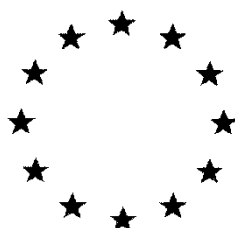


European Commission



**Draft Renewal Assessment Report prepared according to
Regulation (EC) N° 1107/2009**

Heptamaloxyloglucan

Volume 3 – B.7 (AS)

Rapporteur Member State: France
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Version History

When	What
2020-09	Initial RAR

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B.7. RESIDUE DATA

B.7.1. STORAGE STABILITY OF RESIDUES

No supervised residue trials have been conducted for heptamaloxyloglucan, and none is required. Therefore no storage stability data are necessary.

RMS conclusion/comments on storage stability of residues

As no residue trials have been conducted and as none is required, no storage stability data is needed.

B.7.2. METABOLISM, DISTRIBUTION AND EXPRESSION OF RESIDUES

B.7.2.1. Plants

Heptamaloxyloglucan is a molecule signal that can naturally stimulate the metabolism of grapevine to increase its tolerance to cold. It acts as an elicitor exhibiting chemical structure and conformation of XFG xyloglucan heptamer when it protects grape wine plants against frost. As the results of its binding by receptors at the cell surface, second messengers including changes in redox ratio, membrane potential and production of active oxygen species are generated and diffused to specific targets within the cell to bring about physiological responses occurring on the time scale of minutes. The early responses *e.g.* the increase of glutathione reductase activity and a shift in the partitioning of photosynthates toward soluble sugar synthesis are the mechanisms underlying acclimation to cold temperatures.

Heptamaloxyloglucan is a branched xyloglucan molecule extracted from apples. It is made of 7 glucidic monomer units, which are D-glucopyranosyl and terminal D-glucitol (in the main chain) and D-xylopyranosyl, D-galactopyranosyl and L-fucopyranosyl (in side chains) (See figures 7.2-1 and 7.2-3 below). All these hexose and hexol residues are natural components of the apple and of other dicotyledone plants, where they are major constituents of cellulose and hemicellulose molecules, which are the principal components of cell walls.

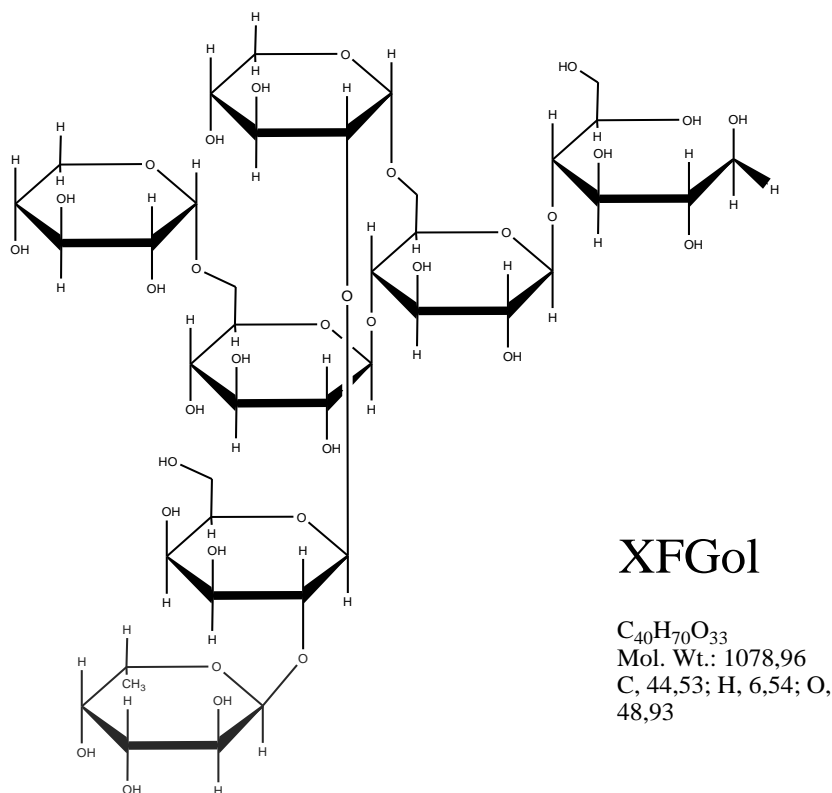
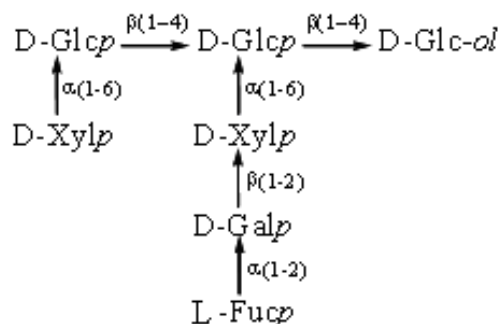


Figure 7.2-1 : Semi-developed Haworth representation



Xyl p for xylopyranosyl

Glc p for glucopyranosyl

Fuc p for fucopyranosyl

Gal p for galactopyranosyl

Glc-ol for glucitol

Figure 7.2-2: IUPAC representation of oligosaccharide chains

Additional information can be retrieved from the following literature data issued from previous submission (KCA 6.2.1/01) and from new literature review (see paragraph B.7.8):

Reference number:

Report:

Guidelines:

GLP:

Abstract

KCA 6.2.1/01 (KCA 5.1/01) submitted in the original DAR

Buchanan B.B., Gruissen W., and Jones R.L., 2000

Biochemistry and Molecular Biology of Plants

Not relevant (book)

Not relevant (book)

Xyloglucans are synthesized in the ER-Golgi apparatus as soluble polymers, they are modified by acetylation and remain soluble until they can be cross-linked at the cell surface. Therefore, short-chain xyloglucans, similar or identical to heptamaloxyloglucan are natural major components of dicotyledone plants. Xyloglucan molecules account for ca 10% of cell wall constituents in dicotyledones.

RMS comments:

The applicant is referring to a book chapter describing the structure and the composition of the cell wall. From this reference, it can be conclude that xyloglucans, which are similar to the heptamaloxyloglucan, are natural components in plant.

Reference number:

KCA 6.2.1/02 (KCA 6.3.1/01)

Report:

Jovanovic-Malinovska R., Kuzmanova S., Winkelhausen E., 2014

Oligosaccharide profile in fruits and vegetables as sources of prebiotics and functional foods

International Journal of Food Properties, 17:949–965, 2014

Guidelines:

Not relevant (public literature)

GLP:

Not relevant (public literature)

Material and Methods:

Identification and quantification of low molecular weight carbohydrates (LMWC) content, i.e. monosaccharide and oligosaccharide contents has been investigated in a selection of fruits and vegetables. LMWC have been extracted with ethanol (80%, 50°C, 1 hour) from 32 fruits, including 3 apple species, and 41 vegetables. They were dried and analyzed by high performance chromatography (HPLC). Monosaccharides including fructose, glucose, sorbitol, mannitol and xylitol; and oligosaccharides including fructooligosaccharides (FOS) and raffinose family oligosaccharides (RFO) were identified and quantified thanks to standards.

Findings:

This study describes the monosaccharides and oligosaccharides profile of a wide range of fruits and vegetables. It shows that monosaccharides are more abundant in fruits than in vegetables and that most fruits and vegetables contain oligosaccharides (FOS and RFO). The respective amounts differ from a species of fruit or vegetable to another and different groups are proposed according to the oligosaccharide content.

Conclusion:

Oligosaccharides have been identified and quantified in a large and diverse collection of fruits. This study support that they are naturally present in fruits. With monosaccharides and polysaccharides, they represent a fraction of the total carbohydrate content of fruits.

RMS comments:

The applicant referred to a study that describes the quantity of some oligosaccharides present in 32 different fruits and 41 different vegetables. This publication only provide detailed information on the amount of selected oligosaccharides (sugar alcohols, mono-, di- and oligosaccharides, in particular fructooligosaccharides and raffinose-family oligosaccharides) present in the fruits and in the vegetables samples. This study does not provide information regarding the potential natural occurrence of heptamaxyloglucan or related compound in fruits or in vegetables. However this study demonstrate that sorbitol (= glucitol) which is one of the glucidic monomer units of heptamaloxyloglucan is naturally present in 18 fruits and 12 vegetables among analysed ones.

Reference number:

KCA 6.2.1/03 (KCA 6.3.1/02)

Report:

Jovanovic-Malinovska R., Kuzmanova S., Winkelhausen E., 2015

Application of ultrasound for enhanced extraction of prebiotic oligosaccharides from selected fruits and vegetables

Ultrasonics Sonochemistry 22 (2015) 446–453

Guidelines:

Not relevant (public literature)

GLP:

Not relevant (public literature)

Material and Methods:

This study presents the use of ultrasound assisted extraction (UAE) for extraction of oligosaccharides from fruits and vegetables. It compares the yield of extraction obtained through conventional extraction with ethanol (85%, 50°C, 1h) and UAE in different conditions of solvent, time and temperatures. Identification and quantification of oligosaccharides is performed by high performance chromatography (HPLC). The analysis is made for fructooligosaccharides (FOS) and raffinose family oligosaccharides (RFO).

Findings:

UAE is found as an efficient method for extraction of oligosaccharides from fruits and vegetables. Higher yields of FOS and RFO extraction are obtained thanks to UAE compared to conventional extraction with ethanol. The total amount of oligosaccharides extracted with UAE is almost 2-fold higher. For example, in nectarine, around 2 g of oligosaccharides are obtained from 100 g of fresh weight with UAE vs. around 1 g with ethanol extraction.

Conclusion:

Oligosaccharides are natural components of fruits and UAE is an efficient method of extraction of these components.

RMS comments:

The applicant referred to a study that compares the efficiency of several extraction methods for the extraction of some oligosaccharides from fruits and vegetables. This publication provide also information on the amount of oligosaccharides (1-kestose, nystose and 1F-b-fructofuranosylnystose from the fructo-oligosaccharides, and raffinose and stachyose from the raffinose family oligosaccharides) that were searched for in the fruits and in the vegetables samples.

Nevertheless, this study does not provide information regarding the potential natural occurrence of heptamaloxyloglucan or related compound that could be found in the fruits or in the vegetables.

General conclusion for metabolism, distribution and expression of residue in vines

Heptamaloxyloglucan is a signal molecule (elicitor) naturally occurring in plant tissues. Heptamaloxyloglucan being a natural component of edible plants, no metabolism or distribution study is required. The residue will be identical to edible plant components and therefore, no toxicologically relevant residue will occur in plants after treatment with EL101GV (Technical Heptamaloxyloglucan).

