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ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted: [*OP, please insert in the EN version in alphabetical order.*]

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | Data protection |
|---|--|---|---|--------------------|--|
| Juice of the stems of the <i>Angelica keiskei</i> plant ('Ashitaba stem juice') | Specified food category | Maximum levels (expressed on the juice) | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Ashitaba (<i>Angelica keiskei</i>) stem juice. The labelling of food supplements containing the juice of the stems of the <i>Angelica keiskei</i> plant (Ashitaba system juice) shall bear a statement that they should be consumed by adults only, excluding pregnant and lactating women. | | Authorised on [...] [<i>OP, please insert the date dd.mm.yyyy - 20th day following its publication</i>]. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with |
| | Food Supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women | 137 mg/day | | | |

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Article 26 of Regulation (EU) 2015/2283.

Applicant: “Japan Bio Science Laboratory (JBSL)-USA, Inc.”, 1547 Palos Verdes Mall No 131, Walnut Creek, California 94597, United States of America.

During the period of data protection, the novel food sjuice of the stems of the *Angelica keiskei* plant (‘Ashitaba stem juice’) is authorised for placing on the market within the Union only by “Japan Bio Science Laboratory (JBSL)-USA, Inc.” unless a subsequent applicant obtains

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authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of “Japan Bio Science Laboratory (JBSL)-USA, Inc.”.

End date of the data protection: [...][*OP please insert the date dd.mm.yyyy – after 5 years*].

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(2) Table 2 (Specifications), the following entry is inserted in alphabetical order: [OP, please insert in the EN version in alphabetical order.]‘

| Authorised Novel Food | Specification |
|---|--|
| <p>Juice of the stems of the <i>Angelica keiskei</i> plant ('Ashitaba stem juice')</p> | <p>Description: The novel food is a viscous yellow liquid obtained via physical means from the stems of mature <i>Angelica keiskei</i> ('Ashitaba') plants. It is placed on the market as a mixture with cyclodextrins at an approximate ratio of 30% of Ashitaba stem juice to 70% cyclodextrins following a series of steps involving pasteurisation of the Ashitaba stem juice, mixing with cyclodextrins, sterilisation, freeze-drying, and sieving.</p> <p><i>Angelica keiskei</i> is native to Japan and is called Ashitaba in Japanese hence the reference to Ashitaba stem juice.</p> <p>Source: <i>Angelica keiskei</i> (family <i>Apiaceae</i>)</p> <p>Characteristics/Composition of the juice: Chalcones (xanthoangelol +4-hydroxyderricin) (% w/v): 1.0 – 2.25 Carbohydrates (%): 5.0 – 7.5 Water (%): 90.0-95.0 Fat (% w/v): 0.1-0.3 Protein (% w/v): 0.15-0.45 Sum of angular-type dihydropyranocoumarins: ≤ 10 mg/kg Sum of furanocoumarins: ≤ 100 mg/kg</p> <p>Heavy metals: Lead: ≤ 0.1 mg/kg Arsenic: ≤ 0.3 mg/kg Mercury: ≤ 0.1 mg/kg</p> |

Cadmium: ≤ 1.0 mg/kg

Microbiological criteria:

Total viable aerobic count: $\leq 1\ 000$ CFU/g

Total yeast/moulds count: ≤ 100 CFU/g

Escherichia coli: Absence in 10 g

Coliforms: ≤ 30 CFU/g

Salmonella spp.: Absence in 25 g

CFU: Colony Forming Units

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