Scientific Opinion on the energy conversion factor of d-tagatose for labelling purposes

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Scientific Opinion on the energy conversion factor of D-tagatose for labelling purposes

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA),
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Abstract

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on the energy conversion factor of D-tagatose to be used for calculating the energy value of foods to be declared in nutrition labelling. Energy conversion factors for nutrients for the purpose of nutrition labelling have been set based on the concept of metabolisable energy (ME). The same methodology has been applied to calculate the energy conversion factor for D-tagatose in this opinion. The assessment is based on a dossier prepared for Nutrilab NV and submitted by Bioresco Ltd. At present, data are insufficient to derive an accurate ME value for D-tagatose. Relying on the human data indicating a mean absorption rate of 80% (range 69–88%) and a urinary excretion of either 1% or 5%, the corresponding energy values for D-tagatose would be 2.8 kcal/g (11.8 kJ/g) and 2.96 kcal/g (12.4 kJ/g), respectively. Taking into account that the remaining 20% of D-tagatose which is not absorbed in the small intestine is fermented in the colon and may deliver at least some energy, e.g. in form of short-chain fatty acids, the Panel concludes that a rounded estimate of the energy conversion factor for D-tagatose based on the available data and calculated as ME would be 3 kcal/g (12.5 kJ/g). The Panel considers that additional data on the absorption, distribution, metabolism and excretion of D-tagatose in humans would help in the calculation of a more accurate energy conversion factor for D-tagatose based on the concept of ME.

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Summary

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on the energy conversion factor of D-tagatose to be used for calculating the energy value of foods to be declared in nutrition labelling. The energy conversion factor should be established in a comparable way to the establishment of the energy conversion factors for other nutrients that have been set for the purpose of nutrition labelling such as carbohydrate (4–17 kJ/g), protein (4–17 kJ/g) or fat (9–37 kJ/g).

Energy conversion factors for nutrients for the purpose of nutrition labelling have been set based on the concept of metabolisable energy (ME). The same methodology has been applied to calculate the energy conversion factor for D-tagatose in this opinion.

The assessment of the energy conversion factor of D-tagatose is based on the dossier – summary of the scientific evidence prepared for Nutrilab NV, Bekkevoort, Belgium, and submitted by Bioresco Ltd.

The energy content of food as measured by complete combustion is termed gross energy (GE). The term ME encompasses the energy available after accounting for losses of the ingested energy in faeces (FE), urine (UE), gases from fermentation in the large intestine (GaE) and waste products lost from surface areas (SE). Not all ME is available for the production of adenosine triphosphate (ATP). When energy losses as heat resulting from microbial fermentation and obligatory thermogenesis (i.e. excess heat relative to glucose during ATP synthesis) are subtracted from ME, the result is an expression of the energy content of food that will be available to the body for ATP production, which is referred to as net metabolisable energy (NME).

Fractional absorption of D-tagatose in the small intestine in six human subjects and one pig was around 80%. Under different experimental conditions, lower absorption rates in pigs of about 26% and in rats of about 20% were also reported. Available studies in humans, pigs and rats consistently report urinary losses of D-tagatose to range between about 1% and 5% of the ingested dose. It has been also consistently shown in animals that most, if not all, of the D-tagatose not absorbed in the small intestine is metabolised by the microbiota of the large intestine, and that there is an adaptive increase in the fermentation capacity as a consequence of D-tagatose intake. However, it is unclear in which proportions fermentation products of D-tagatose (i.e. short-chain fatty acids (SCFA), lactate, pyruvate, hydrogen, methane) are formed by the microbiota of the large intestine and to which extent they are available as energy source to humans.

