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The legal difficulties of novel food and advertising health benefits

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With our collaboration partner **meyer.science** we resolve complex preliminary scientific and technical questions using the know-how of the scientists from the pharmaceutical, food chemistry and food technology sectors.

- how do food act in the human body, influence the human microbiome and ultimately human health?
- and, if this is the case, these substances are permitted [**Novel Food**] and may be advertised with these effects [**Health Claims**]?

Key Messages

- yes, novel food law is complex
- but companies make it difficult for themselves
 - submitting applications without (legally) checking whether they need to applications
 - without verifying from a retrospective view how EFSA ticks, just hoping for their studies
 - companies that do not know the Commission/EFSA network

Novel Food intended for Human Microbiome

- **2'-Fucosyllactose**
- 2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)
- **3-Fucosyllactose** (3-FL) (microbial source)
- 3-Fucosyllactose ('3-FL') (produced by a derivative strain of E. coli BL21(DE3))
- 3-Fucosyllactose ('3-FL') (produced by derivative strain of E. coli K-12 DH1)
- Lacto-N-fucopentaose I and 2'-Fucosyllactose ('LNFP-I and 2'-FL') mixture (produced using a derivative strain of E. coli K-12 DH1)

Humane milk
oligosaccharides
(HMO)

Novel Food intended for Human Microbiome

- **3'-Sialyllactose** (3'-SL) sodium salt (microbial source)
- 3'-Sialyllactose ('3'-SL') sodium salt (produced by derivative strains of E. coli BL21(DE3))
- 3'-Sialyllactose (3'-SL) sodium salt (produced using a derivative strain of E. coli W (ATCC 9637))
- **6'-Sialyllactose** (6'-SL) sodium salt (microbial source)
- 6'-Sialyllactose ('6'-SL') sodium salt (produced by derivative strains of E. coli BL21(DE3))
- 6'-Sialyllactose (6'-SL) sodium salt (produced by derivative strain of E. coli W (ATCC 9637))

Novel Food intended for Human Microbiome

- **Akkermansia muciniphila** (pasteurised)
 - Foods for special medical purposes (FSMP),
Food supplements - $3,4 \times 10^{10}$ cells/day
- **Clostridium butyricum** MIYAIRI 588 (CBM 588)
 - Food Supplements, $1,35 \times 10^8$ CFU/day
- **Galacto-oligosaccharide (GOS)**

probiotics

prebiotic

specific GOS/FOS mixture
(patented by Nestle)
has been permitted for IF
for decades

Novel Food intended for Human Microbiome

- Lacto-N-neotetraose
- Lacto-N-tetraose ('LNT') (microbial source)

“The human milk oligosaccharide LNT (Lacto-N-Tetraose) is one of the most abundant HMOs in breast milk and represents the group of basic neutral HMOs”

Definition: any food that was **not used for human consumption to a significant degree within the Union before 15 May 1997** + that falls under at least one of the following categories:

- i) food with a new or intentionally **modified molecular structure**
- ii) food **consisting** of, isolated from or **produced** from **microorganisms**, fungi or algae
- iii) material of mineral origin

iv) **plants** or their parts

⇒ exception: history of safe food use within the Union

- **traditional propagating practices** used for food production before 15.5.1997
- **non-traditional propagating practices** used for food production before 15.5.1997, where those practices do **not give rise to significant changes** in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances

- v) **animals** or their parts
 - ⇒ exception: animals obtained by traditional breeding practices
- vi) **cell/tissue culture** derived from animals, plants, microorganisms, fungi or algae
- vii) **production process** not used for food production, which gives rise to *significant changes* in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances
- viii) food consisting of engineered **nanomaterial**

„health claim“

= „any claim that states, suggests or implies that a **relationship** exists between a **food** category, a food or one of its constituents and **health**“

(Art. 2 para. 2 No. 5 HCR 1924/2006)

CJEU, C-544/10, 6.9.2012:

„[...] it must be noted that that definition provides no information as to whether that relationship must be direct or indirect, or as to its intensity or duration. In those circumstances, the term **‘relationship’ must be understood in a broad sense.**“

ECJ + BGH jurisdiction on health claims

“The term ‘health claim’ must not only apply to a link which implies an improvement in health status thanks to the consumption of a food, but must also cover **any link which implies that negative or harmful effects on health** which in other cases accompany or follow such consumption are absent or less pronounced, i.e. the mere maintenance of a good state of health despite potentially harmful consumption (ECJ – Deutsches Weintor, „bekömmlich“)

A health claim can also be made if, according to the **understanding of the average consumer**, which is naturally also influenced by prior expectations and knowledge, a connection between the component of a food and the consumer's state of health is suggested, such as with ‘**prebiotics**’ or ‘**with prebiotic fibres**’, even with ‘artificial words’ such as ‘**combiotics**’ (BGH).

EU Commission on „probiotics“

Decision on how the European Commission deals with **probiotics as 'health claims'** (case 2273/2023/MIK)

- **WHO definition** of „probiotics“:

„live microorganisms which when administered in adequate amounts confer a health benefit on the host “

= **health claim** - not only „nutritional claim“ or a „neutral descriptor“

- But, no favourable scientific opinion of EFSA for probiotics due to
 - lack of scientific evidence on the effects of probiotics on a healthy population
 - insufficient characterisation of the strains of microorganisms used in the relevant foods
 - the poor quality of studies
 - and undefined claims

Health Claims on Human Microbiome

- “**Barley grain** fibre contributes to an increase in **faecal bulk**”
- “Consumption of **beta-glucans** from oats or barley as part of a meal contributes to the **reduction of the blood glucose** rise after that meal”
- “**Chicory** inulin contributes to normal **bowel function by increasing stool frequency**”
- “**Lactitol** contributes to normal **bowel function by increasing stool frequency**”
- “Live **cultures in yoghurt** or fermented milk **improve lactose digestion** of the product in individuals who have difficulty digesting lactose”
- “Dried **plums/prunes** of contribute to normal **bowel function**” (Prunus domestica L.)
- „**Rye fibre** contributes to normal **bowel function**“
- “**Sugar beet fibre** contributes to an increase in **faecal bulk**”
- “**Wheat bran fibre** contributes to an **acceleration of intestinal transit**”
- “**Wheat bran fibre** contributes to an increase in **faecal bulk**”

Reg. 1924/2006 differentiates between specific and general health claims:

- **specific Health Claims** (Art. 10 para. 1, 13, 14 Reg. 1924/2006) require **authorisation**
⇒ authorised health claims are listed in the
Union list Reg. 432/2012
- **general, non-specific Health Claims** (Art. 10 para. 3) need no authorisation but may only be used if „**accompanied by an authorised specific health claim**“

Art. 13

- the role of a nutrient or other substance in **growth, development** and the **functions of the body**
- **psychological and behavioural functions**
- **slimming** or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet

Art. 14

- reduction of **disease risk** claims
- claims referring to **children's development and health**





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