RMS general conclusion on metabolism, distribution and expression of residues in plants:

No plant metabolism study has been submitted by the applicant and none is required. Indeed, heptamaloxyloglucan is a natural plant compound and it will not be possible to distinguish between the natural one and the one that come from the application of plant protection product.

Furthermore, if heptamaloxyloglucan is consumed it will be broken down to simple sugars naturally presents in fruits and vegetables and will be used as an energy source and will exhibit no toxic effects.

B.7.2.2. Poultry

The intended use pattern of heptamaloxyloglucan only includes grape-vine which is not considered as livestock feed items used in the EU. Residues of heptamaloxyloglucan in crops or parts of crops fed to animals are therefore not likely. Whenever it would occur, heptamaloxyloglucan is a natural component of dicotyledone plants and therefore a natural component of livestock diet. In consequence, no residues of heptamaloxyloglucan can occur in livestock.

No study on the metabolism, distribution and expression of residues in livestock is therefore required.

RMS conclusion:

No poultry metabolism study has been provided by the applicant and none are required as grapes or related by-products are not used as feed items. Furthermore, heptamaloxyloglucan is a natural plant compound and then a natural component of livestock diet.

B.7.2.3. Lactating ruminants

See above point (Metabolism in poultry).

RMS conclusion:

No ruminant metabolism study has been provided by the applicant and none are required as grapes or related by-products are not used as feed items. Furthermore, heptamaloxyloglucan is a natural plant compound and then a natural component of livestock diet.

B.7.2.4. Pigs

See above point (Metabolism in poultry).

RMS conclusion:

No pig metabolism study has been provided by the applicant and none are required as grapes or related by-products are not used as feed items. Furthermore, heptamaloxyloglucan is a natural plant compound and then a natural component of livestock diet.

B.7.2.5. Fish

See above point (Metabolism in poultry).

RMS conclusion:

No fish metabolism study has been provided by the applicant and none are required as grapes or related by-products are not used as feed items. Furthermore, heptamaloxyloglucan is a natural plant compound and then a natural component of livestock diet.

B.7.3. MAGNITUDE OF RESIDUE TRIALS IN PLANTS**B.7.3.1. Grapes**

No supervised residue trials have been conducted for heptamaloxyloglucan (EL101GV Technical substance), and none is required.

The intended application rate is less than 0.5 g a.s./ha per application (437 mg a.s./ha), 2 g a.s./ha in total. Considering the yield of grapevine, which was 6 677 kg/ha in 2017 (Agreste – Statistique agricole annuelle), a maximum of 0.3 mg a.s./kg grape could be expected if the totality of the applied active substance was found in berries, which is a very worst case. In fact applications are made from budding to the 6 leaves stage, so before flowering and as the active substance is highly soluble (558 g/L), it will certainly disappear from leaves surface as last application is achieved more than 4 months before harvest.

Furthermore, data on natural occurrence of monosaccharides and oligosaccharides quantified in fruits can be retrieved from the following literature data (see literature review in paragraph B.7.8):

Reference number:	KCA 6.3.1/01 (KCA 6.2.1/02)
Report:	Jovanovic-Malinovska R., Kuzmanova S., Winkelhausen E., 2014 Oligosaccharide profile in fruits and vegetables as sources of prebiotics and functional foods International Journal of Food Properties, 17:949–965, 2014
Guidelines:	Not relevant (public literature)
GLP:	Not relevant (public literature)

Material and Methods:

See section 6.2.1.

Findings:

Quantification of monosaccharides and oligosaccharides contents in selected fruits is presented in tables Table 7.3-1 and 7.3-2.

Conclusion:

Monosaccharides and polysaccharides are naturally present in fruits; considering results on grapes, red grape contains the highest levels of monosaccharides, with 8.13 ± 0.3 , 13.75 ± 0.5 and 0.83 ± 0.06 g/100 g fresh fruits of fructose, glucose and sucrose respectively. White grape contains 7.58 ± 0.3 , 11.72 ± 0.6 and 0.70 ± 0.04 g/100 fresh fruits of fructose, glucose and sucrose respectively. Total oligosaccharides were quantified up to 0.08 g/100 g fresh fruits in red grape whereas only traces were detected in white grape.

Table 7.3-1 : Sugar and sugar alcohol content in selected fruits

Sample	Moisture	Fructose	Glucose	Sucrose	Sorbitol	Mannitol	Xylitol
g/100 g fresh weight of edible sample							
Apple, Golden Delicious	87 ± 0.67	0.45 ± 0.020 ^a	2.04 ± 0.110 ^a	1.18 ± 0.068 ^a	0.68 ± 0.020 ^a	nd ^a	nd ^a
Apple, Idared	85 ± 0.89	2.27 ± 0.111 ^b	3.47 ± 0.172 ^b	5.73 ± 0.299 ^b	nd ^b	nd ^a	nd ^a
Apple, Petrovka	87 ± 0.21	3.96 ± 0.223 ^c	2.33 ± 0.108 ^a	1.93 ± 0.084 ^c	nd ^b	nd ^a	0.21 ± 0.018 ^b
Apricot	87 ± 0.38	0.30 ± 0.009 ^a	0.86 ± 0.060 ^c	3.46 ± 0.106 ^d	nd ^b	nd ^a	nd ^a
Blackberry	71 ± 0.17	3.25 ± 0.214 ^d	3.55 ± 0.129 ^b	nd ^e	3.15 ± 0.169 ^c	nd ^a	nd ^a
Blueberry	85 ± 0.18	5.87 ± 0.317 ^e	10.64 ± 0.542 ^d	0.78 ± 0.049 ^f	0.96 ± 0.075 ^d	nd ^a	nd ^a
Cherry	86 ± 0.23	2.32 ± 0.167 ^b	4.63 ± 0.243 ^e	0.31 ± 0.024 ^{ef}	0.16 ± 0.012 ^b	nd ^a	0.08 ± 0.007 ^c
Currant, black	78 ± 0.29	4.08 ± 0.123 ^c	5.17 ± 0.271 ^f	0.60 ± 0.042 ^f	1.21 ± 0.073 ^e	nd ^a	0.13 ± 0.012 ^d
Currant, red	83 ± 0.66	2.29 ± 0.083 ^b	3.24 ± 0.173 ^b	0.51 ± 0.030 ^f	nd ^b	nd ^a	nd ^a
Fig, common	73 ± 1.74	5.79 ± 0.223 ^e	7.47 ± 0.348 ^g	1.69 ± 0.091 ^c	0.09 ± 0.007 ^b	nd ^a	0.21 ± 0.019 ^b
Fig, wild green	88 ± 2.12	1.00 ± 0.061 ^f	1.07 ± 0.063 ^c	0.50 ± 0.034 ^f	0.12 ± 0.009 ^b	nd ^a	0.19 ± 0.018 ^b
Grape, red Vranec	74 ± 0.23	8.13 ± 0.301 ^g	13.75 ± 0.513 ^h	0.83 ± 0.058 ^f	nd ^b	nd ^a	nd ^a
Grape, white Smederevka	74 ± 1.71	7.58 ± 0.273 ^h	11.72 ± 0.582 ⁱ	0.70 ± 0.042 ^f	nd ^b	nd ^a	nd ^a
Medlar	67 ± 1.34	1.96 ± 0.094 ^{bi}	3.22 ± 0.175 ^b	nd ^e	nd ^b	nd ^a	nd ^a
Melon, honeydew	87 ± 0.62	3.05 ± 0.141 ^d	4.53 ± 0.194 ^f	6.48 ± 0.392 ^g	0.08 ± 0.006 ^b	nd ^a	nd ^a
Melon, Polidor	88 ± 1.46	2.48 ± 0.083 ^{bi}	3.20 ± 0.138 ^b	3.65 ± 0.199 ^d	nd ^b	nd ^a	nd ^a
Mulberry, black	82 ± 1.33	4.00 ± 0.291 ^c	6.70 ± 0.363 ^g	0.91 ± 0.051 ^{af}	nd ^b	nd ^a	nd ^a
Mulberry, white	79 ± 0.78	4.35 ± 0.301 ^c	6.56 ± 0.371 ^g	1.08 ± 0.064 ^{af}	nd ^b	nd ^a	nd ^a
Nectarine	88 ± 0.44	1.15 ± 0.052 ^f	1.50 ± 0.083 ^{ac}	3.50 ± 0.198 ^d	1.08 ± 0.079 ^{de}	nd ^a	0.28 ± 0.026 ^e
Peach, yellow-green	86 ± 0.14	0.86 ± 0.050 ^{af}	1.26 ± 0.063 ^{ac}	5.36 ± 0.251 ⁱ	0.14 ± 0.010 ^b	nd ^a	nd ^a
Pear	83 ± 0.01	4.50 ± 0.193 ^c	4.21 ± 0.243 ^{be}	2.44 ± 0.180 ^h	2.45 ± 0.192 ^f	nd ^a	0.12 ± 0.012 ^d
Plum, cherry	83 ± 0.21	2.14 ± 0.121 ^b	6.95 ± 0.384 ^g	0.95 ± 0.047 ^{af}	0.06 ± 0.005 ^b	nd ^a	0.18 ± 0.017 ^b
Plum, Ciruela	88 ± 0.54	2.99 ± 0.125 ^d	5.02 ± 0.269 ^{ef}	0.72 ± 0.050 ^f	tr ^b	nd ^a	0.16 ± 0.015 ^d
Plum, red	86 ± 1.63	1.63 ± 0.103 ^{bif}	5.53 ± 0.274 ^f	1.11 ± 0.081 ^a	0.12 ± 0.009 ^b	nd ^a	0.09 ± 0.009 ^c
Pomegranate	76 ± 0.16	0.66 ± 0.041 ^{af}	14.82 ± 0.823 ^j	0.34 ± 0.023 ^{ef}	0.08 ± 0.007 ^b	nd ^a	nd ^a
Pumpkin	87 ± 0.52	0.41 ± 0.027 ^a	0.82 ± 0.054 ^c	4.79 ± 0.26 ^j	0.06 ± 0.006 ^b	nd ^a	0.09 ± 0.008 ^c
Quince	75 ± 1.35	2.64 ± 0.124 ^{bd}	4.52 ± 0.231 ^{ef}	0.79 ± 0.060 ^f	0.12 ± 0.009 ^b	nd ^a	0.10 ± 0.010 ^{cd}
Raspberry	84 ± 1.43	2.46 ± 0.117 ^{bd}	3.80 ± 0.193 ^{be}	0.32 ± 0.019 ^{ef}	nd ^b	nd ^a	0.22 ± 0.021 ^b
Sour cherry	77 ± 0.03	3.57 ± 0.129 ^{cd}	9.24 ± 0.484 ^j	0.82 ± 0.054 ^f	nd ^b	nd ^a	nd ^a
Strawberry, common	91 ± 1.26	1.38 ± 0.062 ^f	1.64 ± 0.086 ^{ac}	0.60 ± 0.040 ^f	0.14 ± 0.011 ^b	nd ^a	0.32 ± 0.031 ^f
Strawberry, woodland	82 ± 0.73	2.16 ± 0.131 ^{bd}	3.22 ± 0.170 ^b	1.19 ± 0.094 ^a	0.08 ± 0.007 ^b	nd ^a	0.14 ± 0.013 ^d
Watermelon	90 ± 1.46	2.37 ± 0.142 ^{bd}	2.49 ± 0.133 ^{ab}	1.68 ± 0.082 ^c	nd ^b	0.12 ± 0.011 ^b	nd ^a

*Data are expressed as mean ± standard deviation ($n = 3$); nd: not detected; tr: trace amount; means with different superscript letters within a same column are significantly different ($p < 0.05$).

