Commission Implementing Regulation (EU) 2018/1133 of 13 August 2018 authorising the placing on the market of dried aerial parts of Hoodia parviflora as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1133

of 13 August 2018

authorising the placing on the market of dried aerial parts of *Hoodia parviflora* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001[(1)], and in particular Article 12 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470[(2)] was adopted, which establishes a Union list of authorised novel foods.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.

(4) On 21 October 2014, the company Desert Labs, Ltd ('the applicant') made a request to the competent authority of Ireland to place dried aerial parts of *Hoodia parviflora* on the Union market as a novel food within the meaning of point (e) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council[(3)]. The application requests for dried aerial parts of *Hoodia parviflora* to be used in foods including beverages, biscuits, confectionary, savoury snacks, soups and broths, tea, coffee and water. It is also intended for use in food supplements.

(5) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not

been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.

(6) While the request for placing dried aerial parts of *Hoodia parviflora* on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.

(7) On 24 August 2015, the competent authority of Ireland issued its initial assessment report. In that report, it came to the conclusion that dried aerial parts of *Hoodia parviflora* meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(8) On 28 August 2015, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by some Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 with regard to insufficient characterisation of the novel food, limited assessment of allergenicity, insufficient data to exclude the risk for children older than 12 years, insufficient information on the specifications, stability, intake assessment and on toxicological data.

(9) In view of the objections raised by some Member States, the Commission consulted the European Food Safety Authority ('the Authority') on 25 January 2016, asking it to carry out an additional assessment for dried aerial parts of *Hoodia parviflora* as novel food in accordance with Regulation (EC) No 258/97.

(10) On 20 September 2017, the Authority adopted 'Scientific Opinion on the safety of dried aerial parts of *Hoodia parviflora* as a novel food pursuant to Regulation (EC) No 258/97'[(4)]. That opinion, although elaborated and adopted by the Authority under Regulation (EC) No 258/97 is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(11) In its opinion, the Authority did not establish the safety of dried aerial parts of *Hoodia parviflora* in foods at the uses and use levels proposed by the applicant because the intake would exceed the level which is considered as safe (0,134 mg/kg bw). However, the Authority concluded that dried aerial parts of *Hoodia parviflora* are safe for adults when added to food supplements at a maximum daily dose of 9,4 mg which corresponds to the safe level of intake for an adult with a default body weight of 70 kg.

(12) That opinion gives sufficient grounds to establish that dried aerial parts of *Hoodia parviflora* in the proposed uses and use levels when used as an ingredient in food supplements, comply with Article 12(1) of Regulation (EU) 2015/2283.

(13) On 24 January 2018, the applicant made a request to the Commission for protection of proprietary data for two studies submitted in support of the application namely, reports of the 14-day dose-finding oral toxicity study of dried aerial parts of *Hoodia parviflora*[(5)], and of the 90-day oral toxicity study[(6)], served as basis for the Bench Mark Dose (BMD) analysis and for deriving safe intake levels for human.

(14) On 18 February 2018, the Authority considered[7] that in elaborating its opinion on dried aerial parts of *Hoodia parviflora* as a novel food the data from the report of the 90-day oral toxicity study served as basis for the BMD analysis and for deriving safe intake levels for humans. Therefore, it is considered that the conclusions on the safety of dried aerial parts of *Hoodia parviflora*, could not have been reached without the data from the report of that study.

(15) Following the receipt of the Authority's opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the study, and their claim to an exclusive right of reference to that study, as referred to in points (a) and (b) of Article 26(2) of Regulation (EU) 2015/2283.

(16) The applicant has also declared that, at the time the application was submitted, it held proprietary and exclusive rights of reference to the study under national law and that therefore third parties could not lawfully access or use that study. The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283.

(17) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the 90-day oral toxicity study contained in the applicant's file should not be used by EFSA for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the applicant for a period of five years.

(18) However, restricting the authorisation of this novel food and of the reference to the study contained in the applicant's file for the sole use of the applicant does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting the authorisation under this Regulation.

(19) Directive 2002/46/EC of the European Parliament and of the Council[8] lays down requirements on food supplements. The use of dried aerial parts of *Hoodia parviflora* should be authorised without prejudice to that Directive.

(20) 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

1 Dried aerial parts of *Hoodia parviflora* as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2 For a period of five years from the date of entry into force of this Regulation only the Applicant:

Company: Desert Labs, Ltd

Address: Kibbutz Yotvata, 88820, Israel

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the same novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Desert Labs, Ltd.

3 The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

4 The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

Article 2

The study contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the applicant as fulfilling the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Desert Labs, Ltd.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 4

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, 13 August 2018.

For the Commission

The President

Jean-Claude JUNCKER