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## Safety of whey basic protein isolate for extended uses in foods for special medical purposes and food supplements for infants pursuant to Regulation (EU) 2015/2283

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### Abstract

In 2018, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) concluded that whey basic protein isolate obtained by ion exchange chromatography from skimmed cow's milk is safe for human consumption under the proposed conditions of use as infant and follow on formula, meal replacement beverages, foods for special medical purposes and food supplements. Following a request from the European Commission, the EFSA NDA Panel was asked to deliver a scientific opinion on whey basic protein isolate for extended uses in foods for special medical purposes and food supplements for infants as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The applicant seeks to extend the conditions of use to infant (powder 30 mg/100 g and reconstituted 3.9 mg/100 mL) and follow on formulae (powdered 30 mg/100 g and reconstituted 4.2 mg/100 mL) as foods for special medical purposes as well as in food supplements for infants (25 mg/day). The Panel considers that the proposed extended uses would not increase the potential intake of the NF compared to that assessed in its 2018 opinion. The Panel concludes that whey basic protein isolate is safe at the extended uses and use levels.

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## Summary

The European Commission implementing regulation (EU) 2018/1632 authorised, in accordance with Regulation (EC) 2283/2015 and following the European Food Safety Authority (EFSA)'s Opinion, the placing on the market of whey protein isolates as a novel food (NF) ingredient to be used in infant and follow on formulae, total diet replacements, foods for special medical purposes and food supplements.

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver a scientific opinion on whey basic protein isolate for extended uses in foods for special medical purposes and food supplements for infants as a NF pursuant to Regulation (EU) 2015/2283. The assessment of the safety of this NF, which follows the methodology set out in the EFSA Guidance on the preparation and presentation of an application for authorisation of a novel food Regulation (EU) 2015/2283 and in the European Commission implementing Regulation (EU) 2017/2469, is based on the data supplied in the application.

In 2018, the EFSA NDA Panel concluded that whey basic protein isolates obtained by ion exchange chromatography from skimmed cow's milk was safe for human consumption under the proposed conditions of use. In the application subject of that assessment, the applicant intended to target the NF to infants (infant and follow-on formulae), the general adult population (meal replacement beverages) and the general population above 1 year of age (foods for special medical purposes (FSMP) and food supplements). The Panel considered margins of exposure (MOE) of 81, 72 and 154 to be sufficient for infants, toddlers and the adult population, respectively.

The applicant intends to market the use of the NF in FSMP and food supplements as alternative sources to its use in infant and follow on formula. The Panel notes that the use levels for the FSMP formulae for infants proposed by the applicant are identical to the use levels of the NF for infant and follow on formulae assessed by EFSA in 2018. Considering a combined intake of 5 mg/kg body weight (bw) per day from food supplements plus 20 mg/kg bw per day from either FSMP formula or from the authorised use in infant and follow-on formula, the MOE would result to 80 which is considered sufficient by the Panel, in line with the conclusions of its Opinion from 2018.

The Panel concludes that the NF, whey basic protein isolate, is safe under the new proposed conditions of use.

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## 1. Introduction

### 1.1. Background and Terms of Reference as provided by the European Commission

On 10 October 2018, the company Armor Protéines S.A.S. submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) No 2015/2283<sup>1</sup> to update the entry for Bovine Milk Basic Whey Protein Isolate in the Union list of authorised novel foods entry to extent its uses in food supplements and foods for special medical purposes for infants up to 12 months of age.

In accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asks the European Food Safety Authority to provide a scientific opinion by carrying out the assessment for the extension of use of the novel food Bovine Milk Basic Whey Protein Isolate.

## 2. Data and methodologies

### 2.1. Data

The assessment of the safety of whey protein isolates at the new proposed uses and use levels is based on the data provided by the applicant and the scientific opinion on the safety of whey basic protein isolates (EFSA NDA Panel, 2018).

### 2.2. Methodologies

The assessment follows the methodology set out in the EFSA guidance on novel food (NF) applications and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of Regulation (EU) 2015/2283 and in Article 7 of the Commission Implementing Regulation (EU) 2017/2469.

This assessment concerns only risk that might be associated with consumption of the NF under the proposed conditions of use, and is not an assessment of the efficacy of whey basic protein isolate with regard to any claimed benefit.

## 3. Assessment

On 27 June 2018, the EFSA NDA Panel concluded that whey basic protein isolates obtained by ion exchange chromatography of skimmed cow's milk was safe for human consumption under the proposed conditions of use (EFSA NDA Panel, 2018). In the application subject of that assessment, the applicant intended to target the NF to infants (infant and follow-on formulae), the general adult population (meal replacement beverages) and the general population above 1 year of age (foods for special medical purposes (FSMP) and food supplements). Taking into account the source, the production process and the nature of the NF and the no observed adverse effect level (NOAEL) of 2,000 mg/kg body weight (bw) per day, the highest dose tested in a subchronic rat study, the Panel considered margins of exposure (MOE) of 81, 72 and 154 to be sufficient for infants, toddlers and the adult population, respectively.