Table 7.3-2 Oligosaccharides content separated via HPLC in selected fruits

Sample	GF ₂	GF ₃	GF ₄	Total FOS	Raffinose	Stachyose	Total RFO
g/100 g fresh weight of edible sample							
Apple, Golden Delicious	0.07 ± 0.005 ^a	nd ^a	nd ^a	0.07 ± 0.005 ^a	nd ^a	nd ^a	nd ^a
Apple, Idared	0.09 ± 0.008 ^{ab}	nd ^a	nd ^a	0.09 ± 0.008 ^a	nd ^a	nd ^a	nd ^a
Apple, Petrovka	0.11 ± 0.009 ^b	0.11 ± 0.008 ^b	0.07 ± 0.006 ^b	0.29 ± 0.023 ^b	nd ^a	tr ^b	tr ^b
Apricot	0.08 ± 0.004 ^{ab}	nd ^a	nd ^a	0.08 ± 0.004 ^a	tr ^b	tr ^b	tr ^b
Blackberry	nd ^c	nd ^a	nd ^a	nd ^c	nd ^a	nd ^a	nd ^a
Blueberry	0.18 ± 0.014 ^d	0.32 ± 0.014 ^c	tr ^a	0.50 ± 0.028 ^d	nd ^a	nd ^a	nd ^a
Cherry	0.22 ± 0.011 ^e	0.10 ± 0.009 ^b	nd ^a	0.32 ± 0.020 ^b	nd ^a	nd ^a	nd ^a
Currant, black	0.08 ± 0.006 ^{ab}	nd ^a	nd ^a	0.08 ± 0.006 ^a	nd ^a	nd ^a	nd ^a
Currant, red	0.15 ± 0.009 ^f	0.20 ± 0.011 ^d	tr ^a	0.35 ± 0.020 ^b	nd ^a	nd ^a	nd ^a
Fig, common	tr ^g	0.09 ± 0.008 ^b	nd ^a	0.09 ± 0.008 ^a	nd ^a	nd ^a	nd ^a
Fig, wild green	0.19 ± 0.015 ^d	0.11 ± 0.010 ^b	tr ^a	0.20 ± 0.025 ^e	nd ^a	nd ^a	nd ^a
Grape, red Vranec	0.08 ± 0.007 ^{ab}	tr ^a	nd ^a	0.08 ± 0.007 ^a	nd ^a	nd ^a	nd ^a
Grape, white Smederevka	nd ^c	tr ^a	nd ^a	tr ^c	nd ^a	nd ^a	nd ^a
Medlar	nd ^c	nd ^a	nd ^a	nd ^c	nd ^a	nd ^a	nd ^a
Melon, honeydew	nd ^c	0.09 ± 0.007 ^b	nd ^a	0.09 ± 0.007 ^a	nd ^a	tr ^b	tr ^b
Melon, Polidor	0.19 ± 0.014 ^d	0.11 ± 0.008 ^b	tr ^a	0.30 ± 0.022 ^b	tr ^b	tr ^b	tr ^b
Mulberry, black	0.13 ± 0.009 ^f	0.17 ± 0.006 ^d	tr ^a	0.30 ± 0.015 ^b	nd ^a	nd ^a	nd ^a
Mulberry, white	0.16 ± 0.013 ^{df}	0.19 ± 0.010 ^d	tr ^a	0.35 ± 0.023 ^b	nd ^a	nd ^a	nd ^a
Nectarine	0.18 ± 0.011 ^d	0.65 ± 0.015 ^f	0.06 ± 0.005 ^b	0.89 ± 0.030 ^f	nd ^a	nd ^a	nd ^a
Peach, yellow-green	nd ^c	tr ^a	nd ^a	tr ^c	nd ^a	nd ^a	nd ^a
Pear	0.15 ± 0.004 ^f	0.32 ± 0.012 ^c	0.09 ± 0.007 ^c	0.56 ± 0.023 ^g	nd ^a	nd ^a	nd ^a
Plum, cherry	nd ^c	0.09 ± 0.008 ^b	nd ^a	0.09 ± 0.008 ^a	nd ^a	nd ^a	nd ^a
Plum, Ciruela	nd ^c	0.08 ± 0.007 ^b	nd ^a	0.08 ± 0.007 ^a	nd ^a	nd ^a	nd ^a
Plum, red	0.12 ± 0.007 ^f	nd ^a	nd ^a	0.12 ± 0.007 ^a	nd ^a	nd ^a	nd ^a
Pomegranate	nd ^c	0.11 ± 0.010 ^b	nd ^a	0.11 ± 0.010 ^a	nd ^a	nd ^a	nd ^a
Pumpkin	tr ^g	nd ^a	nd ^a	tr ^c	nd ^a	nd ^a	nd ^a
Quince	tr ^g	nd ^a	nd ^a	tr ^c	nd ^a	nd ^a	nd ^a
Raspberry	0.32 ± 0.009 ^h	0.12 ± 0.010 ^b	0.07 ± 0.006 ^b	0.51 ± 0.025 ^d	nd ^a	nd ^a	nd ^a
Sour cherry	0.11 ± 0.008 ^{bf}	0.22 ± 0.009 ^d	tr ^a	0.33 ± 0.017 ^b	nd ^a	nd ^a	nd ^a
Strawberry, common	nd ^c	nd ^a	nd ^a	nd ^c	nd ^a	nd ^a	nd ^a
Strawberry, woodland	0.09 ± 0.008 ^{ab}	nd ^a	nd ^a	0.09 ± 0.008 ^a	nd ^a	nd ^a	nd ^a
Watermelon	0.29 ± 0.009 ⁱ	0.44 ± 0.018 ^g	0.08 ± 0.007 ^b	0.81 ± 0.024 ^h	nd ^a	nd ^a	nd ^a

*Data are expressed as mean ± standard deviation ($n = 3$); GF₂: 1-kestose; GF₃: nystose; GF₄: 1^F-β fructofuranosylnystose; nd: not detected; tr: trace amount; means with different superscript letters within a same column are significantly different ($p < 0.05$).

RMS comments:

The applicant referred to a study that describes the quantity of some oligosaccharides present in 32 different fruits and 41 different vegetables. This publication only provides detailed information on the amount of oligosaccharides (sugar alcohols, mono-, di- and oligosaccharides, in particular fructooligosaccharides and raffinose-family oligosaccharides) that were searched for in the fruits and in the vegetables. This study does not provide information regarding the potential natural occurrence of heptamaloxyloglucan or related compound (glycans, xyloglycans...) in fruits or in vegetables. However this study demonstrate that sorbitol (= glucitol) which is one of the glucidic monomer units of heptamaloxyloglucan is naturally present in 18 fruits and 12 vegetables among those analysed.

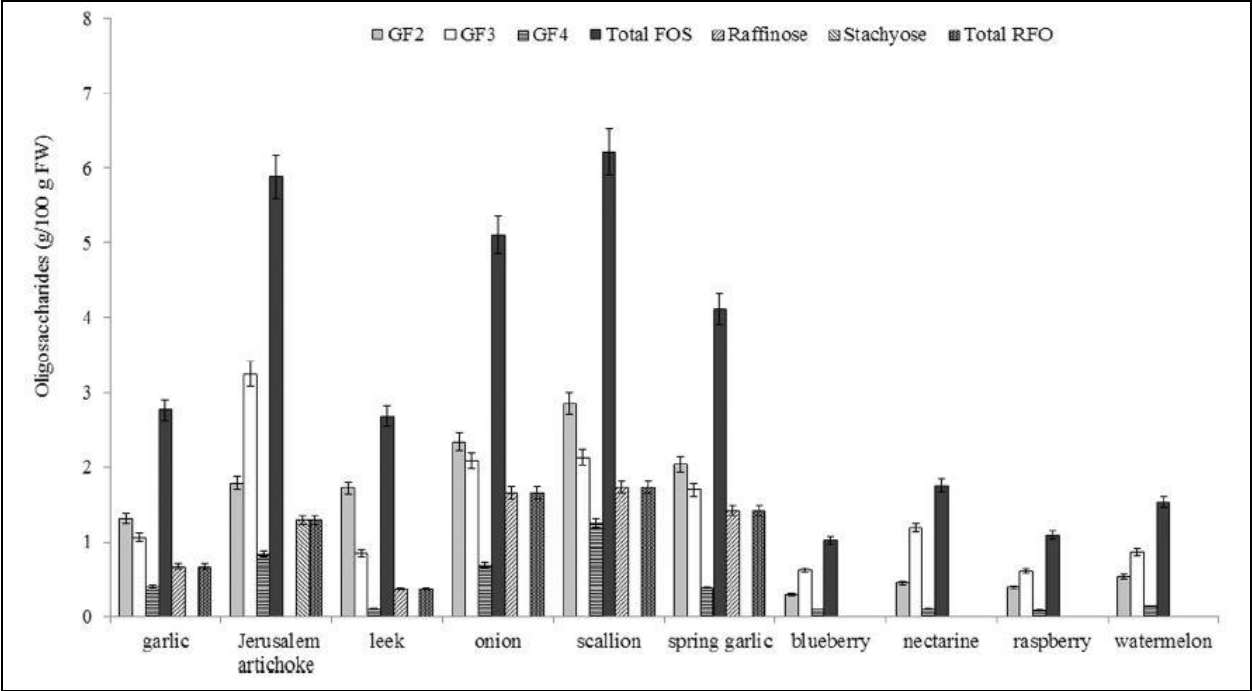
Reference number:	KCA 6.3.1/02 (KCA 6.2.1/03)
Report:	Jovanovic-Malinovska R., Kuzmanova S., Winkelhausen E., 2015 Application of ultrasound for enhanced extraction of prebiotic oligosaccharides from selected fruits and vegetables Ultrasonics Sonochemistry 22 (2015) 446–453
Guidelines:	Not relevant (public literature)
GLP:	Not relevant (public literature)

Material and Methods:
See section 6.2.1.