The Panel notes that the energy conversion factors for labelling purposes in the European legislation have been estimated as ME for other nutrients. At present, data are insufficient to derive an accurate ME value for D-tagatose. Based on a GE value for D-tagatose of 3.75 kcal/g (15.7 kJ/g), fractional absorption rates of 20% (one study in rats), 25% (one study in pigs) and 80% (one human study on ileostomy patients and one study in a pig) of the ingested amount, and urinary losses between 1% and 5%, ME values between 2.06 and 3.33 kcal/g (8.62 and 13.97 kJ/g) can be obtained, on the assumption that fermentation yields only 50% of the GE of D-tagatose and that SE losses are negligible. FSANZ (2004) assumes that fermentation yields 70% of the GE of D-tagatose and that 5% of fermented D-tagatose is lost as GaE. This would result in ME values between 2.67 and 3.45 kcal/g (11.15 and 14.44 kJ/g). However, estimates for energy yield from fermentation of D-tagatose are based on multiple assumptions that are not corroborated by experimental data in humans.

Relying on the human data indicating a mean absorption rate of 80% (range 69–88%) and a urinary excretion of either 1% or 5%, the Panel considers that the corresponding energy values for D-tagatose would be 2.8 kcal/g (11.8 kJ/g) and 2.96 kcal/g (12.4 kJ/g), respectively. Taking into account that the remaining 20% of D-tagatose which is not absorbed in the small intestine is fermented in the colon and may deliver at least some energy, e.g. in form of SCFA, the Panel concludes that a rounded estimate of the energy conversion factor for D-tagatose based on the available data and calculated as ME would be 3 kcal/g (12.5 kJ/g).

The Panel considers that additional data on the absorption, distribution, metabolism and excretion of D-tagatose in humans would help in the calculation of a more accurate energy conversion factor for D-tagatose based on the concept of ME.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

Council Directive 90/496/EEC of 24 September 2000 on nutrition labelling for foodstuffs and amending Directives 2003/120/EC and 2008/100/EC, specifies the energy conversion factors that shall be used for calculating the energy value to be declared in nutrition labelling. The Commission has received a request from a company for the evaluation of the energy conversion factor of D-tagatose, a monosaccharide. The energy conversion factor for carbohydrates is set in Directive 90/496/EEC at 4–17 kJ/g.

1.1.2. Terms of Reference

In accordance with Article 29 (1) (a) of Regulation (EC) No 1781/2002, the European Commission asks the European Food Safety Authority (EFSA) to provide a scientific opinion on the energy conversion factor of D-tagatose to be used for calculating the energy value of foods to be declared in nutrition labelling. The energy conversion factor should be established in a comparable way to the establishment of the energy conversion factors for other nutrients that have been set for the purpose of nutrition labelling such as carbohydrate (4–17 kJ/g), protein (4–17 kJ/g) or fat (9–37 kJ/g).

1.2. Interpretation of the Terms of Reference

Council Directive 90/496/EEC has been repealed by Regulation (EC) No 1169/2011[1], which establishes in Annex XIV the conversion factors to be used for the calculation of the energy content to be declared in food labels. The European Commission requests that the energy conversion factor for D-tagatose should be established in a comparable way to the establishment of the energy conversion factors for other nutrients, such as carbohydrate (4–17 kJ/g), protein (4–17 kJ/g) or fat (9–37 kJ/g). EFSA notes that the energy conversion factors that have been set in Regulation (EC) No 1169/2011 for the above-mentioned macronutrients for the purpose of nutrition labelling are the same as in Council Directive 90/496/EEC, and that those values were calculated using the concept of metabolisable energy (ME). The European Commission confirmed this view. Therefore, EFSA interprets this mandate as a request for a scientific opinion on the energy conversion value of D-tagatose to be used for calculating the energy value of foods to be declared in nutrition labelling based on the concept of ME.

2. Data and methodologies

2.1. Data

The assessment of the energy conversion factor of D-tagatose is based on the dossier – summary of the scientific evidence prepared for Nutrilab NV, Bekkevoort, Belgium. Date: 7 April 2008. Submitted by Bioresco Ltd.

2.2. Methodologies

Energy conversion factors for nutrients for the purpose of nutrition labelling have been set based on the concept of ME. The same methodology will be applied to calculate the energy conversion factor for D-tagatose in this opinion.

