

Food Safety Compliance training

Labelling



With our Food Safety Compliance for QA managers training we go back to the basics, the foundation to properly fulfill the complex function of a QA manager, now and in the future.

Contents

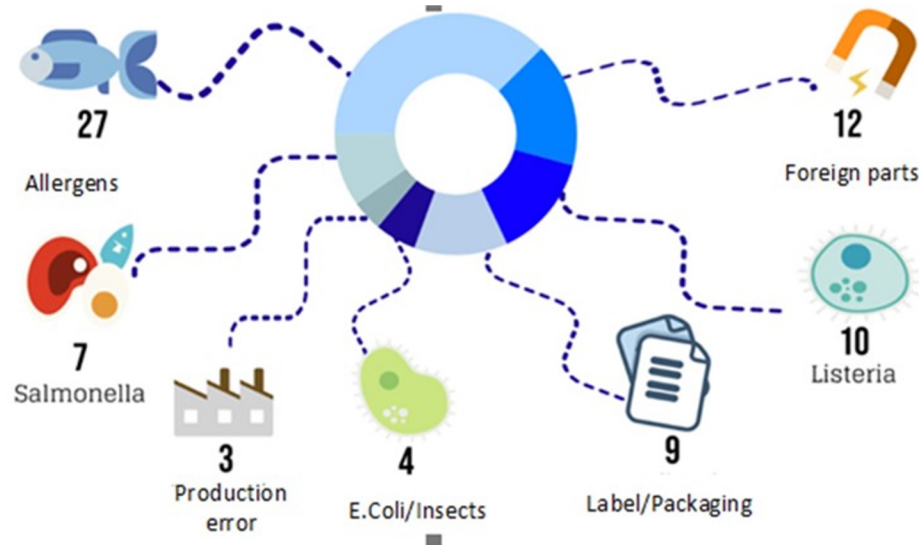
1. **Food Safety Compliance**
2. Labeling: Required information for packaged food
3. Labeling: Origin regulation
4. Labeling: Claims and European regulations

In which field do we operate?

- Dynamic playing field
- 2000 quality requirements
- 100 suppliers
- 100 customers
- 100 employees
- 400 legislative changes



Legislation: Recall (VMT overview 2019)



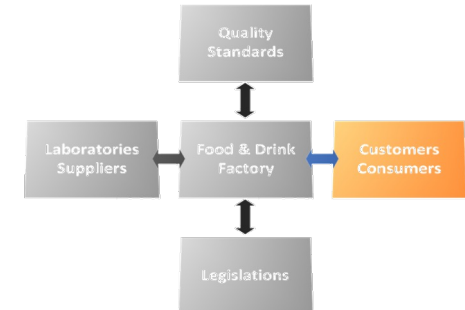
Food Factory

- Product and Data. Record everything yourself that you enter in customer portals / promise to customers.
- Example: PS in Food service, broker in product information, what the Food Factory pays for, upside-down world!
- From Product-to-Product information to Transparency and Customer Intimacy.
- As a brand owner, a producer can best build up a relationship with the consumer.
- This causes the consumer to ask for the producer ?



Customer & Consumer

- Product Integrity
- Ingredient declaration
- Nutritional values
- Origin
- Claims
- Allergens
- Produced where, which checks?
- Food Production
- Food Defense
- Food Fraud
- 2020: Origin regulation
- 2021: Nutri-score



Contents

1. Food Safety Compliance
2. **Labeling: Required information for packaged food**
3. Labeling: Origin regulation
4. Labeling: Claims and European regulations

Regulation 1169/2011

- Involves “providing food information to consumers.”
 - (pre)packaged: via the packaging or the label
 - unpackaged: (after) with the food
- Several directives merged into one new regulation
- All existing regulations will be retained + new regulations
- No simplification (yet)



Regulation 1169/2011

- Considerations
- Consumer protection
- Enable thoughtful choices
- Free movement
- No deception
- 1 regulation



1. Ingredient list

- Considerations
- Consumer protection
- Enable thoughtful choices
- Free movement
- No deception
- 1 regulation

Required information (art. 9)

- Name of the food
- List of ingredients
- Allergen labeling
- Quantitative ingredient declaration
- Net quantity
- Best before date
- Special storage conditions and / or conditions of use if omission is misleading
- Operator's name and address
- (country of origin or place of provenance – as required)
- Instructions for use when food is difficult to use without these instructions for use
- (Alcohol percentage for drinks > 1,2%)
- Nutritional value labeling (NEW!)