Findings:
Quantification of total oligosaccharides contents in selected fruits are presented in Figure 7.3-1.

Conclusion:
Oligosaccharides are naturally present in fruits. In selected fruits, total oligosaccharides measured range from >1 g (blueberry, raspberry) to almost 2 g (nectarine, watermelon) from 100 g of fresh weight fruits.

Figure 7.3-1: Individual fractions of FOS and RFO in selected fruits and vegetables yielded by ultrasound assisted extraction under optimized conditions (ethanol concentration 63%, v/v, 40°C, time 10 min)



GF2: 1-kestose, GF3: nystose, GF4: 1F-b-fructofuranosylnystose (GF4), FOS: fructo-oligosaccharides, RFO: Raffinose Family Oligosaccharides (RFO).

RMS comments:

The applicant referred to a study that compares the efficiency of several extraction methods for the extraction of some oligosaccharides from fruits and vegetables. This publication also provides information on the natural amount of oligosaccharides (1-kestose, nystose and 1F-b-fructofuranosylnystose from the fructo-oligosaccharides, and raffinose and stachyose from the raffinose family oligosaccharides) that were searched for in the fruits and in the vegetables. Nevertheless, this study does not provide information regarding the potential natural occurrence of heptamaloxyloglucan or related compound (eg: glucans, xyloglucans) that can be found in the fruits or in the vegetables analysed.

General conclusion for magnitude of residue in grapes

Considering the intended use (low dose level applications, performed early in the season before flowering), heptamaloxyloglucan is not expected to be present in grapes at harvest. Even if the totality of applied active substance is considered to be present in grapes at harvest, the level calculated is far below natural levels of oligosaccharides or monosaccharides in grapes:

for 100 g of grapes, a level of 0.03 mg heptamaloxyloglucan is calculated. Considering that heptamaloxyloglucan contains two D-galactopyranosyl and using the mass molecular weight of heptamaloxyloglucan and glucose (1078.96 and 180.156 g/mol respectively), 0.03 mg heptamaloxyloglucan can give 0.01 mg glucose (for 100 g of grapes). In available literature, 13.75 g glucose/100 g of grape is reported.

In addition, heptamaloxyloglucan is included in Annex IV of EU Regulation 396/2005, which lists active substances for which no MRLs are required.

In the USA, EPA has concluded that the establishment of an exemption from tolerance under 40 CFR 180.940(a) for residues of D-Glucopyranose, oligomeric, decyl octyl glycosides when used as an inert ingredient in an antimicrobial food-contact surface sanitizing solution is safe under FFDCA section 408 (Federal Register / Vol. 78, No. 212 / Friday, November 1, 2013 / Rules and Regulations).

RMS general conclusion on magnitude of residue in grapes

No supervised grapes residue trials have been conducted for heptamaloxyloglucan, and none is required.

Heptamaloxyloglucan is a natural plant compound and it will not be possible to distinguish between the natural one and the one that come from the application of plant protection product.

Furthermore, considering the intended use (total application rate of 1.75 g/ha up to BBCH 16) and the high solubility of active substance (558 g/l), it will certainly disappear from leaves surface as last application is achieved more than 4 months before harvest. Therefore, the use of heptamaloxyloglucan as plant protection product is not expected to result in an increase of glycans or xyloglucans naturally present in grapes.

Moreover, if heptamaloxyloglucan is consumed it would be broken down to simple sugars naturally presents in fruits and vegetables and will be used as an energy source and will exhibit no toxic effects.

Finally, due to its absence of toxicity, heptamaloxyloglucan is currently included in Annex IV of EU Regulation 396/2005, which lists active substances for which no MRLs are required and in the framework of the renewal it is proposed to maintain heptamaloxyloglucan in the Annex IV of regulation 396/2005/EC

B.7.4. FEEDING STUDIES

The intended use pattern of heptamaloxyloglucan only includes grape-vine which is not considered as feed items used in the EU. Residues of heptamaloxyloglucan in crops or parts of crops fed to animals are therefore not likely. Whenever it would occur, heptamaloxyloglucan is a natural component of dicotyledone plants and therefore a natural component of livestock diet. In consequence, no residues of heptamaloxyloglucan can occur in products of animal origin, and no livestock feeding studies are required.

RMS conclusion

No feeding study has been provided by the applicant and none are required as grapes or related by-products are not used as feed items.

Furthermore as heptamaloxyloglucan is a natural plant compound and then a natural component of livestock diet.

B.7.5. EFFECTS OF PROCESSING

Heptamaloxyloglucan is a branched xyloglucan molecule extracted from apples. It is made of 7 glucidic monomer units, which are D-glucopyranosyl and terminal D-glucitol (in the main chain) and D-xylopyranosyl, D-galactopyranosyl and L-fucopyranosyl (in side chains). All these hexose and hexol residues are natural components of the apple and of other dicotyledone plants, where they are major constituents of cellulose and hemicellulose molecules, which are the principal components of cell walls.

Xyloglucans are synthesized in the ER-Golgi apparatus as soluble polymers, they are modified by acetylation and remain soluble until they can be cross-linked at the cell surface. Therefore, short-chain xyloglucans, similar or identical to heptamaloxyloglucan are natural major components of dicotyledone plants. Xyloglucan molecules account for ca 10% of cell wall constituents in dicotyledones (Buchanan B.B., Gruissen W., and Jones R.L., *Biochemistry and Molecular Biology of Plants*, 2000, KCA 6.2.1/01).

The effects of the vinification process on the nature of heptamaloxyloglucan residue will be similar to those on the xyloglucans naturally present in the cell walls of grapes. They are not susceptible to result in the formation of toxicologically relevant residues.

Some supportive data can be obtained from the public literature (see literature review in paragraph B.7.8):

Reference number:	KCA 6.5/01
Report:	Forgo P., Kiss A., Korózs M., Rapi S., 2013 Thermal degradation and consequent fragmentation of widely applied oligosaccharides Microchemical Journal 107 (2013) 37–46
Guidelines:	Not relevant (public literature)
GLP:	Not relevant (public literature)

Material and Methods:

The thermal degradation process of a collection of different types of oligosaccharides used as food ingredients has been investigated. The collection is representative of a variety of oligosaccharide structures, it includes fructooligosaccharides, raffinose, cyclodextrins, inulin-type fructans and starch oligosaccharides. Each compound was exposed to different temperatures for 10 min from 150 to 220°C and the decomposition products were analyzed by high performance liquid chromatography (HPLC) method using evaporative light scattering (ELS).

Findings:

All the samples of oligosaccharides have preserved the composition and structure till 150°C, mild changes are detected from 190°C and intense decomposition started at 210°C. The decomposition processes include mainly chain degradation and the formation of low molecular weight components.

Conclusion:

This study shows that at least until 150°C and 170°C, oligosaccharides have preserved composition and structure.

RMS comments:

The applicant referred to a study that investigated the thermal degradation process of different types of oligosaccharides used as food ingredients. This study demonstrate that sample of oligosaccharides tested (fructo-oligosaccharides, cyclodextrins, raffinose and resistant starch) have preserved their composition and their structure up to 170 °C. Consequently it is expected that heptamaloxyloglucan if present will preserve its structure and will not be degraded. However, in this study only effect of temperature on the degradation of oligosaccharide has been investigated. Whereas the effect of pH and enzymatic degradation on the structure and on the composition of oligosaccharides which are also with temperature key parameters of wine making have not been investigated.

Reference number:	KCA 6.5/02
Report:	Rondeau P., Gambiera F., Jolibert F., Brosse N., 2013 Compositions and chemical variability of grape pomaces from french vineyard Industrial Crops and Products 43 (2013) 251– 254
Guidelines:	Not relevant (public literature)
GLP:	Not relevant (public literature)

Material and Methods:

The composition in carbohydrates, tannins and oil of grape pomace originating from red and white winemaking from eight areas of production of French vineyard has been studied. Carbohydrate insoluble fraction content was measured after extraction and hydrolysis into monosaccharides (72% sulfuric acid, 1h). Monosaccharides (fucose, rhamnose, arabinose, galactose, glucose, xylose, mannose, galacturonic acid and glucuronic acid) were quantified using high-performance anion-exchange chromatography with pulsed amperometric detection (HPAEC-PAD). The carbohydrate content was calculated as the sum of each monosaccharide content. Oil and tannins were quantified with separately with appropriate methods.

Findings:

Pomace samples has been shown to contained 20 to 46% w/w of carbohydrates, mainly glucan and xyloglucans, 20 to 21% of tanins, and 3 to 6% of oils.

Analysed levels of fucose, galactose, xylose and mannose in the hydrolysates of the pomaces are presented in Table 7.5-2.

Table 7.5-1 : Monosaccharide compositions of grape pomaces (g per 100 g of dry pomace)

Area of production	Fuc	Rha	Ara	Gal	Glc	Xyl	Man	GalUA	GlcUA	Total
Alsace	0.17	0.43	1.49	2.04	21.54	4.59	2.66	4.13	0.24	37.29
Aquitaine	0.25	0.67	2.21	2.77	26.34	3.23	4.67	5.99	0.33	46.44
Beaujolais	0.10	0.29	0.68	1.27	12.36	2.35	2.11	2.13	0.16	21.44
Bourgogne	0.16	0.58	1.52	2.05	16.30	2.23	3.20	5.38	0.30	31.72
Champagne	0.11	0.34	1.70	1.89	18.71	6.96	1.87	4.55	0.31	36.45
Languedoc	0.15	0.35	0.38	1.74	17.42	3.38	2.80	2.78	0.22	29.70
Val de Loire	0.08	0.42	0.97	1.41	9.85	1.49	1.97	3.05	0.24	19.47
Provence	0.15	0.37	1.28	1.92	17.43	3.74	2.78	3.99	0.22	31.87

^a All data are yields of monosaccharides (g) par 100 g of dry pomace.

Conclusion:

This study reports the quantification of the carbohydrate content of grape pomace. Grape pomace is a by-product obtained from grape marc and thus, it constitutes a fraction of the grape total content in carbohydrates. It supports that that the background in terms of xyloglucans in grape is significant compared to the quantity of active substance (xyloglucan oligosaccharide heptamaloxyloglucan) applied during treatment.

RMS comments:

The applicant referred to a study that provide information regarding the nature and the quantity of carbohydrate present in 8 different grape pomace. This publication demonstrates that glucans and xyloglucans (which are compound very similar to the heptamaloxyloglucan) are naturally present in grapes.

