



2024/1768

27.6.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1768

of 26 June 2024

approving the basic substance *Onobrychis viciifolia* (sainfoin) dried pellets in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 23(5) in conjunction with Article 13(2) thereof,

Whereas:

- (1) On 18 March 2021, the Commission received an application from Multifolia Sas for the approval of *Onobrychis viciifolia* (sainfoin) dried pellets as a basic substance to be used in plant protection as a nematicide in grapevines.
- (2) After the admissibility check, the application, as received in March 2021, was accompanied by the information required under Article 23(3), second subparagraph, of Regulation (EC) No 1107/2009.
- (3) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance pursuant to Article 23(4) of Regulation (EC) No 1107/2009. The Authority provided the Commission with a technical report on *Onobrychis viciifolia* (sainfoin) dried pellets on 9 December 2022 ⁽²⁾.
- (4) The Commission presented the review report ⁽³⁾ and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 21 March 2024 and 23 May 2024, respectively.
- (5) The information provided by the applicant shows that *Onobrychis viciifolia* (sainfoin) dried pellets is currently on the market as animal feed and as a fertiliser. Moreover, it is not predominantly used for plant protection purposes, but *Onobrychis viciifolia* (sainfoin) dried pellets is useful in plant protection. Based on the information provided in the application and the technical report from the Authority, it can also be concluded that *Onobrychis viciifolia* (sainfoin) dried pellets is not a substance of concern. It does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects and is not placed on the market as a plant protection product. Consequently, *Onobrychis viciifolia* (sainfoin) dried pellets meets the conditions set out in Article 23(1) of Regulation (EC) No 1107/2009.
- (6) No relevant evaluation, carried out in accordance with other Community legislation was available.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

⁽²⁾ EFSA (European Food Safety Authority), 2023. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of sainfoin (*Onobrychis viciifolia* var. Perly) dried pellets to be used in plant protection as a nematicide in grapevines (EFSA supporting publication 2023:EN-7763, 94 pp., doi:10.2903/sp.efsa.2023.EN-7763).

⁽³⁾ Final Review report for the basic substance *Onobrychis viciifolia* (sainfoin) dried pellets finalised by the Standing Committee on Plants, Animals, Food and Feed on 23 May 2024 in view of the approval of *Onobrychis viciifolia* (sainfoin) dried pellets as basic substance in accordance with Regulation (EC) No 1107/2009.

- (7) After examination of the application and all related documents, it may be expected that *Onobrychis viciifolia* (sainfoin) dried pellets satisfies, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve *Onobrychis viciifolia* (sainfoin) dried pellets as a basic substance.
- (8) The Commission invited the applicant to submit its comments on the technical report of the Authority and on the Commission's draft review report. The applicant submitted its comments, which have been carefully examined.
- (9) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions for the approval.
- (10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾ should be amended accordingly.
- (11) 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

Approval of a basic substance

The substance *Onobrychis viciifolia* (sainfoin) dried pellets as specified in Annex I is approved as a basic substance subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth 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, 26 June 2024.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Specific provisions
<i>Onobrychis viciifolia</i> (sainfoin) dried pellets CAS No: Not available CIPAC No: Not available	Not available	1 000 g/kg Relevant impurities: Arsenic (1 g/kg), Cadmium (0,1 g/kg), Chromium-VI (0,1 g/kg), Mercury (1 g/kg), Nickel (0,1 g/kg), Lead (0,3 g/kg)	17 July 2024	<i>Onobrychis viciifolia</i> (sainfoin) dried pellets shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Onobrychis viciifolia</i> (sainfoin) dried pellets (PLAN/2024/790 RR rev1) and in particular Appendices I and II thereof.

(1) Further details on identity, specification and manner of use of the basic substance are provided in the review report.

In Part C of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Specific provisions
'26	<i>Onobrychis viciifolia</i> (sainfoin) dried pellets CAS No: Not available CIPAC No: Not available	Not available	1 000 g/kg Relevant impurities: Arsenic (1 g/kg), Cadmium (0,1 g/kg), Chromium-VI (0,1 g/kg), Mercury (1 g/kg), Nickel (0,1 g/kg), Lead (0,3 g/kg)	17 July 2024	<i>Onobrychis viciifolia</i> (sainfoin) dried pellets shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Onobrychis viciifolia</i> (sainfoin) dried pellets (PLAN/2024/790 RR rev1) and in particular Appendices I and II thereof.

(1) Further details on identity, specification and manner of use of basic substance are provided in the review report.'