3. Assessment

3.1. Introduction

D-Tagatose is a monosaccharide that was authorised as a novel food in the European Union (EU) in June 2005 based on an opinion of the UK Advisory Committee for Novel Foods and Processes (ACNFP) (FSA, 2005). The estimated daily intakes of D-tagatose considered in the different safety assessments

[1] 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.

vary from about 4–5 g/day for the mean consumer to about 10 g/day for the 90th percentile consumer, but higher intakes of 15–20 g/day are conceivable (FSA, 2005).

In recognition of the need for the allocation of an appropriate energy conversion factor for D-tagatose for labelling purposes, the US Food and Drug Administration (US FDA) has accepted a factor of 1.5 kcal/g (6 kJ/g) (FDA, 2001). In Australia/New Zealand, a factor of 2.5 kcal/g (11 kJ/g) was attributed to D-tagatose for that purpose (FSANZ, 2004). Regulation (EC) No 1169/2011[1] (repealing Council Directive 90/496/EEC on nutrition labelling for foodstuffs, as amended) specifies that the energy conversion factors that shall be used for calculating the energy value to be declared in nutrition labelling for glycaemic carbohydrates is 17 kJ/g (4 kcal/g).

The energy content of food as measured by complete combustion is termed gross energy (GE). The term ME encompasses the energy available after accounting for losses of the ingested energy in faeces (FE), urine (UE), gases from fermentation in the large intestine (GaE), and waste products lost from surface areas (SE). Not all ME is available for the production of adenosine triphosphate (ATP). When energy losses as heat resulting from microbial fermentation and obligatory thermogenesis (i.e. excess heat relative to glucose during ATP synthesis) are subtracted from ME, the result is an expression of the energy content of food that will be available to the body for ATP production, which is referred to as net metabolisable energy (NME) (FAO, 2003).

In the EU legislation, the energy conversion factors for nutrients for labelling purposes have been calculated as ME.

3.2. Characterisation and intended use

D-Tagatose is a naturally occurring, sweet ketohexose related to D-galactose and is the C-4 epimer of D-fructose. D-Tagatose occurs in *Sterculia setigera* gum, a partially acetylated acidic polysaccharide, and also in low concentrations in heated cow's milk produced from lactose (FSA, 2005). D-Tagatose was originally developed as a sugar substitute for energy and weight control and has been used as low-energy sweetener in soft drinks and yoghurts.

3.3. Absorption, metabolism and excretion

3.3.1. Absorption

There is only one human study investigating the absorption of D-tagatose. Normén et al. (2001) administered a controlled diet with 15 g of D-tagatose daily for 3 weeks to six subjects with ileostomy, with less than 10 cm of the terminal ileum removed due to ulcerative colitis. Subjects were otherwise healthy and the time since the operation ranged between 5 and 27 years. Ileostomy effluents were collected every second hour to minimise bacterial degradation. The bags were immediately sealed and frozen in containers filled with dry ice. Mean recovery of the ingested D-tagatose over 24 h in the ileostomy was about 19%, leading to a mean apparent absorption of 81% (range 69–88%).

An absorption study (Levin et al., 1995, unpublished report) was performed in one pig fed with 5% of D-tagatose in the diet, which was restricted to 85% of its normal quantity of feed. In addition, bacteriostatics were included as well as Celite, an insoluble ash, as inert markers. Analyses of samples of digested material, removed hourly from the cannulated ileum over a period of 8 h, showed that 78% of the D-tagatose was absorbed from the small intestine.

In a study in eight pigs fed twice daily a restricted diet (40 g/kg body weight per day) containing 10% D-tagatose for 18 days, a mean (± SEM) digestibility of D-tagatose of 25.8% (± 5.6) was reported, as determined in the distal third of the small intestine (Laerke and Jensen, 1999). Chromic oxide was used as a digestibility marker. In this study, the pigs were killed 3 h after the morning meal, the gastrointestinal tract was removed and its contents analysed. The digestibility was calculated from the concentration of D-tagatose in the intestinal content in relation to its concentration in the diet.

A third study in pigs (Johansen and Jensen, 1997) was available to the Panel only as an abstract and thus could not be evaluated.