Furthermore, monosaccharides composition was also determined in this study following sulfuric acid hydrolysis. It was shown that fucose, galactose and xylose which are ones of the glucidic monomer units of heptamaloxyloglucan are naturally present in grapes.

General conclusion on effects of processing

Applications are made before flowering and as the active substance is highly soluble, it will certainly disappear from leaves surface as last application is achieved more than 4 months before harvest. No residues of heptamaloxyloglucan are expected in berries at harvest and therefore no residues are expected after process into wine.

Supportive literature data show that at temperature occurring during wine making process, oligosaccharides preserve composition and structure. They are not susceptible to result in the formation of toxicologically relevant residues. In addition, analyses in pomace samples show that carbohydrates naturally occur at levels above the applied level of active substance.

RMS general conclusion on effect of processing

No study investigating the effect of processing on the nature and on the quantity of heptamaloxyloglucan has been submitted and none is required.

Heptamaloxyloglucan is a natural plant compound of low toxicity and it will not be possible to distinguish between the natural one and the one that come from the application of plant protection product. Furthermore, considering the intended use (total application rate of 1.75 g/ha up to BBCH 16) and the high solubility of active substance (558 g/l), it will certainly disappear from leaves surface as last application is achieved more than 4 months before harvest. Therefore, the use of heptamaloxyloglucan as protection plant product is not expected to result in an increase of glycans or xyloglucans naturally present in grape.

Additionally as stated in the initial DAR :

“Heptamaloxyloglucan is a branched xyloglucan molecule extracted from apples. It is made of 7 glucidic monomer units, which are D-glucopyranosyl and terminal D-glucitol (in the main chain) and D-xylopyranosyl, D-galactopyranosyl and L-fucopyranosyl (in side chains). All these hexose and hexol residues are natural components of the apple and of other dicotyledone plants, where they are major constituents of cellulose and hemicellulose molecules, which are the principal components of cell walls.

The effects of the vinification process on the nature of Heptamaloxyloglucan residue will be similar to those on the xyloglucans naturally present in the cell walls of grapes. They are not susceptible to result in the formation of toxicologically relevant residues.

It can also be noticed that galacturonases (enzymes cocktail) used at the first step of heptamaloxyloglucan production, are also used in the process of wine clarification in order to solubilise long chain polysaccharides (pectins and xyloglucans) in soluble ones. So, this kind of enological treatment is susceptible to induce heptamaloxyloglucan production in wine produced from non treated grapes.”

B.7.5.1. Nature of the residue

Due to the reasons presented above, no studies on the effects of processing are required.

RMS comments/conclusion

No study investigating the effect of processing are required. See RMS general conclusion on effect of processing above.

B.7.5.2. Distribution of the residue in peel and pulp

Due to the reasons presented above, no studies on the effects of processing are required.

RMS comments/conclusion

Not required. See also RMS general conclusion on effect of processing above.

B.7.5.3. Magnitude of residues in processed commodities

Due to the reasons presented above, no studies on the effects of processing are required.

RMS comments/conclusion

No study investigating the magnitude of residues in processed fraction are required. See RMS general conclusion on effect of processing above.

B.7.6. RESIDUES IN SUCCEEDING OR ROTATIONAL CROPS

The intended use pattern of heptamaloxyloglucan only includes grape-vine (permanent culture). Succeeding crops are therefore not considered relevant. In addition, heptamaloxyloglucan being a natural component of plant, it is rapidly degraded by soil macro- and micro-organisms as a natural component of humus. In consequence, no theoretical consideration of the nature and the level of residues in succeeding crops and no succeeding crop studies have been performed.

RMS conclusion:

Grape-vine, the only representative use is a permanent crop. Consequently, studies investigating the nature and the quantity of residue in rotational crops are not required.

Furthermore, as stated by the applicant and the initial DAR:

“Heptamaloxyloglucan being a natural component of plant, it is rapidly degraded by soil macro- and micro-organisms as a natural component of humus. In consequence, no theoretical consideration of the nature and the level of residues in succeeding crops and no succeeding crop studies have been performed.”

B.7.6.1. Metabolism in rotational crops

Due to the reasons presented above, no studies on rotational crops are required.

B.7.6.2. Magnitude of residues in rotational crops

Due to the reasons presented above, no studies on rotational crops are required.

B.7.7. OTHER STUDIES**B.7.7.1. Effect on the residue level in pollen and bee products**

Heptamaloxyloglucan is a natural component of bee diet. No acute or chronic risk for bees is expected.

RMS conclusion

Considering the intended use (total application rate of 1.75 g/ha up to BBCH 16) and the high solubility of active substance (558 g/l), heptamaloxyloglucan will certainly disappear from leaves surface at flowering. Therefore, the use of heptamaloxyloglucan as protection plant product is not expected to result in significant residue in pollen and bee product (> 0.05mg/kg).

B.7.8. REVIEW OF SCIENTIFIC LITERATURE**Methodology used by the applicant for literature review:**

For the literature data, the aim is to find scientific peer-reviewed open literature, as required by Article 8(5) of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market, on Heptamaloxyloglucan and its relevant metabolites dealing with toxicological and toxicokinetic studies, residues, fate and behavior in the environment and ecotoxicological studies which are published within the last ten years from various data sources.

The following databases have been consulted to complete the scientific peer-reviewed open literature on Heptamaloxyloglucan and its relevant metabolites:

1. Pubmed, 2. ScienceDirect, 3. Europe PMC, 4. Agricola

The search was analysed manually for each relevant reference without using dedicated software. Any removal of ambiguity or de-duplication was done manually based on the literature unique ID (e.g., PMID) or title of the literatures.

Search strategy

The main parameters that allow the characterization of the literature search are listed below. Trade names were not considered in the literature search as they are covered by the search on Heptamaloxyloglucan: any trade name should be found without reference to the active substance.

Date span of the literature search

The search identified scientific peer-reviewed open literatures published in last 10 years (≥ 2008).

Databases used in the literature review

The literature review has been performed using a broad collection of relevant databases for the literature search (see Table below).

Table 7.8-1 List of databases for the literature search of Heptamaloxyloglucan

Database	Date of the Latest Database Update Included in the Search
1. Pubmed	2018/09
2. ScienceDirect	2018/09
3. Europe PMC	2018/09
4. Agricola	2018/09

Search terms for the literature review

The Table 7.8-2 presents the General Search terms and Section Specific Search terms for the database search on Heptamaloxyloglucan. The information used for screening the selected databases to identify all relevant publications consists of common names, as far as available.

The General Search terms are intended to cover all data requirements whereas the Section Specific Search terms are keywords dedicated to their respective sections (Toxicology, Residues, Ecotoxicology, Fate and Environment).

Active substance EL101GV is an oligosaccharide made of 7 glucidic monomer units. There are β -1,4 linkages on the main chain between the two D-glucopyranosyl units and terminal D-glucitol, and α -1,2, β -1,2 and α -1,6 linkages between the various monomer units present in side chains. The latter side chain-monomers are D-xylopyranosyl (α -1,6-linked to D-glucopyranosyl), D-galactopyranosyl (β -1,2-linked to D-xylopyranosyl) and L-fucopyranosyl (α -1,2-linked to D-galactopyranosyl). Therefore these terms have been used for the literature search.

Table 7.8-2 : List of Search terms for the database search

Heptamaloxyloglucan	
Common names / ISO name	Heptamaloxyloglucan
General Search terms:	In all fields: Heptamaloxyloglucan - Oligoxyloglucan - Heteroglycan – Xyloglucan Only in title: Saccharide - Oligosaccharide - Monosaccharide - Sorbitol - Xylose Glucopyranosyl - Glucopyranose - Glucitol - Xylopyranosyl - Xylopyranose Galactopyranosyl - Galactopyranose - Fucopyranosyl - Fucopyranose
Section Specific Search terms:	See table 7.8-3

Search results

A total of 17 611 summary records was retrieved before removing duplicates, divided as:

Table 7.8-3: List of publications after first search and compilation of all databases

Database	Specific Search terms	First search
1_Pubmed Hepta-sorbi	In abstract: Heptamaloxyloglucan OR Oligoxyloglucan OR Heteroglycan OR Xyloglucan OR In title: Saccharide OR Oligosaccharide OR Monosaccharide OR Sorbitol AND 01/01/2008 – 23/10/2018	2 731
2_Pubmed glucitolxylose	In title: Xylose OR Glucitol AND 01/01/2008 – 23/09/2018	1 136
3_Pubmed Pyran	In title Glucopyranosyl OR Glucopyranose OR Xylopyranosyl OR Xylopyranose OR Galactopyranosyl OR Galactopyranose OR Fucopyranosyl OR Fucopyranose AND 01/01/2008 – 07/09/2018	352

Database	Specific Search terms	First search
4_ScienceDirect Xyloglyca	In title, abstract, or author-specified keywords Heptamaloxyloglucan OR Oligoxyloglucan OR Heteroglycan OR Xyloglucan AND 2008-2018	368
5_ScienceDirect Sacch	In title Saccharide OR Oligosaccharide OR Monosaccharide OR Sorbitol OR Xylose OR Glucopyranosyl OR Glucopyranose OR Glucitol AND 2008-2018	3 032
6_ScienceDirect pyran	In title Xylopyranosyl OR Xylopyranose OR Galactopyranosyl OR Galactopyranose OR Fucopyranosyl OR Fucopyranose AND 2008-2018	56
7_EuropePMChepta	(ABSTRACT:"oligoxyloglucan" OR ABSTRACT:"heptamaloxyloglucan" OR ABSTRACT:"heteroglycan" OR ABSTRACT:"xyloglucan" OR TITLE:"saccharide" OR TITLE:"oligosaccharide" OR TITLE:"monosaccharide") AND (SRC:"AGR" OR SRC:"CTX" OR SRC:"PAT" OR SRC:"PPR" OR SRC:"MED") ¹ AND (FIRST_PDATE:[2008-01-01 TO 2018-09-24])	2 949
8_EuropePMCxylose	(TITLE:"sorbitol" OR TITLE:"xylose" OR TITLE:"glucopyranosyl" OR TITLE:"glucopyranose" OR TITLE:"glucitol" OR TITLE:"xylopyranosyl" OR TITLE:"xylopyranose" OR TITLE:"galactopyranosyl" OR TITLE:"galactopyranose" OR TITLE:"fucopyranosyl" OR TITLE:"fucopyranose") AND (FIRST_PDATE:[2008-01-01 TO 2018-09-24])	2 136
9_NAL hept	In any field: Heptamaloxyloglucan Oligoxyloglucan Heteroglycan Xyloglucan In title: Saccharide Oligosaccharide Monosaccharide Sorbitol (search done 09/2018)	23
10_NAL pyran	In title Xylose glucitol Glucopyranosyl Glucopyranose Xylopyranosyl Xylopyranose Galactopyranosyl Galactopyranose Fucopyranosyl Fucopyranose (search done 09/2018)	12
11_NAL articles hepta	In any field: Heptamaloxyloglucan Oligoxyloglucan Heteroglycan Xyloglucan (search done 09/2018)	1 073
12_NAL articles sacc	In title: Saccharide Oligosaccharide Monosaccharide Sorbitol glucitol (search done 09/2018)	1 986
13_NAL articles pyran	In title Xylose Glucopyranosyl Glucopyranose Xylopyranosyl Xylopyranose Galactopyranosyl Galactopyranose Fucopyranosyl Fucopyranose (search done 09/2018)	1 757
Total		17 611

The total of publications before removing duplicates was summarised in the Table below:

Table 7.8-4: List of publications after removing of too old literature (before 2007)

	Heptamaloxyloglucan
Total number of publications retrieved (with duplicates) (global search results)	17 611
Total number of too old publications (Before 2008)	2 670
Total number of publications retrieved removing too old literature	14 941

After removing duplicates, the total number of publications is presented below:

Table 7.8-5 : List of publications after removing duplicates/triplicates

	Heptamaloxyloglucan
Total number of publications retrieved removing too old literature	14 941
Total removed publications (duplicates/triplicates)	8 977
Total number of publications retrieved after removing of duplicates	5 964

Evaluation

The evaluation of the search results was performed according to the EFSA Guidance Document (EFSA Journal 2011;9(2):2092).