Additional required information (art. 10 and annex iii)

- **Additional required information when applicable***
- “packaged in protective atmosphere”
- Products with (sugar(s) and) sweetener(s), incl. Aspartame and polyols
- Products with glyceric acid or ammonium salt
- Products with caffeine
- Products with added phytosterols or stanols
- Frozen meat, meat preparations and unprocessed fishery products: date of (1st) freezing (also see annex x)
- * Largely from RI. 2008/5

Denomination (art. 17 and annex vi)

- Name in EU regulations, e.g., milk powder, milk chocolate, fruit juice, olive oil
- Name in national regulations, e.g., yogurt, mayonnaise
- Usual name in a member state, e.g., tompouce or croquette; or
- Description of food, e.g., low-fat drinking yogurt with fruit juice and added calcium (UHT)
- No factory or trademark or brand name

Denomination (annex vi)

- Physical state or specific treatment if omission is misleading, e.g., powder, refrozen, UHT
- “Thawed” required if food has been deep-frozen before sale and sold thawed.
- Not for:
 - Ingredients - If freezing is a necessary step in the production process
- No negative impact on safety or quality (e.g., butter exempt in consideration 28)

Denomination (annex vi)

- “sticky meat” or “sticky fish” giving the impression of 1 piece but consists of several pieces: extra mention of “composed of pieces of meat / fish”.
- Meat products, meat preparations or fishery products with added proteins of another animal origin: state by name the presence of these proteins and their origin (e.g., beef product with added chicken protein)

Imitation products (annex vi)

- Imitation products: food in which an ingredient expected by the consumer (because it is naturally present or normally used) has been replaced in part or whole by another ingredient.
- Close to the product name, give indication of ingredient used to substitute in font size > 75% of name size (and minimum 1.2 mm).
- Examples: ‘evaporated skimmed milk with vegetable oil for oil’ or “Stracciatella ice cream with pieces of cocoa-fantasy”

Ingredient list (art. 18-19, annex vii)

- Not required on:
 - Fresh vegetables and fruit
 - Cheese, butter, etc. if no other ingredients are added than milk components, enzymes and cultures of microorganisms (and salt)
 - Foodstuffs from 1 ingredient where the name of the foodstuff is identical to that of the ingredient or clarifies the nature of the ingredient (e.g., sugar or semi-skimmed milk)
- No longer an exception for alcoholic drinks
- Ingredient list: all ingredients in order of decreasing weight during preparation (except ingredients <2% in end product – can be in any order at the end)
- Starts with the word “ingredients”

Ingredient list (art. 18, 20, annex vii)

- Ingredients: any substance, including additives and enzymes, used in food production and present in the end product.
- Do not label as ingredients:
 - carry-over additives (present in ingredients or food, but no technological function in final product) (Ver, 1333/2008)
 - Technological additives
 - Carriers
 - Water that is only used to restore a concentrated or hydrated ingredient
 - Added water: not listed if <5% in end product (except for meat(preparations)), unprocessed fishery products and bivalve mollusks

Ingredient list (annex vii)

- Ingredient name: follow rules for naming food
- Category name can be used for some ingredients, e.g., for breadcrumbs, herbs/spices <2% sugar, cocoa butter
- Use of category name is voluntary, it is always possible to name all ingredients separately with specific names
- Starch category name: for ingredient starch or modified starch (physical or with enzymes) NB additive starch: category name “modified starch” – E number not mandatory.
- For starch as an ingredient or additive: vegetable origin mandatory if gluten can be present

Ingredient list (annex vii)

- Category name vegetable oils and fats:
 - With category name: always mention specific vegetable origin, e.g., vegetable oils (sunflower oil, coconut oil) or vegetable oils (sunflower, coconut)
 - “in varying proportions” when applicable
 - “wholly hardened” or “partially hardened” required as applicable
- Specification of specific vegetable species is not required for vegetable oils or fats used. In carriers, processing aids, etc.
- Category name animal oils and fats:
 - Specific type not required
 - “wholly hardened” or “partially hardened” required as applicable

Ingredient list (annex vii)

- Additives:
- Category name additives + specific name or
- Category name additives + E number
- For example, emulsifier (E322, soy) or emulsifier (soy lecithin)
- Aroma's: either aroma or more specific name from
- Aroma regulation (Ver. 1334/2008, e.g. natural vanilla aroma with other natural flavors)(NL: "downgrading", other countries unknown whether this is allowed) "Natural" is allowed if it complies with aroma regulation art. 16

Ingredient list (annex vii)

- Compound ingredient: name + all ingredients or all ingredients integrated in the total list
- Compound ingredient breakdown is not required if:
- Compound ingredient is < 2% and regulated in EU, e.g. milk powder (additives are!)
- Mixtures of herbs / spices < 2% (additives are!)
- Compound ingredient does not need a list of ingredients e.g. cheese, sugar
- NB: allergens are always required!