One study in rats reported an intestinal absorption rate of D-tagatose of about 20% (Saunders et al., 1999) based on results obtained in two germ-free unadapted rats to which a single dose of [U-^{14}C]-labelled D-tagatose was orally administered. Intestinal absorption was estimated from the sum of ^{14}C expired as $^{14}CO_2$ and recovered in tissues and carcass 6 h after dosing, assuming that this time frame reflects absorption and metabolism of absorbed nutrients by mammalian enzymes in rats.

3.3.2. Metabolism

It has been proposed that the absorbed D-tagatose could be metabolised in the liver via a pathway similar to that of D-fructose. D-Tagatose is phosphorylated to D-tagatose 1-phosphate by fructokinase (Raushel and Cleland, 1973) and then cleaved by aldolase B to enter glycolysis at the level of D-glyceraldehyde and dihydroxyacetone phosphate (Martínez et al., 1987).

3.3.3. Excretion

In a human study on eight volunteers on a diet providing 30 g/day of D-tagatose for 2 weeks, urinary excretion of D-tagatose ranged between 0.7% and 5.3% of the ingested dose (Buemann et al., 1998).

No or negligible amounts of D-tagatose were found in faeces of pigs ingesting a 10% D-tagatose diet for 14 consecutive days (Laerke and Jensen, 1999). Negligible amounts of D-tagatose in faeces were also reported in pigs on either a 10% or 20% D-tagatose diet, whereas about 5% of the ingested D-tagatose was excreted in urine, irrespective of whether the diet contained 10% or 20% of D-tagatose, and 2% was lost as hydrogen (Jørgensen and Laerke, 1998; unpublished report).

In adapted rats fed a diet with 10% D-tagatose for 28 days, a total of 9% of the ingested dose of ^{14}C-labelled D-tagatose was recovered in faeces after 24 h. About 1.8% of the ^{14}C was found in D-tagatose and 1.3% in short-chain fatty acids (SCFA), pyruvate and lactate. The fate of the remaining 5.9% of ^{14}C was not further specified (Saunders et al., 1999). After 72 h, the total percentage of the ^{14}C dose recovered in faeces was 11.4%, while in the unadapted rats, the recovery of D-tagatose in faeces was about 28.7% of the ingested dose.

In rats and pigs, increased numbers of D-tagatose degrading bacteria and disappearance of watery stools after few days of D-tagatose ingestion indicate adaptation of the microbiota to the consumption of D-tagatose (Laerke and Jensen, 1999; Saunders et al., 1999). D-Tagatose did not appear to be utilised as a substrate by the microbiota in the stomach and small intestine of pigs, whereas it was readily fermented by the microbiota in the caecum and colon (Laerke et al., 2000). It was estimated that about 51% of the energy of D-tagatose is recovered as SCFA when D-tagatose is fermented *in vitro* by adapted caecal and colonic bacteria (Laerke et al., 2000).

The mean recovery over a period of 72 h of $^{14}CO_2$ in breath from ^{14}C-labelled D-tagatose given orally to adapted rats was 67.9% (Levin et al., 1995; Saunders et al., 1999), while in germ-free animals, the recovery was only 22% (Saunders et al., 1999). This suggests that the observed difference in the expired $^{14}CO_2$ between adapted and germ-free rats may have derived from bacterial metabolism. In this study, the percentage of the ^{14}C dose recovered in urine and carcass of adapted rats amounted to 5.2% and 10.1%, respectively. This indicates that a total of 83.2% of the ingested radiolabelled D-tagatose has been absorbed (either as D-tagatose in the small intestine or as SCFA and other degradation products of the microbiota in the large intestine), of which 78% has been metabolised (67.9%) or retained (10.1%).

The Panel notes that fractional absorption of D-tagatose in the small intestine in six human subjects and one pig was around 80%. Under different experimental conditions, lower absorption rates in pigs of about 26% and in rats of about 20% were also reported. Available studies in humans, pigs and rats consistently report urinary losses of D-tagatose to range between about 1% and 5% of the ingested dose. It has been also consistently shown in animals that most, if not all, of the D-tagatose not absorbed in the small intestine is metabolised by the microbiota of the large intestine, and that there is an adaptive increase in the fermentation capacity as a consequence of D-tagatose intake. However, it is unclear in which proportions fermentation products of D-tagatose (i.e. SCFA, lactate, pyruvate, hydrogen, methane) are formed by the microbiota of the large intestine and to which extent they are available as energy source to humans.