Rapid assessment on the literature review

A rapid assessment based on the reading of the titles allows performing a first selection. The number of obviously irrelevant publications appears in Table 7.8-6, documenting the study selection process.

Table 7.8-6 : List of publications after rapid assessment

	HEPTAMALOXYLOGLUCAN			
Study selection process	Toxicology	Residues	Fate	Ecotoxicology
Number of publications excluded after rapid assessment for relevance according to title	5 731			
Number of publications further assessed in detail (possible relevant literature for at least one section according to title)	233			

Detailed assessment on the literature review

Those publications, which have passed the rapid assessment, have been evaluated based on abstract and full text versions for each section. The criteria for the relevance assessments are described in Table 7.8-6 above.

For sake of clarity only the result regarding the residues section are further presented.

Table 7.8-7 : Results of the study selection process for residues section

	Study selection process	Residues
Assessment according to title	Number of possible relevant publications (title relevant for at least one section)	70
Assessment "section"	Number of publications further assessed according to abstract for respective section (possible relevant literature for this section)	70
	Number of publications excluded according to irrelevance of abstract for respective section (excluded literature for this section) Table 7.8-10	64
	Number of publications further assessed according to full-text for respective section (possible relevant literature for this section) Table 7.8-8 + Table 7.8-9	6
	Number of publications excluded according to irrelevance of full-text for respective section (excluded literature for this section) Table 7.8-9	2
	Number of publications not excluded for relevance after detailed assessment (i.e. relevant publications) (included literature) Table 7.8-8	4

The results of the detailed assessment for residues section are shown in Tables 7.8-8 to 7.8-10.

Relevant literature:

In Table 7.8-8: Report of all relevant studies after detailed assessment of full-text documents

No relevant literature according to full-text:

In Table 7.8-9: Report of studies relevant according to abstract but excluded after detailed assessment of full-text

No relevant literature according to abstract:

In Table 7.8-10: Report of studies relevant according to title but excluded after detailed assessment of abstract (C)

Table 7.8-8: Report of all relevant studies for residues section after detailed assessment of full-text documents

KCA - SANCO Data Point	Author(s)	Year	Title	Source	Classification of study
RESIDUES					
KCA 6.2.1 / KCA 6.3.1	Jovanovic-Malinovska, Ruzica; Kuzmanova, Slobodanka; Winkelhausen, Eleonora	2015	Application of ultrasound for enhanced extraction of prebiotic oligosaccharides from selected fruits and vegetables	Ultrasonics Sonochemistry Vol 22 Pages 446-453	b) EFSA guidance point 5.4.1: The study results are in line with the available regulatory data requested. The data are considered as supportive data.
KCA 6.2.1 / KCA 6.3.1	Jovanovic-Malinovska, Ruzica; Kuzmanova, Slobodanka; Winkelhausen, Eleonora	2014	Oligosaccharide Profile in Fruits and Vegetables as Sources of Prebiotics and Functional Foods	International journal of food properties Vol 17 Pages 949-965	b) EFSA guidance point 5.4.1: The study results are in line with the available regulatory data requested. The data are considered as supportive data.
KCA 6.5	Forgo, Peter; Kiss, Attila; Korózs, Marietta; Rapi, Sándor	2013	Thermal degradation and consequent fragmentation of widely applied oligosaccharides	Microchemical Journal Vol 107 Pages 37-46	b) EFSA guidance point 5.4.1: The study results are in line with the available regulatory data requested. The data are considered as supportive data.
KCA 6.5	Rondeau, Pierangelo; Gambier, François; Jolibert, Franck; Brosse, Nicolas	2013	Compositions and chemical variability of grape pomaces from French vineyard	Industrial Crops and Products Vol 43 Pages 251-254	b) EFSA guidance point 5.4.1: The study results are in line with the available regulatory data requested. The data are considered as supportive data.

Table 7.8-9 : Report of studies relevant according to abstract but excluded after detailed assessment of full-text for residues section

Author(s)	Year	Title	Source	Reason for not including in dossier
RESIDUES				
Okada, Hideki; Fukushi, Eri; Yamamori, Akira; Kawazoe, Naoki; Onodera, Shuichi; Kawabata, Jun; Shiomi, Norio	2010	Novel fructopyranose oligosaccharides isolated from fermented beverage of plant extract	Carbohydrate Research Vol 345 Pges 414-418	not relevant - no precision on plant extract used (extract of fruits and vegetables), no quantification of mono or oligosaccharides
Stick, Robert V.; Williams, Spencer J.	2009	Chapter 9 - Disaccharides, Oligosaccharides and Polysaccharides	Elsevier Pages 321-341	not relevant - only description of the different disaccharides, oligosaccharides and polysaccharides such as cellulose, starch, glycogen, sucrose, fructans, mannans, etc. but no specific data linked to apple or grape

Table 7.8-10 : Report of studies relevant according to title but excluded after detailed assessment of abstract for residues section

Author(s)	Year	Title	Source	Reason for not including in dossier
RESIDUES				
Aguayo, María Francisca; Ampuero, Diego; Mandujano, Patricio; Parada, Roberto; Muñoz, Rodrigo; Gallart, Marta; Altabella, Teresa; Cabrera, Ricardo; Stange, Claudia; Handford, Michael	2013	Sorbitol dehydrogenase is a cytosolic protein required for sorbitol metabolism in Arabidopsis thaliana	Plant science 205-206 63-75	Study in Arabidopsis thaliana, not relevant for residue section considering representative use
Aprea, E.; Charles, M.; Endrizzi, I.; Laura Corollaro, M.; Betta, E.; Biasioli, F.; Gasperi, F.	2017	Sweet taste in apple: the role of sorbitol, individual sugars, organic acids and volatile compounds	Sci Rep 7 44950	Sensory study, not relevant for residue section
Balthazar, C. F.; Silva, H. L. A.; Vieira, A. H.; Neto, R. P. C.; Cappato, L. P.; Coimbra, P. T.; Moraes, J.; Andrade, M. M.; Calado, V. M. A.; Granato, D.; Freitas, M. Q.; Tavares, M. I. B.; Raices, R. S. L.; Silva, M. C.; Cruz, A. G.	2017	Assessing the effects of different prebiotic dietary oligosaccharides in sheep milk ice cream	Food Research International 91 38-46	Industry application of using prebiotic oligosaccharides, not relevant for residue section
Basu, Santanu; Shivhare, U. S.	2013	Rheological, Textural, Microstructural, and Sensory Properties of Sorbitol-Substituted Mango Jam	Food and bioprocess technology 6 1401-1413	Not relevant for processing study according to abstract (not intended use)
Basu, Santanu; Shivhare, U. S.; Singh, T. V.; Beniwal, V. S.	2011	Rheological, textural and spectral characteristics of sorbitol substituted mango jam	Journal of food engineering 105 503-512	Not relevant for processing study according to abstract (not intended use)
Battaglia, M.	2017	Assessment of a Registered Dietitian Administered Fermentable Oligosaccharide Disaccharide, Monosaccharide, and Polyol Elimination Diet Experience	Journal of the Academy of Nutrition and Dietetics 117 A17	Effect on human health, not relevant for residue section

Author(s)	Year	Title	Source	Reason for not including in dossier
Bouaziz, Fatma; Helbert, Claire Boisset; Romdhane, Molka Ben; Koubaa, Mohamed; Bhiri, Fatma; Kallel, Fatma; Chaari, Fatma; Driss, Dorra; Buon, Laurine; Chaabouni, Semia Ellouz	2015	Structural data and biological properties of almond gum oligosaccharide: Application to beef meat preservation	International journal of biological macromolecules 72 472-479	Not relevant for residue section considering the intended use
Bozkurt, M.; Bintas, E.; Kirkan, S.; Aksit, H.; Kucukyilmaz, K.; Erbas, G.; Cabuk, M.; Aksit, D.; Parin, U.; Ege, G.; Kocer, B.; Seyrek, K.; Tuzun, A. E.	2016	Comparative evaluation of dietary supplementation with mannan oligosaccharide and oregano essential oil in forced molted and fully fed laying hens between 82 and 106 weeks of age	Poult Sci 95 2576-2591	Not relevant for residue section considering that the intended use is not fed to livestock
Bozkurt, M.; Küçükyilmaz, K.; Çatli, A. U.; Çinar, M.	2008	Growth Performance and Slaughter Characteristics of Broiler Chickens Fed with Antibiotic, Mannan Oligosaccharide and Dextran Oligosaccharide Supplemented Diets	International journal of poultry science 7 969-977	Not relevant for residue section considering that the intended use is not fed to livestock
Bozkurt, M.; Kucukyilmaz, K.; Catli, A. U.; Cinar, M.; Bintas, E.; Coven, F.	2012	Performance, egg quality, and immune response of laying hens fed diets supplemented with mannan-oligosaccharide or an essential oil mixture under moderate and hot environmental conditions	Poult Sci 91 1379-86	Not relevant for residue section considering that the intended use is not fed to livestock
Hill, T. M.; Bateman, H. G.; Aldrich, J. M.; Schlotterbeck, R. L.	2008	Oligosaccharides for Dairy Calves	The Professional Animal Scientist 24 460-464	Not relevant for residue section considering that the intended use is not fed to livestock
Hodoniczky, Jason; Morris, Carol A.; Rae, Anne L.	2012	Oral and intestinal digestion of oligosaccharides as potential sweeteners: A systematic evaluation	Food Chemistry 132 1951-1958	Oral and intestinal digestibility of oligosaccharides, not relevant for residue section
Jahani-Moghadam, M.; Amanlou, H.; Nikkhah, A.	2009	Metabolic and productive response to ruminal protein degradability in early lactation cows fed untreated or xylose-treated soybean meal-based diets	Journal of animal physiology and animal nutrition 93 777-786	Not relevant for residue section considering that the intended use is not fed to livestock
Kartal, O.; Mahlow, S.; Skupin, A.; Ebenhoh, O.	2011	Carbohydrate-active enzymes exemplify entropic principles in metabolism	Mol Syst Biol 7 542	Not relevant for residue section according to abstract (enzymatic bioreaction)