Ingredient list – “nano” (art. 2, 18)

- Synthetic nanomaterial ingredient: (“nano”) required after ingredient name.
- Synthetic nanomaterial: deliberately produced material with 1 or more dimensions <100 nm. or composed of discrete parts, internal or surface, of which 1 or more dimensions are <100 nm.
- Currently no examples are known of ingredients where (“nano”) must be stated.

2. Required information on the label

Product labeling checklist

Item	Compulsory	Remarks
1. Product name / invented name	No	Product is not the same as the commodity-legal name
2. Legal name plus addition such as: <ul style="list-style-type: none">- When using sweeteners;- When using alternative ingredients, which are not usually associated with the conscious product;- When using sugar (s) together with sweeteners;- When using proteins and / or water for more than 5% (with meat and fish products);- When using specific additives (for meat preparation ... composed of pieces of meat (if applicable)).	Yes	<p>Certain additions to the names must be mentioned in the names, others may be mentioned in the same field of vision. Only the presence of proteins and water is necessary, not the amount of water or proteins</p> <p>If applicable, it is mandatory to include the condition of the product together with the product-legal name. Please note, there are additional obligations to state the condition in case the consumer would otherwise be misled (this concerns, for example, products that have been deep-frozen and have now been thawed.)</p>

Allergen labeling (art. 21 and annex ii)

Some exceptions, e.g. corn syrup and wheat-based maltodextrin, fish gelatin as carrier for vitamins, completely refined soybean oil and fat

14 mandatory to (incl. Products on	Indicate allergens based on it)
Gluten-containing grains	Nuts
Crustaceans	Celery
Eggs	Mustard
Fish	Sesame seed
Groundnuts (peanuts)	Sulphur dioxide and sulphites > 10 mg / kg or l)
Soy	Lupine
Milk (incl. Lactose)	Molluscs

Allergen labeling (art. 21)

- Required to label allergenic ingredients, but also allergenic ingredients auxiliary material, additives, carrier, etc.
- Allergen must be stated in the list of ingredients (or by name if list is missing) + must be emphasized by font that clearly distinguishes it from the rest of the list ingredients.
- FNLI recommendation: use of font
- If the same allergen is used several times, then allergen must be stated each time (e.g. with footnote)
- (See also, EU CIE Guidelines and FNLI Manual/VWA Info Sheet 83, 14/10/2008)

Ingredient list example

- Changes indicated in blue (allergens underlined and specific types of vegetable oil/fat indicated)
- Ingredients: yoghurt; sugar; cream; 3,8% fruit (3,2% lemon, 0,6% lime juice); glucose(-fructose) syrup; hardened coconut fat; 1,5% biscuit pieces (sugar, wheat-, rice- and legume flour, wheat- and potato starch, chicken egg protein, sunflower oil, salt, flavoring); 1% low-fat cottage cheese; milk protein; egg; butter; maltodextrin; gelatin; emulsifiers: soy lecithin, E472b; flavoring

Quantitative ingredient declaration (QUID) (art. 22, annex viii)

- QUID is required when naming a food or in a list of ingredients for ingredients such as:
 - In name or associated with that name (e.g., % strawberry in strawberry yoghurt)
 - Is emphasized in words, images or graphics (e.g., picture of a peach)
- QUID is not required for ingredients such as:
 - Quantity of ingredients must be indicated according to other EU rules
 - Used in small doses to enhance flavor (e.g., paprika in chips)
 - Not essential to determine consumer choice (e.g., fruit in liqueur or rye in rye bread)

Net Quantity (art. 23, annex ix)

- Net quantity required in l, cl, ml, kg or g, but not if:
 - Other kind of content is mentioned, e.g., average quantity (“mark”, directive 76/211/EEC)
 - Foods that are usually sold by the piece and the number of pieces can be clearly seen
 - Contents < 5g or 5ml
 - Font size of content is regulated (directive 76/211/EEC)