3.4. Methods

The energy value of foods or food constituents may be estimated either directly from results of *in vivo* studies (e.g. energy balance studies, indirect calorimetry) or from data on their metabolic fate (factorial calculation model). ME can be determined using the factorial calculation model according to the following formula: ME = GE − (FE + UE + GaE + SE).

3.4.1. Energy balance methods

Three *in vivo* studies on the energy value of D-tagatose were provided by the applicant.

In one study conducted in rats (unpublished report of Biospherics Inc. by Saunders et al., 1994), the retained energy was calculated to be 0 kJ/g D-tagatose. Calculations of either ME or NME were not performed, and therefore, no conclusions can be drawn from this study to estimate the energy conversion factor for D-tagatose.

The second study examined the contribution of D-tagatose to energy requirements in growing rats by determining its NME value (Livesey and Brown, 1996). Two groups of 30 rats each were adapted for a period of 21 days to a basal diet supplemented with either sucrose (5%) or D-tagatose (10%). Each group was then split at random into three subgroups. One of the subgroups continued the assigned treatment for 40 days, one discontinued the treatment (i.e. basal diet without supplement for 40 days), and one was killed for body composition analysis. The daily intake of the basal diet was fixed. Body weights were determined at the start of the experiment, at the end of the 21-day adaptation period, and at the end of the 40-day balance period. The GE of the basal diet, of D-tagatose and of sucrose was also determined. From these data, it was calculated that D-tagatose had a NME of −0.12 kcal/g (−0.5 kJ/g).

The Panel notes that other studies have shown that D-tagatose is absorbed at least to some extent in the small intestine in rats (Jørgensen and Laerke, 1998; Saunders et al., 1999) and to a greater extent in humans (Normén et al., 2001), and that otherwise, it is nearly completely fermented by the microbiota in the large intestine (Laerke and Jensen, 1999). Thus, the results reported by Livesey and Brown (1996) lack biological plausibility, which might be attributed to the study design or the methodology applied.

In the third study (Jørgensen and Laerke, 1998; unpublished report), six growing pigs received randomly three diets containing either 20% sucrose, 10% sucrose and 10% D-tagatose, or 20% D-tagatose during 2 weeks each. During the second week, faecal digestibility of dietary nutrients was estimated, and protein, fat and energy balance, urinary output of D-tagatose, amount of methane and hydrogen expired, and the faecal composition and output of SCFA and lactate were analysed. Digestible energy (DE) was estimated based on indirect calorimetry measurements and on nitrogen and carbon balance. The energy utilisation of GE from either basal diet plus sucrose and/or D-tagatose (MJ/day) was regressed to the daily total amount of the measured parameters DE (DE = GE − FE − GaE), CH_4 energy, H_2 energy, urine energy and ME in MJ/day. Energy digestibility decreased from 85.3% to 79.8% when replacing 20% sucrose with 20% D-tagatose. The energy digestibility in the total ration decreased by 0.292% for each per cent inclusion of D-tagatose in the diet, when assuming a linear response. From the equation DE/GE, % = 85.8 − 0.292 × D-tagatose %, the digestibility of D-tagatose was calculated as 56.6%.

Although a linear response was assumed, the authors noted that the data points could also indicate a curvilinear function with a smaller response with the 10% D-tagatose diet than with the 20% D-tagatose diet. When metabolisability (ME/GE) of D-tagatose was estimated by the difference method in this study, using literature values for sucrose, the resulting values for the 10% and 20% D-tagatose diets were 74% and 57%, respectively.

About 5% of the ingested D-tagatose was excreted in the urine, independently of the intake of D-tagatose at either 10% or 20% in the diet, and 2% lost as hydrogen. Only minor or no losses of D-tagatose were observed in faeces and D-tagatose did not contribute to methane excretion.