Author(s)	Year	Title	Source	Reason for not including in dossier
Kirilin, Alexey; Wärnå, Johan; Tokarev, Anton; Murzin, Dmitry Yu	2014	Kinetic Modeling of Sorbitol Aqueous-Phase Reforming over Pt/Al ₂ O ₃	Industrial & Engineering Chemistry Research 53 4580-4588	Not relevant for residue section according to abstract (chemical catalysis reaction)
Kleintop, Adrienne E.; Echeverria, Dimas; Brick, Leslie A.; Thompson, Henry J.; Brick, Mark A.	2013	Adaptation of the AOAC 2011.25 Integrated Total Dietary Fiber Assay To Determine the Dietary Fiber and Oligosaccharide Content of Dry Edible Beans	Journal of agricultural and food chemistry 61 9719-9726	Not relevant for residue section considering the intended use
Lagaert, S.; Belien, T.; Volckaert, G.	2009	Plant cell walls: Protecting the barrier from degradation by microbial enzymes	Semin Cell Dev Biol 20 1064-73	Not relevant for residue section according to abstract (biochemical reaction to stress)
Lans, Alexa M.; Frelka, John C.; Paluri, Sravanti; Vodovotz, Yael	2018	Physical properties and sensory analysis of galacto-oligosaccharide glassy confections	LWT 96 499-506	Industry application, not relevant for residue section
Li, Pei-jun; Xia, Jin-lan; Nie, Zhen-yuan; Shan, Yang	2016	Pectic oligosaccharides hydrolyzed from orange peel by fungal multi-enzyme complexes and their prebiotic and antibacterial potentials	LWT - Food Science and Technology 69 203-210	Prebiotic properties of pectic oligosaccharides, not relevant for residue section
Lioret, Pascal	2011	Food product, useful as madeleines, financiers and muffins, comprises a paste comprising egg, and a cereal product, where the paste further comprises a first polyol sweetener and a second sweetener such as glycerin and/or sorbitol	ST MICHEL HOLDING	Not relevant industrial food process
Liu, Zhiqian; Rochfort, Simone	2015	Identification and quantitative analysis of oligosaccharides in wheat flour using LC–MS	Journal of Cereal Science 63 128-133	Not relevant for residue section considering the intended use
Lucyszyn, Neoli; Lubambo, Adriana F.; Ono, Lucy; J6, Tatiane A.; de Souza, Clayton F.; Sierakowski, Maria Rita	2011	Chemical, physico-chemical and cytotoxicity characterisation of xyloglucan from Guibourtia hymenifolia (Moric.) J. Leonard seeds	Food hydrocolloids 25 1242-1250	Not relevant for residue section considering the intended use
Maki, K. C.; Gibson, G. R.; Dickmann, R. S.; Kendall, C. W.; Chen, C. Y.; Costabile, A.; Comelli, E. M.; McKay, D. L.; Almeida, N. G.; Jenkins, D.; Zello, G. A.; Blumberg, J. B.	2012	Digestive and physiologic effects of a wheat bran extract, arabino-xylan-oligosaccharide, in breakfast cereal	Nutrition 28 1115-21	Not relevant for residue section considering the intended use

Author(s)	Year	Title	Source	Reason for not including in dossier
Manisseri, Chithra; Gudipati, Muralikrishna	2010	Bioactive xylo-oligosaccharides from wheat bran soluble polysaccharides	LWT - Food Science and Technology 43 421-430	Not relevant for residue section considering the intended use
Martinez, M.; Gullon, B.; Yanez, R.; Alonso, J. L.; Parajo, J. C.	2009	Direct enzymatic production of oligosaccharide mixtures from sugar beet pulp: experimental evaluation and mathematical modeling	J Agric Food Chem 57 5510-7	Not relevant for residue section considering the intended use
Martinov, Jelena; Krstić, Miodrag; Spasić, Snežana; Miletić, Srdjan; Stefanović-Kojić, Jovana; Nikolić-Kokić, Aleksandra; Blagojević, Duško; Spasojević, Ivan; Spasić, Mihajlo B.	2017	Apple pectin-derived oligosaccharides produce carbon dioxide radical anion in Fenton reaction and prevent growth of Escherichia coli and Staphylococcus aureus	Food Research International 100 132-136	Health beneficial effects, not relevant for residue section
Mateo, Soledad; Puentes, Juan G.; Sánchez, Sebastián; Moya, Alberto J.	2013	Oligosaccharides and monomeric carbohydrates production from olive tree pruning biomass	Carbohydrate Polymers 93 416-423	Not relevant for residue section considering the intended use
Matusek, A.; Merész, P.; Le, T. K. D.; Örsi, F.	2011	Fructo-oligosaccharide degradation in apple pulp matrix	Acta alimentaria 40 182-193	Effects of temperature, pH and apple pulp characteristics on fructo-oligosaccharide degradation, not relevant for residue section
Meinert, L.; Schafer, A.; Bjerregaard, C.; Aaslyng, M. D.; Bredie, W. L.	2009	Comparison of glucose, glucose 6-phosphate, ribose, and mannose as flavour precursors in pork; the effect of monosaccharide addition on flavour generation	Meat Sci 81 419-25	Not relevant for residue section considering that the intended use is not fed to livestock
Mendes, Joana A. S.; Prozil, Sónia O.; Evtuguin, Dmitry V.; Lopes, Luísa P. Cruz	2013	Towards comprehensive utilization of winemaking residues: Characterization of grape skins from red grape pomaces of variety Touriga Nacional	Industrial crops and products 43 25-32	Not relevant for residue section according to abstract (no quantification in mg/kg)
Moon, Jin Seok; Shin, So Yeon; Choi, Hye Sun; Joo, Wooha; Cho, Seung Kee; Li, Ling; Kang, Jung-Hyun; Kim, Tae-Jip; Han, Nam Soo	2015	In vitro digestion and fermentation properties of linear sugar-beet arabinan and its oligosaccharides	Carbohydrate Polymers 131 50-56	Health beneficial effects, not relevant for residue section
Morgan, Natalie K.; Keerqin, Chake; Wallace, Andrew; Wu, Shu-Biao; Choct, Mingan	2018	Effect of arabinoxyloligosaccharides and arabinoxylans on net energy and nutrient utilization in broilers	Animal Nutrition	Not relevant for residue section considering that the intended use is not fed to livestock

Author(s)	Year	Title	Source	Reason for not including in dossier
Morris, Cécile; Morris, Gordon A.	2012	The effect of inulin and fructo-oligosaccharide supplementation on the textural, rheological and sensory properties of bread and their role in weight management: A review	Food chemistry 133 237-248	Effect on human health, and industry application, not relevant for residue section
Morrison, S. J.; Dawson, S.; Carson, A. F.	2010	The effects of mannan oligosaccharide and Streptococcus faecium addition to milk replacer on calf health and performance	Livestock Science 131 292-296	Not relevant for residue section considering that the intended use is not fed to livestock
Nishinari, K.; Takemasa, M.; Yamatoya, K.; Shirakawa, M.	2009	19 - Xyloglucan	Woodhead Publishing 535-566	Not relevant for residue section considering the intended use
Nobre, Clarisse; Cerqueira, Miguel Ângelo; Rodrigues, Lígia Raquel; Vicente, António Augusto; Teixeira, José António	2015	Chapter 19 - Production and Extraction of Polysaccharides and Oligosaccharides and Their Use as New Food Additives	Elsevier 653-679	information from a book, not fully available
Ohkawa, W.; Moriya, S.; Kanahama, K.; Kanayama, Y.	2008	Re-evaluation of sorbitol metabolism in fruit from Rosaceae trees	Acta horticulturae 159-166	Not relevant for residue section according to abstract (enzymatic bioreaction)
Pareyt, Bram; Goovaerts, Marijke; Broekaert, Willem F.; Delcour, Jan A.	2011	Arabinoxylan oligosaccharides (AXOS) as a potential sucrose replacer in sugar-snap cookies	LWT - Food Science and Technology 44 725-728	Sensory study, not relevant for residue section
Park, Eunhye; Yang, Hyojik; Kim, Yangsun; Kim, Jeongkwon	2012	Analysis of oligosaccharides in beer using MALDI-TOF-MS	Food Chemistry 134 1658-1664	Not relevant for residue section considering the intended use
Park, M. H.	2016	Sucrose delays senescence and preserves functional compounds in Asparagus officinalis L	Biochem Biophys Res Commun 480 241-247	Not relevant for residue section considering the intended use
Pattanayak, Manabendra; Samanta, Surajit; Maity, Prasenjit; Manna, Dilip K.; Sen, Ipsita K.; Nandi, Ashis K.; Panda, Bibhash C.; Chattopadhyay, Sourav; Roy, Somenath; Sahoo, Atish K.; Gupta, Nibha; Islam, Syed S.	2017	Polysaccharide of an edible truffle Tuber rufum: Structural studies and effects on human lymphocytes	International journal of biological macromolecules 95 1037-1048	Not relevant for residue section considering the intended use

