COMMISSION DELEGATED REGULATION (EU) …/…

of XXX

amending Delegated Regulation (EU) No 639/2014 as regards the control measures regarding the cultivation of hemp

THE EUROPEAN COMMISSION,


Whereas:

(1) According to Article 35(3) of Regulation (EU) No 1307/2013 the Commission is empowered to adopt delegated acts making the granting of payments conditional upon the use of certified seeds of certain hemp varieties and the procedure for the determination of hemp varieties and the verification of their tetrahydrocannabinol content referred to in Article 32(6) of the same Regulation. At present, the delegated rules included in Article 9 of Commission Delegated Regulation (EU) No 639/2014 only refer to the obligation to use seed of the varieties listed in the ‘Common Catalogue of Varieties of Agricultural Plant and that the seeds have to be certified in accordance with Council Directive 2002/57/EC. The rules for the determination of hemp varieties and the verification of their THC content rules were previously established in former Article 45 and former Annex of Commission Implementing Regulation (EU) No 809/2014². Since they were not covered by the empowerment referred to in Article 62(2)(e) of Regulation (EU) No 1306/2013 of the European Parliament and Council³, they were repealed by Commission Implementing Regulation (EU) No XXX/2016. It is thus appropriate to transfer the content of former


(2) The procedure for determination of hemp varieties and the verification of the THC content are well adapted for hemp cultivated as main crop, but are not fully suitable for hemp cultivated as catch crop while this cultivation method is appropriate for industrial hemp and compatible with environmental requirements. It is therefore appropriate to adapt both provisions to take into account the characteristics of the hemp cultivated as catch crop.

(3) The drafting of former article 45 of Regulation (EU) No 809/2014, integrated in Article 9 of Delegated Regulation (EU) No 639/2014 through this Regulation, is clarified concerning the Member States obligation to notify the Commission their request for authorising the marketing prohibition of a specific hemp variety.

(4) Delegated Regulation (EU) No 639/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) No 639/2014 is amended as follows:

(1) In Article 9, the following paragraphs are added: [changes from the original Article 45 of 809/2014 are underlined in yellow]

2. "For the purposes of Article 32(6) of Regulation (EU) No 1307/2013, Member States shall establish the system in order to determine the tetrahydrocannabinol content (hereinafter referred to as ‘THC’) of the crops grown as set out in Annex II to this Regulation.

3. The competent authority of the Member State shall keep the records related to findings on the THC content. Such records shall comprise for each variety at least the results in terms of THC content from each sample expressed in percentage to two decimal places, the procedure used, the number of tests carried out, an indication of the point at which the sample was taken and measures taken at national level.

4. If an average of all the samples of a given variety exceeds the THC content as laid down in Article 32(6) of Regulation (EU) No 1307/2013, Member States shall use procedure B of Annex II to this Regulation for the variety concerned in the course of the following claim year. This procedure shall be used in the course of the next claim years unless all the analytical results for the given variety are below the THC content as laid down in Article 32(6) of Regulation (EU) No 1307/2013.

5. If for the second year the average of all the samples of a given variety exceeds the THC content as laid down in Article 32(6) of Regulation (EU) No 1307/2013, the Member State shall notify the Commission the request for authorisation to prohibit the marketing of such variety in accordance with Article 18 of Council Directive 2002/53/EC. Such notification shall be sent by 15 January of the following claim year at the latest. From the following claim year (is it clear enough that this is year N+2 with year N being the 1st year with avg of all samples exceeding THC content?)

the variety subject of this request is not eligible for direct payments in the Member State concerned.

6. Hemp cultivated as main crop shall continue to be cultivated under normal growing conditions in accordance with local practice for at least 10 days from the date of the end of flowering so that the checks provided for in paragraphs 1, 2 and 3 can be made.

7. However, Member States may authorise hemp to be harvested after flowering has begun but before the end of the 10-day period after the end of flowering, provided the inspectors indicate which representative parts of each plot concerned must continue to be cultivated for at least 10 days following the end of flowering for inspection purposes, in accordance with the method laid down in Annex II.

8. Hemp cultivated as catch crop shall continue to be cultivated under normal growing conditions in accordance with local practice at least until the end of the vegetation period.

9. The notification referred to in paragraph 5 shall be made in accordance with Commission Regulation (EC) No 792/2009.

(2) A new Annex is added as follows:

ANNEX II [changes from the original Annex of 809/2014 are underlined in yellow]

Community method for the quantitative determination of Δ9-tetrahydrocannabinol content in hemp varieties

1. Scope and area of application

This method seeks to determine the Δ9-tetrahydrocannabinol (hereinafter referred to as THC) content of varieties of hemp (Cannabis sativa L.) As appropriate, the method involves applying procedure A or B herein described.

The method is based on the quantitative determination of Δ9-THC by gas chromatography (GC) after extraction with a suitable solvent.

1.1. Procedure A

Procedure A shall be used for checks on production as provided for in Article 32(6) of Regulation (EU) No 1307/2013 and Article 30(g) of Regulation (EU) No 809/2014.