Calculating the ME of D-tagatose as the difference between GE (15.67 kJ) and FE (15.67 − 15.67 × 0.566), UE (5% of GE) and GaE (2% of GE), a value of 1.9 kcal/g (7.9 kJ/g) was obtained using the value of 56.6% for DE for the 20% level of D-tagatose. Using the reported value of 74% for ME derived from the difference method for the 10% level of D-tagatose, this would yield an energy value of 2.8 kcal/g (11.6 kJ/g), although this value was not explicitly considered by the authors.

The Panel notes that, out of the three animal studies provided using energy balance methods, only one study in six pigs (Jørgensen and Laerke, 1998; unpublished report) provided data for calculating the ME of D-tagatose. Depending on the dose of D-tagatose and the calculation approach, the results suggest values of either 1.9 kcal/g (7.9 kJ/g) or 2.8 kcal/g (11.6 kJ/g).

3.4.2. Factorial calculation

The applicant presents an estimation of the energy value of D-tagatose using the factorial model, taking into account losses of energy caused indirectly by the fermentation of D-tagatose (e.g. increased faecal excretion of biomass and non-bacterial mass).

3.4.2.1. Energy gain from absorbed and metabolised D-tagatose

The calculation of the energy gain from absorbed and metabolised D-tagatose conducted by the applicant assumes that the fractional absorption of D-tagatose is 25% as reported in rats and pigs (Jensen and Laue, 1998; Laerke and Jensen, 1999; Saunders et al., 1999) and that 5% of the ingested D-tagatose is lost in urine as reported in rats (Saunders et al., 1999). Based on the results from the metabolic studies in rats, the applicant assumed that the absorbed fraction of D-tagatose which is not excreted in urine is fully metabolised, which would yield 3.75 kcal/g (15.7 kJ/g). From this, the applicant calculated that the energy gain from absorbed and metabolised D-tagatose would be 0.75 kcal/g (3.14 kJ/g) of ingested D-tagatose.

The Panel notes that a fractional absorption rate of 80% has been reported in patients with ileostomy (Normén et al., 2001) and also in a study in one pig, and that 1–5% of ingested D-tagatose was recovered in urine in humans (Buemann et al., 1998; Buemann et al., 2000). The Panel also notes that the ileostomy model has been widely used in other absorption studies in humans (e.g. Sandberg et al., 1981; Chapman et al., 1985; Faulks et al., 1997; Witthöft et al., 2006) and considers that this model represents an appropriate approach to estimate absorption of nutrients in healthy humans. Assuming a fractional absorption of D-tagatose in the small intestine of 80% and urinary losses of either 1% or 5%, the energy gain from absorbed and metabolised D-tagatose would be 2.96 and 2.81 kcal/g (12.40 and 11.78 kJ/g), respectively.

3.4.2.2. Energy gain from the absorbed short-chain fatty acids

The applicant assumes that 75% of the ingested D-tagatose is unabsorbed and fully subjected to bacterial fermentation. In this situation, the SCFAs produced during bacterial fermentation would account for about 50% of the GE (combustible energy) of D-tagatose. This assumption is based on studies in pigs (Jensen and Laue, 1998; Laerke et al., 2000) and in humans (Jensen and Buemann, 1998). By applying a correction factor to account for a lower ATP yield from SCFA than from glucose (0.85 mol ATP/kJ SCFA per mol ATP/kJ glucose), the energy gain from absorbed SCFA would be 1.26 kcal/g (Bär, 1990; Livesey, 1993).

The Panel notes that the correction for a lower ATP yield from SCFA than from glucose does not apply to the calculation of ME, but rather to the calculation of NME.

3.4.2.3. Energy loss due to increased faecal biomass

Assumptions on the energy loss due to increased faecal biomass rely on studies investigating the increase in biomass due to the ingestion of fermentable substrates that stimulate bacterial growth. From experiments with lactulose (Weber et al., 1987), lactitol (van Velthuijsen and De Uyl, 1988) and isomalt (Livesey, 1990), the increase in biomass was estimated to be about 14–20% of the ingested amount of fermentable substance. However, the incorporation into the biomass of ^{14}C from ^{14}C-lactitol was only 6.5% (Grimble et al., 1988), 10% from ^{14}C-isomalt (Patzschke et al., 1975; WHO, 1987) and 4.9% from ^{14}C-maltitol (Rennhard and Bianchine, 1976). Up to 6% of ^{14}C from ^{14}C-D-tagatose orally administered to rats was incorporated into faecal biomass.

