



Basic Substance

Onobrychis viciifolia (sainfoin) dried pellets ⁽¹⁾
PLAN/2024/790 RR rev2
23 May 2024

Final Review report for the basic substance
Onobrychis viciifolia (sainfoin) dried pellets
finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting 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

1. PROCEDURE FOLLOWED FOR THE EVALUATION PROCESS

This review report has been established as a result of the evaluation of an application for the approval of *Onobrychis viciifolia* (sainfoin) dried pellets as basic substance provided for in Article 23 of Regulation (EC) No 1107/2009 ⁽²⁾ concerning the placing of plant protection products on the market.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 18 March 2021 an application from Multifolia Sas, hereafter referred to as the applicant, for the approval of the substance *Onobrychis viciifolia* (sainfoin) dried pellets as basic substance to be used in plant protection as a nematicide in grapevines.

The application and attached information were distributed to the Member States and the European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application, which was finalised in a new version in September 2022.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission requested scientific assistance on the evaluation of the application from EFSA, who delivered its views on the specific points raised in the commenting phase.

⁽¹⁾ Report established in accordance with Art. 13 of Regulation (EC) No 1107/2009; does not necessarily represent the views of the European Commission.

⁽²⁾ OJ L 309, 24.11.2009, p. 1-50.

EFSA submitted to the Commission the results of its work in the form of a Technical Report for *Onobrychis viciifolia* (sainfoin) dried pellets on 8 December 2022 ⁽³⁾.

The Commission examined the application, the comments by Member States and EFSA and the EFSA Technical Report on the substance together with the additional information and comments provided by the applicant, before preparing the draft Review Report. The draft Review Report was referred to the Standing Committee on Plants, Animals, Food and Feed for examination and was finalised in the meeting of 23 May 2024.

The present Review Report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA Technical Report, and the comments and clarifications submitted, all these documents are also considered to be part of this Review Report.

2. PURPOSES OF THIS REVIEW REPORT

This Review Report, including the background documents and appendices thereto, has been developed in support of the **Commission Implementing Regulation (EU) 2024/1768⁽⁴⁾** concerning the approval of *Onobrychis viciifolia* (sainfoin) dried pellets as basic substance under Regulation (EC) No 1107/2009.

The review report will be published and made available to any interested party.

Without prejudice to the provisions of Regulation (EC) No 178/2002 ⁽⁵⁾, in particular with respect to the responsibility of operators, following the approval of *Onobrychis viciifolia* (sainfoin) dried pellets as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and the conditions established in sections 4 and 5, and Appendices I and II of this review report.

EFSA has made available to the public all background documents and its final Technical Report as well as the application without the Appendices in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with the derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence, no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

⁽³⁾ 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 nematocide in grapevines. EFSA supporting publication 2023:EN-7763. 94 pp. doi:10.2903/sp.efsa.2023.EN-7763.

⁽⁴⁾ OJ L, 2024/1768, 27.6.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/1768/oj.

⁽⁵⁾ OJ L 31, 1.2.2002 p. 1-24 - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

3. OVERALL CONCLUSION IN THE CONTEXT OF REGULATION (EC) No 1107/2009

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, and the comments and additional information provided by the applicant to address the open points identified in the Technical Report from EFSA, is that there are clear indications that it may be expected that *Onobrychis viciifolia* (sainfoin) dried pellets fulfils the criteria of Article 23 for the uses specified in Appendix II.

The *Onobrychis viciifolia* (sainfoin) dried pellets are composed of material of botanical origin produced by dehydration and compression of aerial parts of the plant sainfoin that belongs to the family *Fabaceae*, genus *Onobrychis* and species *Onobrychis viciifolia*. *Onobrychis viciifolia* (sainfoin) dried pellets are used as an animal feed and as a fertiliser.

The proposed use as basic substance is as a pre-emergence nematicide against *Xiphinema index* in grapevines applied by spreading the pellets onto the soil, followed by incorporating the pellets into the soil at an application rate of 10 tonnes per ha per year.

Considering the absence of a harmonised classification of the main components (quercetin and its derivatives) according to ECHA's Classification and Labelling Inventory ⁽⁶⁾ and the limited exposure to the substance; it can reasonably be assumed that *Onobrychis viciifolia* (sainfoin) dried pellets should not be considered as a substance of concern.

Potential safety concerns, including endocrine disrupting properties, of the main components and information on the exposure for operators, workers, bystanders and residents have not been properly addressed in the basic substance application. Additionally, according to the self-classifications provided by companies to ECHA and harmonised classification according to Regulation (EC) No 1272/2008, there is evidence that components of *Onobrychis viciifolia* (sainfoin) dried pellets may have to be classified, or are classified, as serious eye irritant, respiratory irritant and also as causing skin irritation. However, the components are ubiquitous in plant sources and they are common in the human diet. It can therefore be assumed that *Onobrychis viciifolia* (sainfoin) dried pellets would not lead to exposures above those already occurring, so that safety concerns are not triggered. In fact, with regard to residues in food and feed, EFSA indicated that in combination with a low probability for residues on grapes and leaves due to the specific application method (incorporation of pellets into the soil), it can be reasonably assumed that exposure to the main components through the diet is higher than the exposure from the requested use of *Onobrychis viciifolia* (sainfoin) dried pellets for plant protection in grapevines.

