COMMISSION IMPLEMENTING DECISION (EU) 2017/2375

of 15 December 2017

authorising the placing on the market of *N*-acetyl-D-neuraminic acid as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2017) 8431)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ([1]), and in particular Article 7 thereof,

Whereas:

(1) On 22 September 2015, the company Glycom A/S made a request to the competent authority of Ireland to place synthetic *N*-acetyl-D-neuraminic acid (*N*-acetyl-D-neuraminic acid (NANA)) on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97.

(2) On 8 March 2016, the competent authority of Ireland issued its initial assessment report. In that report it came to the conclusion that *N*-acetyl-D-neuraminic acid meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 15 March 2016, the Commission forwarded the initial assessment report to the other Member States.

(4) Reasoned objections were raised by other Member States within the 60-day period laid down in the first sub-paragraph of Article 6(4) of Regulation (EC) No 258/97.

(5) On 14 July 2016, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for *N*-acetyl-D-neuraminic acid as a novel food ingredient in accordance with Regulation (EC) No 258/97.

(6) On 28 June 2017, EFSA in its 'Scientific Opinion on the safety of *N*-acetyl-D-neuraminic acid as a novel food pursuant to Regulation (EC) No 258/97' ([2]) concluded that *N*-acetyl-D-neuraminic acid is safe when added to foods other than food supplements at the proposed uses and use levels for the general population. For food supplements EFSA established that N-acetyl-D-neuraminic acid is safe at the proposed uses and use levels for individuals above 10 years of age and is also safe for infants below 10 years of age, provided that the combined exposure from different sources does not exceed 11 mg/kg bw.

(7) Therefore, the EFSA opinion gives sufficient grounds to establish that *N*-acetyl-D-neuraminic acid in the proposed uses and use levels for the general population complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97. Furthermore, the opinion also gives sufficient grounds to establish that *N*-acetyl-D-neuraminic acid in the proposed uses and use levels, when used as an ingredient in food supplements, complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97 provided that adequate labelling ensures that the threshold of 11 mg/kg bw is not exceeded by combined exposure from different sources for infants below 10 years of age.

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) EFSA Journal 2017;15(7):4918.

(8) Labelling requirements ensuring that consumers of food supplements are informed about a number of particulars are applicable to products containing *N*-acetyl-D-neuraminic acid already by virtue of Directive 2002/46/EC of the European Parliament and of the Council ([1]), Regulation (EU) No 609/2013 of the European Parliament and of the Council ([2]) and Regulation (EU) No 1169/2011 of the European Parliament and of the Council ([3]). In addition, specific provisions on labelling are required to ensure the safety of food supplements containing N-acetyl-D-neuraminic acid when consumed by infants, young children and children under 10 years of age in combination with breast milk or other foods with added N-acetyl-D-neuraminic acid.

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

N-acetyl-D-neuraminic acid as specified in Annex I to this Decision may be placed on the Union market as a novel food ingredient for the uses defined and at the maximum levels established in Annex II to this Decision.

Article 2

1. The designation of *N*-acetyl-D-neuraminic acid authorised by this Decision on the labelling of the foodstuffs shall be '*N*-acetyl-D-neuraminic acid'.

2. Food supplements containing *N*-acetyl-D-neuraminic acid shall be labelled in line with the presentation requirements applied under Regulation (EU) No 1169/2011 with a statement that the food supplement should not be given to infants, young children and children under 10 years of age where they consume breast milk or other foods with added *N*-acetyl-D-neuraminic acid within the same twenty four hour period.

Article 3

This Decision is addressed to Glycom A/S, Kogle Allé 4, 2970 Hørsholm, Denmark.

Done at Brussels, 15 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

([1]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

([2]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

([3]) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

ANNEX I

SPECIFICATIONS OF N-ACETYL-D-NEURAMINIC ACID (DIHYDRATE)

Definition:

Chemical name	IUPAC names: *N*-Acetyl-D-neuraminic acid (dihydrate) 5-Acetamido-3,5-dideoxy-D-glycero-D-galacto-non-2-ulopyranosonic acid (dihydrate), Synonyms: Sialic acid (dihydrate)
Chemical formula	$C_{11}H_{19}NO_9$ (acid) $C_{11}H_{23}NO_{11}$ ($C_{11}H_{19}NO_9$ *$2H_2O$) (dihydrate)
Molecular mass	309,3 Da (acid) 345,3 (309,3 + 36,0) (dihydrate)
CAS No.	131-48-6 (free acid) 50795-27-2 (dihydrate)

Description: *N*-Acetyl-D-neuraminic acid is a white to off-white crystalline powder.

Specifications:

Parameter	Specifications
Description	white to off-white crystalline powder
pH (20 °C, 5 % solution)	1,7 – 2,5
N-Acetyl-D-neuraminic acid (dihydrate)	> 97,0 %
Water (dihydrate calculates to 10,4 %)	≤ 12,5 % (w/w)
Ash, sulfated	< 0,2 % (w/w)
Acetic acid (as free acid and/or sodium acetate)	< 0,5 % (w/w)
Heavy Metals	
Iron	< 20,0 mg/kg
Lead	< 0,1 mg/kg
Residual proteins	< 0,01 % (w/w)
Residual solvents	
2-Propanol	< 0,1 % (w/w)
Acetone	< 0,1 % (w/w)
Ethyl acetate	< 0,1 % (w/w)
Microbiological specifications	
Salmonella	Absent in 25 g
Aerobic mesophilic total count	< 500 CFU/g
Enterobacteriaceae	Absent in 10 g
Cronobacter (*Enterobacter*) *sakazakii*	Absent in 10 g

Parameter	Specifications
Listeria monocytogenes	Absent in 25 g
Bacillus cereus	< 50 CFU/g
Yeasts	< 10 CFU/g
Moulds	< 10 CFU/g
Residual endotoxins	< 10 EU/mg

CFU: Colony Forming Units; EU: Endotoxin Units.

ANNEX II

Authorised uses of N-Acetyl-D-neuraminic acid

Food category	Maximum level
Infant and follow-on formulae as defined by Regulation (EU) No 609/2013	0,05 g/L of reconstituted formula
Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013	0,05 g/kg for solid foods
Foods for special medical purposes for infants and young children as defined by Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the infants and young children for whom the products are intended but in any case not higher than the maximum levels specified for the category mentioned in Annex II corresponding to the products,
Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013	0,2 g/L (drinks) 1,7 g/kg (bars)
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 [1]	1,25 g/kg
Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,05 g/L
Unflavoured fermented milk-based products, heat treated after fermentation, flavoured fermented milk products including heat-treated products	0,05 g/L (beverages) 0,4 g/kg (solids)
Dairy analogues, including beverage whiteners	0,05 g/L (beverages) 0,25 g/kg (solids)
Cereal bars	0,5 g/kg
Table top sweeteners	8,3 g/kg
Fruit and vegetable-based drinks	0,05 g/L
Flavoured drinks	0,05 g/L
Speciality coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions	0,2 g/kg
Food supplements as defined in Directive 2002/46/EC	300 mg/day for general population older than 10 years 55 mg/day for infants 130 mg/day for young children 250 mg/day for children between 3 to 10 years of age

[1] Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (OJ L 228, 31.7.2014, p. 5).