The applicant argues that the difference between the increased faecal excretion of biomass (about 14–20% of the fermented substrate) and the much lower incorporation of C-atoms from the substrate to the biomass (about 5–10%) suggests that the growing microbial cells incorporate C-atoms also from other sources, which then would not be available to the host. The estimated maximum increase in faecal biomass would be 15–20% of the fermented D-tagatose, and the estimated maximum incorporation of C-atoms from D-tagatose to the biomass would be 5–10%. The average difference of 10% would represent other material incorporated into the biomass, which would result in an energy loss for the host of about 0.2–0.4 kcal/g (0.8–1.7 kJ/g) of the fermented D-tagatose or 0.15–0.30 kcal/g (0.63–1.26 kJ/g) of the ingested D-tagatose, assuming that 25% is absorbed and 75% is fermented.

The Panel notes that no *in vivo* studies were provided which investigated the effects of D-tagatose on faecal biomass directly, and that the effects of lactulose, lactitol and isomalt on faecal biomass may differ from those of D-tagatose.

3.4.2.4. Energy loss due to increased faecal non-biomass

The increase in faecal dry matter in pigs fed a diet with 20% D-tagatose was 0.27 g/g of D-tagatose ingested, and was calculated to be 0.36 g/g of D-tagatose fermented (unpublished report, Jørgensen and Laerke, 1998). On the assumption that the bacterial growth yield is about 15–20% of the

D-tagatose ingested (i.e. 0.15–0.20 g/g D-tagatose), half of the increased faecal dry matter would represent bacteria (i.e. biomass), while the other half would represent a different material. Assuming that this material was secreted protein (mucus, mucosal cells), the applicant calculated that the loss of energy due to increased faecal non-biomass would be from 0.6 to 0.8 kcal/g (from 2.5 to 3.4 kJ/g) of D-tagatose fermented, or from 0.45 to 0.60 kcal/g (from 1.9 to 2.5 kJ/g) of D-tagatose ingested.

The Panel notes that the calculations made by the applicant to derive the energy losses due to increased faecal biomass and non-biomass are based on numerous assumptions which are not substantiated with corresponding experiments.

3.5. Estimation of the energy conversion factor for D-tagatose

On the basis of the calculations and assumptions referred to in Sections 3.4.1 and 3.4.2, the applicant derived an energy conversion factor for D-tagatose of 1.1–1.4 kcal/g (4.6–5.9 kJ/g) which reflects NME, rather than ME.

The Panel notes that the energy conversion factors for labelling purposes in the European legislation have been estimated as ME for other nutrients. At present, data are insufficient to derive an accurate ME value for D-tagatose. Based on a GE value for D-tagatose of 3.75 kcal/g (15.7 kJ/g), fractional absorption rates between 20% (one study in rats), 25% (one study in pigs), 80% (one human study on ileostomy patients and one study in a pig) of the ingested amount, and urinary losses between 1% and 5%, ME values between 2.06 and 3.33 kcal/g (8.62 and 13.97 kJ/g) can be obtained, on the assumption that fermentation yields only 50% of the GE of D-tagatose and that SE losses are negligible. FSANZ (2004) assumes that fermentation yields 70% of the GE of D-tagatose and that 5% of fermented D-tagatose is lost as GaE. This would result in ME values between 2.51 and 3.45 kcal/g (10.51 and 14.44 kJ/g). However, estimates for energy yield from fermentation of D-tagatose are based on multiple assumptions that are not corroborated by experimental data in humans.

4. Conclusions

Relying on the human data indicating a mean absorption rate of 80% (range 69–88%) and a urinary excretion of either 1% or 5%, the corresponding energy values for D-tagatose would be 2.8 kcal/g (11.8 kJ/g) and 2.96 kcal/g (12.4 kJ/g), respectively. Taking into account that the remaining 20% of D-tagatose which is not absorbed in the small intestine is fermented in the colon and may deliver at least some energy, e.g. in form of SCFA, the Panel concludes that a rounded estimate of the energy conversion factor for D-tagatose based on the available data and calculated as ME would be 3 kcal/g (12.5 kJ/g).

5. Recommendations

The Panel considers that additional data on the absorption, distribution, metabolism and excretion of D-tagatose in humans would help in the calculation of a more accurate energy conversion factor for D-tagatose based on the concept of ME.

Steps taken by EFSA

1) The European Commission received a scientific dossier for the evaluation of the energy conversion factor of D-tagatose (i.e. dossier on the energy conversion factor of D-tagatose – summary of the scientific evidence prepared for Nutrilab NV, Bekkevoort, Belgium. Date: 7 April 2008. Submitted by Bioresco Ltd).
2) On 22 January 2009, the Commission forwarded the scientific dossier to EFSA and requested EFSA to deliver a scientific opinion on the energy conversion factor of D-tagatose.
3) On 18 February 2009, EFSA accepted the mandate and agreed to finalise the scientific opinion by May 2010.
4) On 17 May 2010, EFSA informed the Commission that the preparatory work for the draft scientific opinion on the energy conversion factor of D-tagatose was done by the Working Group on Population Reference Intakes (WG on PRI) and that the draft opinion was discussed at the Plenary meeting of the NDA Panel on 28–30 April 2010. However, the Panel found that the opinion required a revision, and thus EFSA requested to postpone the deadline until July 2010.

5) On 7 July 2010, EFSA informed the Commission that the WG on PRI found that there were important data missing to calculate a scientifically sound energy conversion factor based on ME for D-tagatose. A list of questions was prepared by EFSA to be forwarded to the applicant in this respect. EFSA also requested confirmation from the Commission that the energy conversion factors for nutrients to be used for calculating the energy value of foods to be declared in nutrition labelling should be based on the concept of ME, rather than on the concept of NME.
6) On 2 August 2010, the Commission confirmed that the energy conversion factors for nutrients to be used for calculating the energy value of foods to be declared in nutrition labelling should be based on the concept of ME. The Commission also informed EFSA that the Commission will forward the EFSA requests for additional information to the applicant and will send to EFSA the additional information submitted by the applicant once available.
7) On 9 February 2016, the Commission informed EFSA that, on 5 November 2015, the applicant had informed the Commission that no new evidence was available which could be used for calculating the energy conversion factor of D-tagatose based on the concept of ME, and that the applicant had only summarised again its position by using supporting references (additional information submitted by the applicant to the European Commission on April 2014). EFSA was requested by the Commission to provide a scientific opinion based on the original request and the new references provided by the applicant. The Commission also requested EFSA to propose a new deadline for the request considering the current workload of EFSA.
8) On 23 February 2016, EFSA proposed the deadline of 31 December 2016 for the completion of the request. EFSA also informed the Commission about the necessity of a public consultation before adoption of this opinion.
9) On 29 June 2016, the NDA Panel endorsed a Draft Scientific Opinion on the energy conversion factor of D-tagatose for labelling purposes for public consultation.
10) The written public consultation for this document was open from 18 July to 12 September 2016.
11) On 25 October 2016, the NDA Panel endorsed a technical report in which all comments received during the public consultation were addressed and adopted this scientific opinion.

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Abbreviations

ACNFP	UK Advisory Committee for Novel Foods and Processes
ATP	adenosine triphosphate
DE	digestible energy
GaE	energy lost in gases from intestinal fermentation
GE	gross energy
FE	energy lost in faeces
FDA	US Food and Drug Administration
FSA	Food Standards Agency
FSANZ	Food Standards Agency Australia/New Zealand

ME	metabolisable energy
NDA	EFSA Panel on Dietetic Products, Nutrition and Allergies
NME	net metabolisable energy
SCFA	short-chain fatty acids
SE	energy lost in surface areas
SEM	standard error of the mean
UE	energy lost in urine