Amount of	Quantity up to	Min. Height of digits
0	50g of 5cl	2 mm
50g of 5cl	200g of 20cl	3mm
200g of 20cl	1000g of 100cl	4mm
1000g of 100cl	and more	6mm

Expiration date (art. 24, annex x)

- Expiration date required:
 - Date until which food retains its specific properties if properly stored
 - “To be used until...: for perishable products _ storage instructions (see also art. 15 commodities law decision Preparation and Treatment)
 - “Best before (specify day)” or “best before (month or year)” for all other foods
- Date itself is allowed or reference to another place on the label, e.g., best before: see top
- In principle day, month, and year
- Day and month sufficient for <3 months
- Month and year sufficient for 3-18 months
- Year sufficient for >18 months

Storage instructions or conditions of use (art. 25)

- Special storage conditions and/or conditions of use must be indicated if they apply to foodstuffs
- If necessary, for the storage or use of a food after opening the packaging, the storage conditions and / or use-by date are indicated.
- E.g., “Keep refrigerated below 7 degrees Celsius” or “after opening, consume within 3 days.”

(Trade-) Name and address of operator (art. 9)

- The (trade-) name and address of the manufacturer, packer, importer or seller in the EU must be named, for example
- Trade Name
- Business reply number
- Postcode and city
- Country

Instructions (art. 27)

- User manual required if consumer needs it to use the product properly.
- Instructions for use must be drawn up in such a way that food can be used correctly.
- E.g., information on how much water to add to powdered milk for making milk, microwave preparation instructions, etc.

Nutrition declaration (art. 30, 34)

- Nutritional value information required for all foodstuffs.
- Number of exceptions, e.g., foodstuffs with a label with largest surface <25 cm squared (annex v)
- Nutritional info: in table (unless space is limited)
- Table can be placed on the side / back (does not have to be on the front)

Nutrition declaration (art. 31-33)

- Nutritional information refers to product as sold; can be given for food after preparation as sufficiently detailed preparation method.
- Declared values are mean value based on:
 - Analyzes by manufacturer
 - Calculation based on known mean value of ingredients
 - Calculation based on generally accepted data
- Guidance on Tolerances and Rounding Rules will be published soon
- Nutritional info should be per 100g or 100ml
- Only additionally, information may be given per portion if portion size is stated

Nutrition declaration (art. 30)

- 7 required nutrients:
 - Energy
 - Fat
 - Saturated fat
 - Carbohydrates
 - Sugars
 - Proteins
 - Salt (salt = sodium x 2,5)
- + plus, another nutrient that is claimed or added (EU discussion: whether it should be in the table, e.g. omega 3)

Nutrition declaration (art. 30)

- 6 voluntary nutrients: mono and polyunsaturated fat, polyols, starch, fiber, vitamins and minerals (1 or more can be chosen)

Required columns

	100g or 100ml
Energy	...g
Fat, of which	...g
-Saturated fat	...g
-Monounsaturated fat	...g
Carbohydrates, of which	...g
-Sugars	...g
-Polyols	...g
-Starch	...g
-Fiber	...g
-Protein	...g
-Salt	...g
-Vitamins and minerals	units appendix xiii

	Portion
Energy	...% GDA
Fat, of which	...% GDA
-Saturated fat	...% GDA
-Monounsaturated fat	
Carbohydrates, of which	
-Sugars	...% GDA
-Polyols	
-Starch	
-Fiber	
-Protein	...% GDA
-Salt	...% GDA
-Vitamins and minerals	units appendix xiii

Example nutritional values explanation

- Required elements are underlined (do not include on label)
- Nutrient terms are not entirely the same as Annex XV; most clearly for consumer + in line with guideline 90/496
- Vitamins and minerals min. significant amount:
 - 7,5% of ADH/100ml for drinks
 - 15% of ADH/100g or ml for other products or per portion for packaging with 1 portion.
- ADH = Recommended Daily Allowance and is always required for vitamins and minerals in table (annex xiii)

Example nutritional values explanation

- The term “ADH” is not in the regulation, but ‘Aanbevolen Dagelijkse Hoeveelheid: ADH’ is known in NL and therefore preferred
- Salt: Where necessary, it can be stated close to the nutritional table. Salt content is solely attributable to naturally occurring sodium

