SCHEME 1

Notification of and application for authorisation to add vitamins, minerals and/or certain "other substances" to foods, excluding food supplements

All references to Sections and Annexes in this form are to Regulation No 247 of 26 February 2010 on the addition of vitamins, minerals and certain other substances to foods (Regulation on the addition of vitamins etc. to foods) unless otherwise stated.

PART 1 INFORMATION ABOUT THE NOTIFIER OR APPLICANT

See item 1 in Annex 2 and item 1 in Annex 4, part two, Foods other than food supplements

Notifier's/applicant's name and address (EEA producer, EEA importer or others, responsible for the initial placing on the Norwegian market)	
Name of the food business operator:	Country:
Postal address:	Org. no. (applies only to Norwegian food business operators):
Telephone:	Email:

If relevant, name and address of the representative notifying or applying for authorisation on behalf of the food business operator responsible for the initial placing on the Norwegian market	
Name of the representative:	Country:
Postal address:	Org. no. (applies only to Norwegian representatives):
Telephone:	Email:

PART 2 INFORMATION ABOUT THE PRODUCT

A: NAME AND DESCRIPTION OF THE PRODUCT AND ANY TASTE VERSIONS OF THE PRODUCT

Taste versions of the product are products, where the addition of vitamins, minerals and the relevant "other substances" corresponds with the addition in the original product and are within the same food category, but where the addition of ingredients giving taste is different.

See items 2 and 3 in Annex 2 and items 2 and 3 in Annex 4, part two, Foods other than food supplements

The food category to which the product and any taste versions of the product belong (cf. Annex 1 and Annex 3):

Does the product and any taste versions of the product fit into any of the food categories listed in Annex 1 and Annex 3?
Tick as appropriate:

Yes: ☐ No: ☐

You may notify/apply for authorisation even if you do not find a food category suitable for the product in Annex 1 and Annex 3.

Description of the product (for example, range of uses and target group for the product):

Product name and name(s) of the taste versions of the product, if applicable:	Product name:	Product name, taste version 1:	Product name, taste version 2:	Product name, taste version 3:	Product name, taste version 4:

B: INGREDIENTS AND NUTRITIONAL CONTENT

When registering quantity declarations for each substance, it must be stated whether the quantity is given per 100 g, per 100 ml or per portion. If the amount is given per portion, portion size must also be specified.

See items 6 and 7 in Annex 2 and items 6 and 7 in Annex 4, part two, Foods other than food supplements.

Ingredient list (as per Section 1 of the Regulation of 28 November No 1497 on food information to consumers, cf. the Food Information Regulation)	Product ingredient list:	Ingredient list for taste version 1:	Ingredient list for taste version 2:	Ingredient list for taste version 3:	Ingredient list for taste version 4:
Nutrition declaration (as per Section 1 of the Regulation of 28 November No 1497 on food information to consumers, cf. article 30(1) of the Food Information Regulation)					
Energy (kcal)					
Fat (g)					
Saturated fat (g)					
Carbohydrate (g)					
Sugars (g)					
Protein (g)					
Salt (mg)					

B1. ADDITION AND CONTENT OF THE VITAMINS AND/OR MINERALS TO WHICH THE NOTIFICATION RELATES (IT DEPENDS ON THE FOOD CATEGORY TO WHICH THE PRODUCT BELONGS, WHETHER YOU SHOULD PROVIDE INFORMATION ABOUT QUANTITY PER 100 G, PER 100 ML OR PER PORTION)

When registering quantities for each substance, it must be stated whether the quantity is given per 100 g, per 100 ml or per portion. If the amount is given per portion, portion size must also be specified.

See items 4, 5 and 6 of Annex 2

Vitamins and minerals	Name of vitamin formulations and mineral substances, cf. Section 1 cf. Annex II to Regulation (EC) No 1925/2006	Added amount (except natural content) per 100 g, per 100 ml or per portion	Total amount (the sum of added amount and any natural content) per 100 g, per 100 ml or per portion	Content per 100 kcal (optional)
Vitamin A (µg)				
Vitamin D (µg)				
Vitamin E (mg)				
Vitamin K (µg)				
Niacin (mg)				
Vitamin B6 (mg)				
Folic acid (µg)				
Vitamin C (mg)				
Calcium (mg)				
Magnesium (mg)				
Iron (mg)				
Copper (mg)				
Iodine (mg)				
Zinc (mg)				
Manganese (mg)				
Selenium (µg)				
Chromium (µg)				
Molybdenum (µg)				
Fluoride (µg)				
Phosphorus (mg)				
Boron (mg)				

B2. ADDITION AND CONTENT OF "OTHER SUBSTANCES" TO WHICH THE NOTIFICATION OR APPLICATION RELATES (IT DEPENDS ON THE FOOD CATEGORY TO WHICH THE PRODUCT BELONGS, WHETHER YOU SHOULD PROVIDE INFORMATION ABOUT QUANTITY PER 100 G, PER 100 ML OR PER PORTION)

When registering quantity declarations for each substance, it must be stated whether the quantity is given per 100 g, per 100 ml or per portion. If the amount is given per portion, portion size must also be specified.

See items 4, 5, 6 in Annex 4, part two, Foods other than food supplements

Other substances	Substance name	Chemical name	Structural formula	Molecular mass	CAS number	Amount added (except natural content) per 100 g, per 100 ml or per portion	Total amount (the sum of added amount and any natural content) per 100 g, per 100 ml or per portion	Content per 100 kcal (optional)
Substance 1								
Substance 2								
Substance 3								
Substance 4								
Substance 5								
Substance 6								
Substance 7								
Substance 8								
Substance 9								
Substance 10								

PART 3 SPECIFIC REQUIREMENTS FOR NOTIFICATIONS AND APPLICATIONS FOR AUTHORISATION TO ADD CERTAIN "OTHER SUBSTANCES" TO FOODS, EXCEPT FOOD SUPPLEMENTS

DOCUMENTATION THAT THE ADDITION OF THE APPLICABLE "OTHER SUBSTANCE(S)" IS SAFE AND THAT THE SUBSTANCES ARE COVERED BY THE SCOPE OF THE PROVISIONS PURSUANT TO SECTION 6, PARAGRAPHS TWO AND THREE

Items 10 – 12 of Annex 4, part two, Foods other than food supplements, may be replaced by a specification of identity and purity with an E number, or by a specification of a recognized body, such as European Pharmacopoeia (Ph. Eur.), Food Chemicals Codex (FCC) or United States Pharmacopeia (USP).

See items 10, 11 and 12 in Annex 4, part two, Foods other than food supplements

Include the specification and analysis method for the substance/substances for which the notification or application applies.	Insert the filename of the attachment/s: *Example of title: attachment x, item 10 for [name of substance.....]*
Include the description of the method of production for the substance/substances to which the notification or application applies, with a production diagram that includes information about all the raw materials used in production.	Insert the filename of the attachment/s: *Example of title: attachment x, item 11 for [name of substance.....]*
Include toxicological studies and assessments of the substance/substances to which the notification or application applies, and the notifier's or applicant's assessment of why these studies and assessments are relevant.	Insert the filename of the attachment/s: *Example of title: attachment x, item 12 for [name of substance.....]*

PART 4 LEGAL MARKETING IN OTHER EEA COUNTRIES (IF APPLICABLE)

IF THE NOTIFIER OR APPLICANT IS AWARE OF OTHER EEA COUNTRIES WHERE THE SAME PRODUCT (SAME PRODUCT NAME AND CONTENT) IS ALREADY LEGALLY PLACED ON THE MARKET, DOCUMENTATION OF THIS MUST BE SUBMITTED *See item 8 in Annex 2 and item 8 in Annex 4, part two, Foods other than food supplements*	
Include relevant documentation showing that the same product (same product name and content) is legally placed on the market in another EEA country. See Section 4, paragraph two, Section 9, paragraph two and Section 10, paragraph three. If the notification or the application for authorisation contains data, which has already been submitted, assessed and approved in another EEA country, cf. Section 4, paragraph two, Section 9 paragraph two and Section 10, paragraph three, you may use the respective added substance(s) 3 months after that the Norwegian Food Safety Authority has confirmed that all information required in Annex 2 and/or Annex 4, part two, Foods other than food supplements, has been received.	Insert the filename of the attachment/s: *Example of title: attachment x, item 8 for [name of product.....]* Not relevant: ☐

PART 5 IS THE FOOD COVERED BY THE TRANSITIONAL PROVISION IN SECTION 12, PARAGRAPHS THREE AND FOUR?

THE TRANSITIONAL PROVISION IN SECTION 12, PARAGRAPHS THREE AND FOUR FOR FOODS WHICH WERE LEGALLY PLACED ON THE NORWEGIAN MARKET PRIOR TO 1 JANUARY 2020, TO WHICH "OTHER SUBSTANCES" ARE ADDED WHICH ARE COVERED BY THE SCOPE OF THE NEW PROVISIONS, BUT WHERE THE ADDITION DOES NOT COMPLY WITH THE NEW REQUIREMENTS

It is only possible to notify or apply for authorisation pursuant to this transitional provision up to 30 June 2020.

Attach documentation showing that the food, to which the respective "other substance" has been added, in the respective quantity etc., was legally placed on the Norwegian market prior to 1 January 2020.	Insert the filename of the attachment/s: *Example of title: attachment x, Section 12 documentation for [name of product.....]*

SUBMISSION:

This form with any accompanying attachments must be sent to the Norwegian Food Safety Authority:

BY EMAIL:
postmottak@mattilsynet.no

OR BY POST:
Norwegian Food Safety Authority
Felles postmottak
Postboks 383
N-2381 Brumunddal