In 2018, European Commission Implementing Regulation (EU) 2018/1632 granted marketing authorisation of the NF for its uses in infant formula, follow-on formula, total diet replacement foods for weight control, FSMP and food supplements, the latter two uses restricted to children aged 1–3 years, children and adolescents from 3 to 18 years of age and adults.

In this application, the applicant requests the additional uses of the NF for food supplements targeted to infants (up to 12 months of age) and FSMP as an alternative use to the use of the NF in infant and follow on formula (Table 1). The applicant proposes to label the food supplements 'Product should not be consumed in conjunction with infant formula (standard or FSMP) containing basic whey protein isolate'.

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<sup>1</sup> Regulation (EU) 2015/2283 of the European Parliament and of the Council 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 (OJ L 327, 11.12.2015, p. 1).

**Table 1:** Authorised and proposed uses of the NF for infants (children < 12 months of age)

Uses	Max use level
<b>Authorised use</b>	
Infant formulae	30 mg/100 g <sup>(a)</sup>
Follow-on formulae	3.9 mg/100 mL <sup>(b)</sup>
	30 mg/100 g <sup>(a)</sup>
	4.2 mg/100 mL <sup>(b)</sup>
<b>Proposed extended uses</b>	
Food Supplements as defined in Directive 2002/46/EC for infants (< 12 months of age)	25 mg/day
FSMP as defined in Regulation (EU) No 609/2013:	
FSMP for infants (Infant formulae)	30 mg/100 g <sup>(a)</sup>
	3.9 mg/100 mL <sup>(b)</sup>
FSMP for infants (Follow on formulae)	30 mg/100 g <sup>(a)</sup>
	4.2 mg/100 mL <sup>(b)</sup>

FSMP: foods for special medical purposes.

(a): Powder.

(b): Reconstituted.

### 3.1. Anticipated intake/extent of use of the NF (extension of use)

Considering the default body weight of 5 kg proposed by the EFSA Scientific Committee (2012) for the dietary exposure assessments for infants, a daily intake of 25 mg of the NF from its uses as a food supplement, corresponds to 5 mg/kg bw per day.

The Panel notes that the use levels for the FSMP formulae for infants proposed by the applicant are identical to the use levels of the NF for infant and follow on formulae assessed by EFSA (EFSA NDA Panel, 2018). The estimated 95th percentile of the daily intake of the NF from FSMP therefore corresponds to the 95th percentile intake estimate for infants considered by EFSA in its Opinion from 2018 (20 mg/kg bw per day). The Panel notes that this high percentile intake proposed by the applicant and considered by the Panel in 2018 is based on the summary statistics from the EFSA Comprehensive European Food Consumption Database from 2011 and represents an overestimate of the exposure.

Considering the default value of 260 mL/kg bw for high consumption of infant formula by infants below 16 weeks of age as suggested by the EFSA Scientific Committee (2017) and taking into account the intended use level of 3.9 mg/100 mL, the resulting exposure to the NF would amount to 10 mg/kg bw per day.

The applicant intends to market the use of the NF in FSMP and food supplements as alternative sources to its use in infant and follow on formula. However, the Panel notes that a combined unintended intake of 5 mg/kg bw per day from food supplements and 20 mg/kg bw per day from either infant and follow on formulae or from FSMP formulae would not exceed the intake level which were considered safe by the EFSA Opinion of 2018 (EFSA NDA Panel, 2018).

## 4. Discussion

Considering a combined intake of 5 mg/kg bw per day from food supplements plus 20 mg/kg bw per day from either FSMP formulae or from the authorised use in infant and follow-on formula, the MOE would result to 80 which is considered sufficient by the Panel, in line with its conclusions of its Opinion from 2018 (EFSA NDA Panel, 2018).

## 5. Conclusions

The Panel concludes that the NF, whey basic protein isolates, is safe under the new proposed conditions of use.

## Documentation provided to EFSA

- 1) Letter from the European Commission to the European Food Safety Authority with the request for a scientific opinion on the safety of Basic whey protein isolate as a novel food ingredient. Ref. Ares(2019)406975 - 24/01/2019, dated 24 January 2019.

- 2) On 24 January 2019, EFSA received a valid application from the European Commission on whey basic protein isolate as NF, which was submitted by Armor Proteines S.A.S., and the scientific evaluation procedure started.
- 3) During its meeting on 14 March 2019, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of whey basic protein isolate as a NF pursuant to Regulation (EU) 2015/2283.

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## Abbreviations

bw	body weight
FSMP	Foods for special medical purposes
NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
NF	novel food
NOAEL	no observed adverse effect level
MOE	margin of exposure