GDA: Guideline Daily Amount (art. 30, 32-34)

- Voluntary system, but if used then rules of new Regulation must be followed
- Much uncertainty about the exact consequences of these new rules; advice to follow FDE Guidance has been discussed with the Commission but has not (yet) been approved.
- GDA's are only allowed for the 7 mandatory nutrients (energy, fat, saturated fat, carbohydrates, sugars, protein, and salt) in the nutritional value table or as GDA icons on the side/back.
- Front: GDAs can only be repeated for:
 - Energy
 - Energy, fat, saturated fat, sugars and salt and must be in min. 1.2mm and may be in icon form. So, if GDA's are listed on the front, then they must also be listed on the side/back (in table or as icon)

Conclusions

- Minimum font size
- Emphasizing allergens
- New rules for “vegetables oils and fats”
- Labeling of (‘nano’)
- Specific rules for “imitation products”
- Required nutritional labeling
- Rules for GDA labeling

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Origin regulation: applicable article 26.3

- Icons referring to a country (flag, national symbol, colors, landscape)
- “Produced in”
- “Made in”
- “Product from”
- In the case of tomato paste, which states on the can that it is produced in Italy, must the origin of the tomatoes be stated?



Origin regulation: applicable article 26.3

- Common name e.g., English tea
- Protected Geographic Origin (BOB/BGA/GTS)
- Name/address of the company
- “Produced by”
- “Packed in”, “packed by”



Origin regulation: enforcement?

- NVWA: not priority
- Retailers will want to do their best with the house brands...
- Media is focused on it

How it can be so cheap? On almost every can something is mentioned as "made in Italy". But whoever follows the trail will come to a completely different place: Xinjiang, in the west of China. The region where the Uyghur minority lives.

Tomato paste is painfully cheap

Puree cans Pureed tomato for 18 cents? It's possible. But the origin of the stuff is often unimaginable. And there are many indications that the working conditions in production are poor.

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Claims and European regulations*

- Claims on nutrition
- European Nutrition & Health Claims regulation (EC 1924/2006)
- EFSA's claim opinions
- Opportunities
- *Frans van der Sman, Nutrition Scoring Solutions



What are claims?

- A claim is a statement about a product
- It explains the unique benefits of a product
- A claim can be:
 - words, pictures, or both
 - objective – factual and provable
 - subjective – tells a story about a product

Examples



What are claims?

Claims must be substantiated (proven), except for 1 special category:

- Puffery claims are sometimes present in advertisements. It is a grossly exaggerated statement that no normal person would take literally



Claims

Claims come in many guises:

- In words “Drink Positive”, “made from real tea leaves”
- In pictures “natural”, “fresh”

The advertisement features a tall glass filled with a vibrant red liquid, ice cubes, and fresh berries (blackberries and raspberries) with green leaves. The glass is set on a wooden surface against a backdrop of a lush green field and blue mountains under a clear sky. To the right of the glass is a box of Lipton Tea & Honey Iced Tea Mixes, specifically the Blackberry Pomegranate flavor. The box is white with a blue top and features an image of the drink and the Lipton logo. Text on the box includes 'NEW', 'Lipton', 'Tea & Honey', '5 CALORIES', 'Iced Green Tea', and 'Blackberry Pomegranate'.

Lipton® Tea & Honey Iced Tea Mixes are made from Real Tea Leaves, so they have the benefits of Real Tea

Tea contains flavonoids which are thought to be responsible for the health benefits of tea. A diet high in flavonoids is generally associated with helping maintain normal healthy heart function. A recent study showed drinking 3 cups of black tea daily can help maintain a healthy blood pressure.*

In the past it was thought that antioxidant activity was responsible for the benefits of tea, but current research suggests that a variety of dietary compounds (including flavonoids) in tea may be responsible for some of these effects.

For references and more information on tea and health, visit liptoninstituteoftea.org and lipton.com
*The flavonoid content of the Tea & Honey products varies from that of the regular black tea products.

DRINK POSITIVE

Why claims on nutrition?

- You can't taste nutritional properties therefore, communication is necessary. This is done through claims.
- A claim explains – to the consumer – about the unique benefits of a product
- Nutritional claims are often about the nutritional properties of the product

Nutrition and health claims

Nutrition claim:

- A statement on packaging, in any form of marketing or advertising, that suggests that a food has certain nutritional properties.
- Example: “contains calcium”, “low fat”, “source of fiber”

Health claim:

- Such as a nutritional claim + the suggestion that a health benefit can be obtained after consuming the food.
- Example: “calcium helps improve bone density”, “lowers cholesterol”



European Food Safety Authority

Nutrition and health claims

Nutrition claim:

contains..

Health claim:



Berelekkere
toetjes voor
sterke botten!



Benefit

Health



European Food Safety Authority

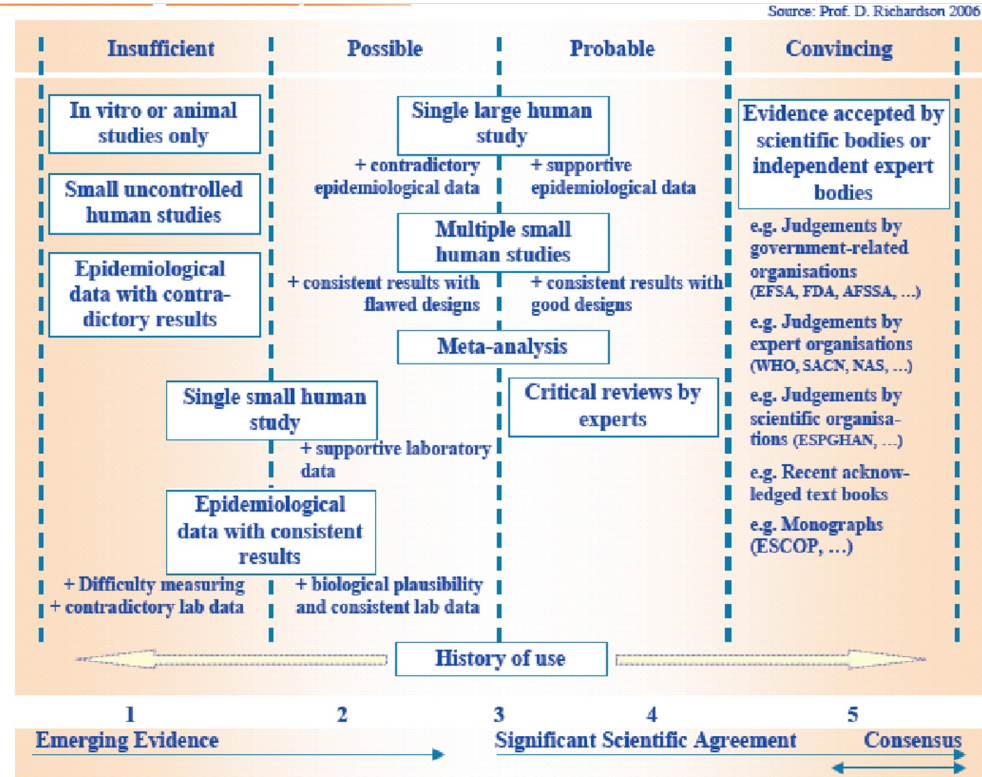
Food Safety Compliance training 2023, module 2



Nutrition and health claim substantiation

- Substantiation = proving what you claim
- Substantiation differs for nutrition claims and health claims
- For health claims, all available evidence must be included to show that there is a relationship between the ingredient and the health benefit.

CRITERIA FOR STRENGTH OF EVIDENCE



See also: **WHO/FAO criteria for strength of the evidence (WHO/FAO, 2003)**

Nutrition and health claim substantiation

In principle a claim file must always be made for health claims.

- Description of the food
- Health benefit and relationship
- Available data (= all data)



Claims regulation

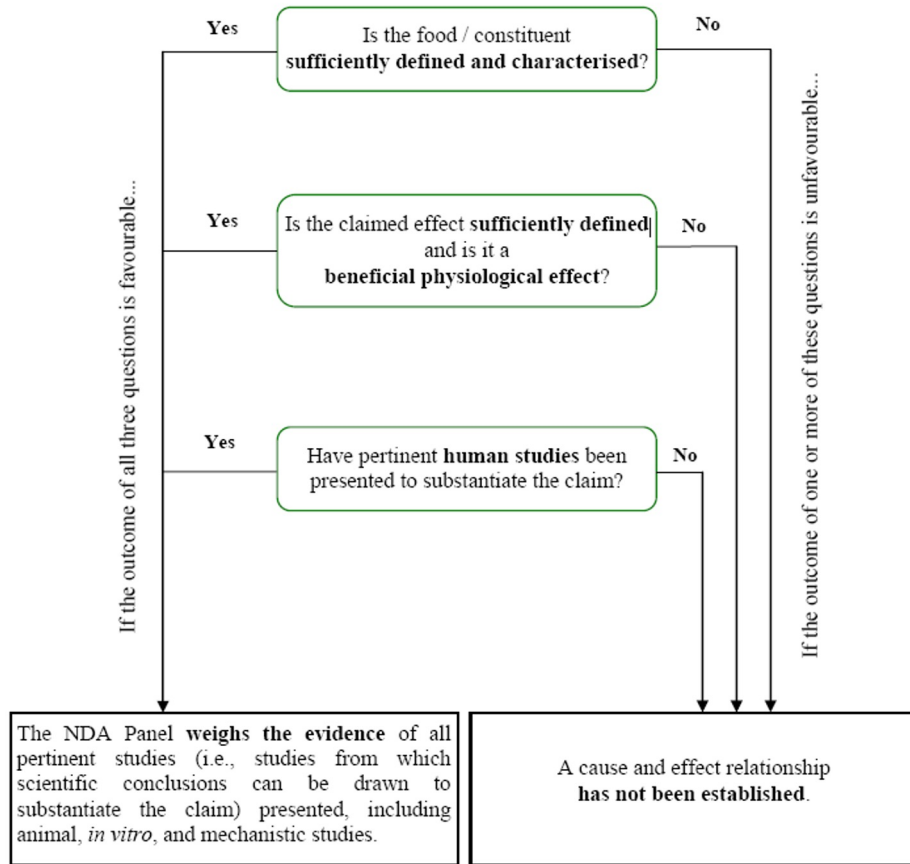
REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 December 2006
on nutrition and health claims made on foods

Claims regulations on nutrition and health claims

- The European Health Claims Regulation (EC 1924/2006) defines the European landscape for making food claims, but even affects discussions in regions outside of Europe.
- The written rule is that in principle you may not make a health claim, unless the specific claim is on a list of accepted claims.
- The European Food and Consumer Product Safety Authority (EFSA) provides scientific assistance for authoring health claims through the publication of scientific opinions.



European Food Safety Authority



Nutrition and health claim substantiation

In principle, a claims file must always be made for health claims



EFSA evaluation

Health claim type	Total claims (n)	Positive (n)	% Positive
<u>Art. 13.1</u> (generic health claims)	2758	523	19.0 %
<u>Art 13.5</u> (new & emerging data and proprietary data)	144	27	18.8 %
<u>Art 14</u> (Disease risk reduction & children's claims)	133	53	39.8 %

Nutrition and health claims, but in plain consumer language

- The starting point...



4. Panel's comments on the proposed wording

4.1. Improvement of endothelium-dependent vasodilation (ID 1155, 1157)

The Panel considers that the following wording reflects the scientific evidence: “Walnuts contribute to the improvement of endothelium-dependent vasodilation”.

> Consumers need help

EC 1924/2006 up to now

- Nutrition and health claims regulation:
 - 80% of claims requests rejected (functional claims)
- *How can we communicate with our consumers in a way that consumers can understand the benefits of our foods?*

Options for nutrition and health claims (Netherlands)

- Preparing an Art. 13.5 & Art. 14 file is not the only route to making claims.
- There is already a list of >200 allowed Art. 13.1 claims...
- Alternative example wording
- Article 10.3 in regulations
- <https://www.koagkag.nl/database-claimsverordening-en-indicatieve-lijst/database>

Options for nutrition and health claims (Netherlands)

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Goedgekeurde bewoording

Vitamine C draagt bij tot de normale werking van het immuunsysteem

- Article 10.3 in regulations

Toegestaan: X heeft een positieve invloed op het immuunsysteem

Article 10.3, what is that?

This article has been present in the regulations since its inception in 2006

Guidelines on this Article:

- “Both national control authorities and food business operators have raised questions about the implementation of Article 10.3.
- In order to ensure consistency in the application of those provisions and to facilitate the work of the control authorities and ensure greater clarity and certainty for economic operators, it is appropriate to issue guidelines.”

HEALTH CLAIMS

Article 10

Specific conditions

3. Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14.

Article 10.3

adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council

Reference to general, non-specific health benefits – Article 10(3)

Article 10(3) allows the use of **easy, attractive statements** which make reference to general, non-specific benefits of a food for overall good health or health-related well-being, without prior authorisation, subject to specific conditions. The use of such statements could be helpful to consumers as they would convey **more consumer-friendly messages**. However, they could be easily misunderstood and/or misinterpreted by consumers, possibly leading to imagine other/better health benefits of a food than those that actually exist. For this reason, when referring to general, non-specific health benefits, it is required to accompany such references by a specific health claim from the lists of permitted health claims in the Union Register. For the purposes of the Regulation, the specific authorised health claim accompanying the statement making reference to general non-specific health benefits, should be made 'next to' or 'following' such statement.

The specific claims from the lists of permitted health claims should bear some relevance to the general reference. As this reference becomes broader, **e.g. 'for good health'**, more health claims from the permitted lists could be eligible to accompany it. Still, attention should be paid to the fact that Article 10 sets rules as regards the context in which health claims are used and given that Article 10 specifically refers to the rules of Chapters II and IV, those rules should also be taken into account if operators wish to comply with the requirement laid down in Article 10(3). Therefore, to avoid misleading consumers, food business operators have the responsibility to demonstrate the link between the reference to general, non-specific benefits of the food and the specific, accompanying, permitted health claim.



Article 10.3 in action: examples







The Panel considers that the following wordings reflect the scientific evidence: "Calcium contributes to normal muscle function and neurotransmission"

* A source of protein which contributes to muscle maintenance.
A varied, balanced diet and a healthy lifestyle are recommended for good health.



EFSA Journal 2009; 7(9):1210

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to calcium and maintenance of bones and teeth (ID 224, 230, 231, 354, 3099), muscle function and neurotransmission (ID 226, 227, 230, 235), blood coagulation (ID 230, 236), energy-yielding metabolism (ID 234), function of digestive enzymes (ID 355), and maintenance of normal blood pressure (ID 225, 385, 1419) pursuant to Article 13(1) of Regulation (EC) N° 1924/2006¹

Article 10.3 in action

Product: Floradix from Salus
(several EU countries)



"TIRED OF BEING TIRED?" is a generic health claim accompanied by a specific authorized health claim

"Iron contributes to the reduction of tiredness and fatigue" is an authorized health claim in the EU Register of Nutrition and Health Claims for Foods

TIRED OF BEING TIRED?

Floradix®
iron contributes to the reduction of tiredness and fatigue

Available from pharmacies and health stores
www.floradix.co.uk
www.naturalmedecine.ie

Tired of being tired?
Try Floradix for more **energy & vitality**

This advertisement was challenged in UK (Advertising Standards Agency, ASA).

The challenge was not upheld, and the claim is allowed.

Product: Vitamin water with different variant names.

defense

raspberry-apple

flavored + other natural flavors
(vitamin c & zinc)

power-c

dragonfruit

flavored + other natural flavors
(vitamin c & taurine)

energy

tropical citrus

flavored + other natural flavors
(b vitamins & guarana)

revive

fruit punch

flavored + other natural flavors
(b vitamins & potassium)

The approach of Vitamin water is using the variant names as implied health claims.

Each variant has different added nutrients which specifically refer to approved Article 13.1 claims, for example **DEFENSE**: “Zinc contributes to the normal function of the immune system”



Vitamin B12 related health claims

- The following wording reflects the scientific evidence: “vitamin B12 contributes to normal energy metabolism”.

Article 10(3) in action: variety names for making implied health claims.

Product: Breakfast
Belvita/LU/Liga



There is an approved claim for
blood glucose rise (Article 13.5),
but the wording is scientific.

Using visuals, Belvita translates
this into consumer language.

Combination of applying Article
10.3 and using flexibility of
wording.



Article 10(3) in action: “Good morning, energy” +
visuals.

“Consumption of products high in slowly digestible starch (SDS)
raises blood glucose concentration less after a meal compared to
products low in SDS”

What should we pay attention to?

- The examples show that it is easy to get lost in the gray zone (or even become misleading).
- A generic claim may only be made when combined with an approved functional claim.
- The approved claim of course also has conditions of use (minimum amount of the active ingredient present).
- Article 10.3 is not intended as a marketing tool.

Conclusion

- Claims are extremely important to both the consumer and the manufacturer
- The European Claims regulations give limited scope for making claims
- Functional claims require a file and a positive EFSA opinion
- There are many options for generic claims

Food Safety Compliance Labelling



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