Author(s)	Year	Title	Source	Reason for not including in dossier
Pena, M. J.; Darvill, A. G.; Eberhard, S.; York, W. S.; O'Neill, M. A.	2008	Moss and liverwort xyloglucans contain galacturonic acid and are structurally distinct from the xyloglucans synthesized by hornworts and vascular plants	Glycobiology 18 891-904	Not relevant for residue section considering the intended use
Pustjens, A. M.; de Vries, S.; Schols, H. A.; Gruppen, H.; Gerrits, W. J.; Kabel, M. A.	2014	Understanding carbohydrate structures fermented or resistant to fermentation in broilers fed rapeseed (Brassica napus) meal to evaluate the effect of acid treatment and enzyme addition	Poult Sci 93 926-34	Not relevant for residue section considering that the intended use is not fed to livestock
Ratnayake, R. M.; Sims, I. M.; Newman, R. H.; Melton, L. D.	2011	Effects of cooking on the cell walls (dietary fiber) of 'Scarlet Warren' winter squash (Cucurbita maxima) studied by polysaccharide linkage analysis and solid-state (13)C NMR	J Agric Food Chem 59 7186-93	Not relevant for residue section considering the intended use
Sampedro, J.; Valdivia, E. R.; Fraga, P.; Iglesias, N.; Revilla, G.; Zarra, I.	2017	Soluble and Membrane-Bound beta-Glucosidases Are Involved in Trimming the Xyloglucan Backbone	Plant Physiol 173 1017-1030	Genetic study, not relevant for residue section
Sancho, Renata A. Soriano; Souza, Jane Delane R. P.; de Lima, Fabíola Aliaga; Pastore, Glaucia Maria	2017	Evaluation of oligosaccharide profiles in selected cooked tubers and roots subjected to in vitro digestion	LWT - Food Science and Technology 76 270-277	Not relevant as root and tuber vegetables are not intended uses
Sidiras, Dimitris; Batzias, Fragiskos; Ranjan, Rajiv; Tsapatsis, Michael	2011	Simulation and optimization of batch autohydrolysis of wheat straw to monosaccharides and oligosaccharides	Bioresource Technology 102 10486-10492	Not relevant for residue section considering the intended use
Sparkman, O. David; Penton, Zeldia E.; Kitson, Fulton G.	2011	Chapter 35 - Sugars (Monosaccharides)	Academic Press 407-410	Data on gas chromatography separation of monosaccharides, amino sugar, sugar alcohol and reduced sugar; not relevant for residue section
Stick, Robert V.; Williams, Spencer J.	2009	Chapter 6 - Monosaccharide Metabolism	Elsevier 225-251	Carbohydrate metabolism (biochemical processes), not relevant for residue section
Suo, Hai-qing; Lu, Lin; Xu, Guo-hui; Xiao, Lin; Chen, Xiao-gang; Xia, Rui-rui; Zhang, Li-yang; Luo, Xu-gang	2015	Effectiveness of dietary xylo-oligosaccharides for broilers fed a conventional corn-soybean meal diet	Journal of Integrative Agriculture 14 2050-2057	Not relevant for residue section considering that the intended use is not fed to livestock
Takahashi, Machiko; Yamamoto, Ryoichi; Sakurai, Naoki; Nakano, Yuki; Takeda, Takumi	2015	Fungal hemicellulose-degrading enzymes cause physical property changes concomitant with solubilization of cell wall polysaccharides	Planta 241 359-370	Not relevant for residue section considering the intended use

Author(s)	Year	Title	Source	Reason for not including in dossier
Torrecillas, Silvia; Montero, Daniel; Izquierdo, Marisol	2014	Improved health and growth of fish fed mannan oligosaccharides: Potential mode of action	Fish & Shellfish Immunology 36 525-544	Not relevant for residue section considering that the intended use is not fed to livestock
US-EPA	2014	D-glucopyranose, oligomeric, decyl octyl glycosides; exemption from the requirement of a tolerance	Focus on Surfactants	No relevance from toxicological point of view
Vargas, Fátima; Domínguez, Elena; Vila, Carlos; Rodríguez, Alejandro; Garrote, Gil	2015	Agricultural residue valorization using a hydrothermal process for second generation bioethanol and oligosaccharides production	Bioresource Technology 191 263-270	Not relevant for residue section considering the intended use
Wang, Yan; Guo, Qingbin; Douglas Goff, H.; LaPointe, Gisèle	2018	Oligosaccharides: Structure, Function and Application	Elsevier	Health beneficial effects, not relevant for residue section
Wicklund, Rachel; Harrison Michael, D.; King, Christopher; Hoffman Andrew, J.; Schwenk, Michelle; Napier, Lori; Nehmer, Warren	2008	Edible composition comprising a slowly digestible or digestion resistant oligosaccharide composition	TATE & LYLE INGREDIENTS	Health effects, not relevant for residue section
Willems, Jamie L.; Low, Nicholas H.	2012	Major Carbohydrate, Polyol, and Oligosaccharide Profiles of Agave Syrup. Application of this Data to Authenticity Analysis	Journal of agricultural and food chemistry 60 8745– 8754	Not relevant for residue section considering the intended use
Young, O. A.; Cummings, T. L.	2008	Effect of Xylose on Sheepmeat Flavors in Casserole-Style Cooking	Journal of food science an official publication of the Institute of Food Technologists 73 S308-S313	Sensory study, not relevant for residue section
Zabotina, O. A.	2012	Xyloglucan and its biosynthesis	Front Plant Sci 3 134	Data on xyloglucan structure and biosynthesis in plant, not specific to grape. Not relevant for residue section.
Zerillo, M. M.; Adhikari, B. N.; Hamilton, J. P.; Buell, C. R.; Levesque, C. A.; Tisserat, N.	2013	Carbohydrate-active enzymes in pythium and their role in plant cell wall and storage polysaccharide degradation	PLoS One 8 e72572	Study on the genome of Pythium species, not relevant for residue section
Zhang, Shanshan; Hu, Haijuan; Wang, Lufeng; Liu, Fengxia; Pan, Siyi	2018	Preparation and prebiotic potential of pectin oligosaccharides obtained from citrus peel pectin	Food Chemistry 244 232-237	Study on prebiotic potential promotion of oligosaccharides, not relevant for residue section

Author(s)	Year	Title	Source	Reason for not including in dossier
Zhang, Zesheng; Lei, Mengmeng; Liu, Rui; Gao, Yunfeng; Xu, Mengying; Zhang, Min	2015	Evaluation of Alliin, Saccharide Contents and Antioxidant Activities of Black Garlic during Thermal Processing	Journal of food biochemistry 39 39-47	Not relevant for residue section considering the intended use
Zhang, Zongying; Wang, Nan; Jiang, Shenghui; Xu, Haifeng; Wang, Yicheng; Wang, Chuanzeng; Li, Min; Liu, Jingxuan; Qu, Changzhi; Liu, Wen; Wu, Shujing; Chen, Xiaoliu; Chen, Xuesen	2017	Analysis of the Xyloglucan Endotransglucosylase/Hydrolase Gene Family during Apple Fruit Ripening and Softening	Journal of agricultural and food chemistry 65 429-434	Gene expression in fruit ripening and softening, not relevant for residue section
Zhou, Da-Nian; Zhang, Bao; Chen, Bo; Chen, Han-Qing	2017	Effects of oligosaccharides on pasting, thermal and rheological properties of sweet potato starch	Food Chemistry 230 516-523	Not relevant for residue section considering the intended use

Conclusion

In the frame of this literature search for the active substance Heptamaloxylglucan, 5 963 references were identified and evaluated for their potential relevances for the data requirements “Toxicological and metabolism studies”, “Residues”, “Fate and behaviour in the environment” and “Ecotoxicological studies”, respectively.

In conclusion, the search did not identify any literatures relevant to the data requirements "Toxicological and metabolism studies". Some publications have been identified as relevant (after detailed assessment of full-text) and have been implemented in their respective sections:

RMS conclusion on the review of scientific literature

Following the literature search performed by the applicant, 4 publications were found to be relevant for the residues section (see table 7.8-8).

The summaries of these publications are available in volume 3 B.7 in the paragraphs reported in the following table. The relevance is also discussed in the corresponding paragraphs.

It is noted that the literature search do not cover the last 2 years (2019 and 2020). However, considering the nature of the active substance, RMS considers that it is not expected that an updated literature search will result in new conclusions regarding its toxicological relevance for consumers.

KCA - SANCO Data Point	Author(s)	Year	Title	Summarised and discussed in paragraphs
KCA 6.2.1 / KCA 6.3.1	Jovanovic- Malinovska, Ruzica; Kuzmanova, Slobodanka; Winkelhausen, Eleonora	2015	Application of ultrasound for enhanced extraction of prebiotic oligosaccharides from selected fruits and vegetables	B.7.2.1 B.7.3.1
KCA 6.2.1 / KCA 6.3.1	Jovanovic- Malinovska, Ruzica; Kuzmanova, Slobodanka; Winkelhausen, Eleonora	2014	Oligosaccharide Profile in Fruits and Vegetables as Sources of Prebiotics and Functional Foods	B.7.2.1 B.7.3.1
KCA 6.5	Forgo, Peter; Kiss, Attila; Korózs, Marietta; Rapi, Sándor	2013	Thermal degradation and consequent fragmentation of widely applied oligosaccharides	B.7.5
KCA 6.5	Rondeau, Pierangelo; Gambier, François; Jolibert, Franck; Brosse, Nicolas	2013	Compositions and chemical variability of grape pomaces from French vineyard	B.7.5

B.7.9. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities ^{2,3} Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used ¹ Y/N If yes, for which data point?
KCA 6.2.1/01 (KCA 5.1/01)	Buchanan B.B., Gruissen W., and Jones R.L.	2000	Biochemistry and Molecular Biology of Plants Public literature (book) GLP non relevant (Public literature) Published	N	N	NA	NA	Yes in initial DAR
KCA 6.2.1/02 KCA 6.3.1/01	Jovanovic-Malinovska R., Kuzmanova S., Winkelhausen E.	2014	Oligosaccharide profile in fruits and vegetables as sources of prebiotics and functional foods International Journal of Food Properties, 17:949–965, 2014 GLP non relevant (Public literature) Published	N	N	NA	NA	No
KCA 6.2.1/03 KCA 6.3.1/02	Jovanovic-Malinovska R., Kuzmanova S., Winkelhausen E.	2015	Application of ultrasound for enhanced extraction of prebiotic oligosaccharides from selected fruits and vegetables Ultrasonics Sonochemistry 22 (2015) 446–453 GLP non relevant (Public literature) Published	N	N	NA	NA	No
KCA 6.5/01	Forgo P., Kiss A., Korózs M., Rapi S.,	2013	Thermal degradation and consequent fragmentation of widely applied oligosaccharides Microchemical Journal 107 (2013) 37–46 GLP non relevant (Public literature) Published	N	N	NA	NA	No

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities ^{2,3} Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used ¹ Y/N If yes, for which data point?
KCA 6.5/02	Rondeau P., Gambiera F., Jolibert F., Brosse N.	2013	Compositions and chemical variability of grape pomaces from french vineyard Industrial Crops and Products 43 (2013) 251– 254 GLP non relevant (Public literature) Published	N	N	NA	NA	No

¹ In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations.

² See Art.3 of Annex of Regulation No 283/2013 and 284/2013

³ The RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).