Based on the provided information and the fact that the pellets are composed of natural substances, EFSA concluded that the environmental exposure from the proposed application rate as a basic substance is comparable with the exposure resulting from the permitted uses in France as a fertiliser *Onobrychis viciifolia* (sainfoin) dried pellets.

Considering that the proposed application rate is comparable with the exposure resulting from the permitted uses as fertiliser and adverse effects have not been reported, this indicates that *Onobrychis viciifolia* (sainfoin) dried pellets has a favourable ecotoxicological profile. EFSA therefore concluded a low risk for birds and mammals (wild), soil micro-

(6) <https://echa.europa.eu/regulations/clp/cl-inventory>.

organisms and aquatic organisms, bees and other arthropods species, biological methods of sewage treatment and other non-target organisms (flora and fauna).

Therefore, considering the EFSA Technical Report and the conditions of use which are described in detail in Appendices I and II, it is concluded that the use of the *Onobrychis viciifolia* (sainfoin) dried pellets would not lead to concerns for human health. Furthermore, no residues or unacceptable effects on the environment are expected for this use.

Onobrychis viciifolia (sainfoin) dried pellets is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Finally, it is not placed on the market as a plant protection product.

Overall, it can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the preparation for use in Appendix I and for the uses as described in Appendix II.

These conclusions were reached within the framework of the uses which were supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Union level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

4. IDENTITY AND BIOLOGICAL PROPERTIES

The properties of *Onobrychis viciifolia* (sainfoin) dried pellets are given in Appendix I.

The *Onobrychis viciifolia* (sainfoin) dried pellets are composed of material of botanical origin produced by dehydration and compression of aerial parts of the plant sainfoin that belongs to the family *Fabaceae*, genus *Onobrychis* and species *Onobrychis viciifolia*.

5. PARTICULAR CONDITIONS TO BE TAKEN INTO ACCOUNT IN RELATION TO THE USES AS BASIC SUBSTANCE OF *ONOBRYCHIS VICIIFOLIA* (SAINFOIN) DRIED PELLETS

Onobrychis viciifolia (sainfoin) dried pellets must be identified by the given specifications in Appendix I and must be used in compliance with the method of preparation and conditions of use as reported in Appendices I and II.

6. LIST OF STUDIES TO BE GENERATED

No further studies were identified which were at this stage considered necessary.

7. UPDATING OF THIS REVIEW REPORT

The information in this report may require to be updated from time to time to take account of technical and scientific developments, as well as of the results of the examination of any information referred to the Commission in the framework of Article 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection, as appropriate, with any amendment of the approval conditions for the *Onobrychis viciifolia* (sainfoin) dried pellets in Part C of Annex of the Regulation (EC) No 540/2011 ⁽⁷⁾.

8. RECOMMENDED DISCLOSURE OF THIS REVIEW REPORT

Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will not be placed on the market as plant protection product hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users of the substance on the existence of this review report.

Further to the publication of this review report, it is recommended that the competent authorities of Member States will make it additionally available to the general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

⁽⁷⁾ OJ L 153, 11.6.2011, p. 1–186.

APPENDIX I
Identity and biological properties
Onobrychis viciifolia (sainfoin) dried pellets

Common name (ISO)	N/A
Chemical name (IUPAC)	N/A
Chemical name (CA)	N/A
Common names	Sainfoin (<i>Onobrychis viciifolia</i>) dried pellets
CAS No	N/A
CIPAC No and EEC No	N/A
FAO specification/ specification in another regulatory context, if available	N/A
Minimum purity	1000 g/kg
Relevant impurities	Arsenic (1 g/kg), Cadmium (0.1 g/kg), Chromium-VI ⁽⁸⁾ (0.1 g/kg), Mercury (1 g/kg), Nickel (0.1 g/kg), Lead (0.3 g/kg)
Molar mass and structural formula	N/A
Mode of Use	Granule application via manure spreading (spreading the pellets onto the soil, followed by incorporating them into the soil)
Preparation to be used	Granule (GR) - dehydrated and compressed pellets from the aerial parts of the plant sainfoin that belongs to the family <i>Fabaceae</i> , genus <i>Onobrychis</i> and species <i>Onobrychis viciifolia</i> .
Function of plant protection	Nematicide

⁽⁸⁾ It is noted that the oxidation state for impurity Cr was not specified in the BSA and therefore it is not known whether Cr is present as VI or not. In case it is present in this oxidation state (i.e. Cr VI), it is considered a relevant impurity being classified. Otherwise, Cr is not classified according to the CLP Regulation.

APPENDIX II
List of uses supported by available data
***Onobrychis viciifolia* (sainfoin) dried pellets**

Crop and/ or situation (a)	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			Remarks*
				Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l)	
Grapevine* Vitis vinifera VITVI	Vitifolia	F	<i>Xiphinema</i> <i>index</i> (XIPHSP)	GR	1000	Manure spreading Soil incorporation is advised	BBCH0 Autumn or Spring On disease spots	1	*	Not applicable	0	10 000 kg/ha 1 000 g/m ²	Already used at a recommended rate of 3500 kg/ha and assessed as appropriate to use at 10 T/ha/year according to standard NFU44-051

* 1 per year

- (a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
- (e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
- (i) g/kg or g/L. Normally the rate should be given for the substance (according to ISO)
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval