have been shown to contribute to susceptibility to TSEs.

(4) Chapter C of Annex VII to Regulation (EC) No 999/2001 sets out the minimum requirements for breeding programmes for resistance to TSEs in ovine animals in the Member States, and point 1 of Part 1 of that Chapter provides that the breeding programme is to concentrate on flocks of high genetic merit. The second paragraph of point 1 permits those Member States where a breeding programme is in place to decide to allow sampling and genotyping of breeding rams only, in flocks not participating in the breeding programme. That provision is used where the breeding programme of a Member State aims at having an impact on the genetic profile of the overall ovine population. Therefore, the random genotyping requirement set out in point 8.2 of Part II of Chapter A of Annex III to Regulation (EC) No 999/2001 should be limited to those Member States carrying out a breeding programme and which allow the sampling and genotyping of breeding rams in flocks not participating in the breeding programme.

(5) The Opinion of the Scientific Panel on Biological Hazards (BIOHAZ) on the Breeding programme for TSE resistance in sheep of 13 July 2006[(2)], of the European Food Safety Authority ('the EFSA Opinion'), considered that the current requirement laid down in point 8.2 of Part II of Chapter A of Annex III to Regulation (EC) No 999/2001 to randomly genotype 100 or 600 ovine animals per year, depending on the sheep population size of the Member State, seems inadequate to monitor the impact of a breeding programme on the overall ovine population of a Member State given the small sample size required. The EFSA Opinion recommended increasing the sampling size and noted that, assuming that the prevalence of the genotype targeted by the monitoring is 50 %, 1 560 animals would need to be tested each year to detect a change of 5 % in the genotype prevalence with a level of confidence of 95 %. Since a change of 5 % in the genotype prevalence at the level of the entire ovine population is unlikely to occur within a year, it is appropriate to carry out such random genotyping once every 3 years.

(6) The EFSA Opinion also recommended collecting epidemiological relevant data, such as the region, flock type and sex of the animal, for *a posteriori* adjustment and the monitoring of a proper sampling design. It is therefore appropriate to give Member States the possibility to determine the exact sampling size and frequency of their representative sampling and genotyping of their national sheep population, taking into account epidemiological data collected during previous sampling campaigns, provided that the sampling design allows at a minimum to detect a change of 5 % in genotype prevalence over a 3-year period, with a level of confidence of 95 %.

(7) The random genotyping requirement set out in point 8.2 of Part II of Chapter A of Annex III to Regulation (EC) No 999/2001 should therefore be deleted and replaced by a requirement set out in Part 1 of Chapter C of Annex VII to that Regulation laying down that Member States carrying out a breeding programme for ovine animals, and allowing the sampling and genotyping of breeding rams in flocks not participating in the breeding programme, should genotype a random sample of ovine animals, representative of the ovine population of the Member State, either of at least 1 560 animals once every 3

years, or of a sample size and at a frequency determined by the Member State based on criteria defined in the previous recital.

(8) Annexes III and VII to Regulation (EC) No 999/2001 should therefore be amended accordingly.

(9) Since the random genotyping is organised per calendar year, this amendment should become applicable on 1 January 2018.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes III and VII to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 May 2017.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Annexes III and VII to Regulation (EC) No 999/2001 are amended as follows:

(1) Annex III is amended as follows:

(a) in Chapter A, in Part II, point 8 is replaced by the following:

8. **Genotyping**

The prion protein genotype for the codons 136, 154 and 171 shall be determined for each positive TSE case in sheep. TSE cases found in sheep of genotypes which encode alanine on both alleles at codon 136, arginine on both alleles at codon 154 and arginine on both alleles at codon 171 shall immediately be reported to the Commission. Where the positive TSE case is an atypical scrapie case the prion protein genotype for the codon 141 shall also be determined.;

(b) in Chapter B, in Part I(A), point 8 is replaced by the following:

8. The genotype, and, where possible, the breed, of each ovine animal found positive to TSE and sampled in accordance with Chapter A, Part II, point 8.;

(2) in Annex VII, in Chapter C, in Part 1, the following point 8 is added:

8. Where the Member State allows, in accordance with the second paragraph of point 1, the sampling and genotyping of breeding rams in flocks not participating in the breeding programme, the prion protein genotype for the codons 136, 141, 154 and 171 shall be determined for a minimum sample representative of the entire ovine population of the Member State, either:

(a) once every 3 years with a minimum sample of at least 1 560 ovine animals; or

(b) at a frequency and with a sample size determined by the Member State based on compliance with the following criteria:

(i) the sampling design takes into account relevant epidemiological data collected during previous surveys, including data concerning the prion protein genotype of sheep for the codons 136, 141, 154 and 171 by breed, region, age, sex and flock type;

(ii) the sampling design allows at a minimum to detect a change of 5 % in genotype prevalence over a 3-year period, with a 80 % power and 95 % confidence level.

(**1**) OJ L 147, 31.5.2001, p. 1.

(**2**) *EFSA Journal* (2006) 382, 1-46.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2017/894.