1.2. Procedure B

Procedure B shall be used in cases as referred to in Article 32(6) of Regulation (EU) No 1307/2013 and Article 36(6) of Regulation (EU) No 809/2014.

2. Sampling

2.1. Samples

(a) Procedure A

(1) (aa) hemp cultivated as main crop

5 Commission Regulation (EC) No 792/2009 of 31 August 2009 laying down detailed rules for the Member States’ notification to the Commission of information and documents in implementation of the common organisation of the markets, the direct payments’ regime, the promotion of agricultural products and the regimes applicable to the outermost regions and the smaller Aegean islands (OJ L 228, 1.9.2009, p. 3).
In a standing crop of a given variety of hemp, a 30 cm part containing at least one female inflorescence of each plant selected shall be taken. Sampling shall be carried out during the period running from 20 days after the start of flowering to 10 days after the end of flowering, during the day, following a systematic pattern to ensure that the sample is representative of the field but excluding the edges of the crop.

Member States may authorise sampling to be carried out during the period from the start of flowering to 20 days after the start of flowering provided that, for each variety grown, other representative samples are taken in accordance with the first subparagraph during the period from 20 days after the start of flowering to 10 days after the end of flowering.

(2) (ab) hemp cultivated as catch crop

In a standing crop of a given variety of hemp, a 30 cm part containing at least one female inflorescence of each plant selected shall be taken, or the top 30 cm of the plant stem if there are no female inflorescences. Sampling shall be carried out just before the end of the vegetation period, once the leaves begin presenting the first signs of yellowing, however no later than the onset of a forecast period of frost, during the day, following a systematic pattern to ensure that the sample is representative of the field but excluding the edges of the crop.

(b) Procedure B: in a standing crop of a given variety of hemp, the upper third of each plant selected shall be taken. Sampling shall be carried out during the 10 days following the end of flowering or, for hemp cultivated as catch crop, just before the end of the vegetation period, once the leaves begin presenting the first sign of yellowing, but no later than the onset of a forecast period of frost, during the day, following a systematic pattern to ensure that the sample is representative of the field but excluding the edges of the crop. In the case of dioecious varieties, only female plants shall be taken.

2.2. Sample size

Procedure A: the sample shall comprise parts of 50 plants per field.

Procedure B: the sample shall comprise parts of 200 plants per field.

Each sample shall be placed in a fabric or paper bag, without crushing it, and be sent to the laboratory for analysis.

The Member State may provide for a second sample to be collected for counteranalysis, if required, to be kept either by the producer or by the body responsible for the analysis.

2.3. Drying and storage of the sample

Drying of the samples shall begin as soon as possible and, in any case, within 48 hours using any method below 70 °C.

Samples shall be dried to a constant weight and to a moisture content of between 8 % and 13 %.

After drying, the samples shall be stored without crushing them at below 25 °C in a dark place.

3. Determination of THC content

3.1. Preparation of the test sample

Stems and seeds over 2 mm in size shall be removed from the dried samples.

The dried samples shall be grinded to obtain a semi-fine powder (passing through a 1 mm mesh sieve).
3.2. The powder may be stored for 10 weeks at below 25 °C in a dark, dry place. 

Reagents and extraction solution.

Reagents

– Δ9-tetrahydrocannabinol, pure for chromatographic purposes,
– Squalane, pure for chromatographic purposes, as an internal standard.

Extraction solution

– 35 mg of squalane per 100 ml hexane.

3.3. Extraction of Δ9-THC

100 mg of the powdered test sample shall be weighed, be placed in a centrifuge tube and 5 ml of extraction solution shall be added containing the internal standard.

The sample shall be placed in an ultrasound bath and be left for 20 minutes. It shall be centrifuged for five minutes at 3 000 r.p.m. and then the supernatant THC solution shall be removed. The solution shall be injected into the chromatograph and a quantitative analysis shall be carried out.

3.4. Gas chromatography

(a) Apparatus

– gas chromatograph with a flame ionisation detector and a split/splitless injector,
– column allowing good separation of cannabinoids, for example a glass capillary column 25 m long and 0.22 mm in diameter impregnated with a 5 % non-polar phenyl-methyl-siloxane phase.

(b) Calibration ranges

At least three points for procedure A and five points for procedure B, including points 0.04 and 0.50 mg/ml Δ9-THC in extraction solution.

(c) Experimental conditions

The following conditions are given as an example for the column referred to in (a):

– oven temperature 260 °C
– injector temperature 300 °C
– detector temperature 300 °C

(d) Volume injected: 1 μl

4. Results

The findings shall be expressed to two decimal places in grams of Δ9-THC per 100 grams of analytical sample dried to constant weight. A tolerance of 0.03 g per 100 g shall apply.

– Procedure A: one determination per test sample.

However, where the result obtained is above the limit laid down in Article 32(6) of Regulation (EU) No 1307/2013, a second determination shall be carried out per analysis sample and the mean value of the two determinations shall be taken as the result.

– Procedure B: the result shall correspond to the mean value of two determinations per test sample.'
Article 2

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

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER