SCHEME 2

Notification of and application for authorisation to add certain "other substances" to 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 4, part one, 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 to Norwegian food business operators only):
Telephone:	Email:

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 *See items 2 and 3 in Annex 4, part one, Food supplements*	
Product name:	
Product form (for example, capsules, ampoules, tablets, etc.):	
Is the food supplement for adults above 18 years? Tick as appropriate: Yes: ☐ No: ☐ You may notify/apply for authorisation even if the product is not for adults above 18 years.	If NO: Describe which age group or target group the food supplement is for:

B: INFORMATION ABOUT THE "OTHER SUBSTANCES" TO WHICH THE NOTIFICATION OR APPLICATION RELATES *See items 4, 5, 6, 7, 8 and 10 in Annex 4, part one, 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)	
Information about the name of the categories of nutrients or other substances with nutritional or physiological effect, that characterises the product or a statement of what type these are (as per Section 7, paragraph three no. 1 of Regulation No 755 of 20 May 2004 relating to food supplements)	

Substance(s)	The name of the substance	Chemical name	Structural formula	Molecular mass	CAS-number	Recommended daily dose	Declaration of content amounts per recommended daily dose pursuant to Section 8 of the Regulation on food supplements	Amount added (except natural content) per recommended daily dose	Total amount (total of the amount added and natural content, if applicable) per recommended daily dose
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 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 11 – 13 of Annex 4, part one, Foods other than food supplements, can 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 11, 12 and 13 in Annex 4, part one, Food supplements

Include the specification and analysis method for the substance/substances to which notification or application applies.	Insert the filename of the attachment/s: *Example of title: attachment x, item 11 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 including information about all the raw materials used in production.	Insert the filename of the attachment/s: *Example of title: attachment x, item 12 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 13 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) ALREADY IS LEGALLY PLACED ON THE MARKET, DOCUMENTATION OF THIS MUST BE SUBMITTED *See item 9 in Annex 4, part one, Food supplements*	
Attach relevant documentation showing that the same product (same product name and content) is legally placed on the market in another EEA country, cf. Section 9, paragraph two and Section 10, paragraph three. If the notification or the application for authorisation contains data, which already has been submitted, assessed and approved in another EEA country, cf. Section 9, paragraph two and Section 10, paragraph three, you may use the respective added substance(s) 3 months after the Norwegian Food Safety Authority has confirmed that all information required in Annex 4, part one, Food supplements, has been received.	Insert the filename of the attachment/s here: *Example of title: attachment x, item 9 for [name of substance.....]* Not relevant: ☐

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

THE TRANSITIONAL PROVISION IN SECTION 12, PARAGRAPHS THREE AND FOUR FOR FOODS, INCLUDING FOOD SUPPLEMENTS, 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 supplement, to which the respective "other substance(s)" 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