Attention reader: This Check-sheet is an English translation of an unofficial version of the Japanese Check-sheet 1
（Update:2024-7-23）

Check-sheet 1

Food additives for Fortification

New designation, revision of standards for use, or specifications

Name of the target substance:

Version:

Date of entry (year/month/day):

- This Check-sheet is used on a trial basis and may be revised without notice.
- We would appreciate your comments about the Check-sheet, for further improvement.

1. Basic information

Applicant information

Note: If there are no changes from the Inquiry Form for Consultation, only the name of the applicant is required.

Please provide the following information:

Name of applicant (company or organization name, etc.):

Address:

Name and affiliation of contact person:

Phone number:

Email:

Note: If an agent for an applicant abroad is submitting this sheet, please provide the following information, too.

Name of agent (company or organization name, etc.):

Address of agent:

Name and affiliation of contact person:

Phone number:

Email:

Relationship to applicant (describe the relationship between the agent and the applicant, and the reason(s) for making an application on behalf of the applicant):

2. Type of application, and possible disclosure of content(s)

(1) Type of application

Select the type of application from the following list. (Tick the selected box.)

If there is no appropriate item, select “Other” and provide specific information.

☐ New designation

☐ Revision of standards for use

☐ Revision of specifications

☐ Other

Select whether or not standards for use should be established when the target substance is used as a food additive.

☐ Need to be established

☐ No need to be established

☐ Unknown

(2) Outline of application

Briefly describe the consumer benefits resulting from the proposed designation (target substance or revision of the specifications and standards). (Description should not exceed 150 words)

(3) Mutual disclosure of target substance information among applicants

Select all the items that can be disclosed regarding the target substance. (Tick the selected box.)

☐ Applicant may disclose the requested content to other applicants:

Items with a check in the box can be disclosed.

☐ All content

☐ Specific requested content*

* Possible part(s)

☐ Name of target substance

☐ Type of application

☐ Use(s)

☐ Name of applicant (company or organization name, etc.)

☐ Name of agent (company or organization name, etc.)

☐ Other (please describe)

☐ No requested content may be disclosed to other applicants.

Notes: In some cases there may be multiple applications for the same target substance from multiple applicants. It may be more convenient for both the suppliers and the users of the food additive to deal with such multiple applications, and to set uniform specifications and standards together. In such cases, it may take more time than usual to assess the differences between the respective sides and to create uniform specifications and standards that encompass the range of each application. However, if the multiple applicants can disclose information on the target substance to each other, and prepare an Overview document together, then the procedure should be conducted more quickly and rationally. In addition, in the section on Findings regarding safety, higher quality safety evaluation and more accurate estimation of the daily intake would be achieved by preparing an Overview document that summarizes the investigational results of the multiple applicants, likely resulting in reduced workload for the parties involved. For this reason, we wish to confirm, in advance, the range of information that may be disclosed to other applicants. We will never disclose to other applicants information for which we have not first received formal disclosure consent from the applicants.

3. Specific information about the target substance

Note: If you want only the revision of standards for use, skip to (5) Draft standards for use to be established.

(1) Type of substance

Select the items that describe the target substance.

☐ Chemically synthesized compound	☐ Refined product from natural raw materials	☐ Cultured and refined product		
☐ Highly purified substance *	☐ Unpurified substance	☐ Mixture	☐ With excipient	☐ With no excipient
☐ Organic substance	☐ Inorganic substance	☐ Salt(s)	☐ Enzyme	☐ Peptide
☐ Low molecular weight-compound	☐ Polymer	☐ Unknown contents		
☐ Other (describe in detail):				

* The target substance has a content of 95.0% or more.

(2) Information on specifications

Enter information on specifications regarding the target substance and the status of your investigation.

Make sure that you use up-to-date information when filling out the form.

(a) Domestic specifications	☐ Obtained	☐ None
Japan's Specifications and Standards for Food Additives	Additive name:	
Japanese Pharmacopoeia	Additive name:	
Japanese Pharmaceutical Excipients	Additive name:	
Other specifications Specify:	Additive name:	

(b) Foreign specifications	☐ Obtained	☐ None
JECFA* specifications (Combined Compendium of Food Additive Specifications)	Additive name:	
FCC (Food Chemicals Codex)	Additive name:	
EU (Commission Regulation (EU) No. 231/2012)	Additive name:	
Other specifications Specify:	Additive name:	

* Joint FAO/WHO Expert Committee on Food Additives

(c) Comparison table of Japanese and foreign specifications	☐ Prepared	☐ In process	☐ To be prepared

(3) Information on substance

Select the description which matches the establishment status of the application for nutrient substance.

☐ Standards have been established*. Substance name:	☐ Substance similar to the application substance.
☐ Other (describe in detail):	

* Standards have been established in Dietary Reference Intakes for Japanese (2020 version), from the Ministry of Health, Labour and Welfare (vitamins, minerals, etc.).

Provide as much information as possible on the target substance with respect to the following items.
If you are not sure about an item, enter “Unknown”.

Name of substance

Provide the Japanese name (e.g., ingredient name) that you wish to use for the substance, as well as its English name, if applying for a new designation.

Japanese name: シアノコバラミン　English name: Cyanocobalamin

Alternative name (if required)

Vitamin B12e

Chemical name (based on the IUPAC rule, or common name)

Coα-[α-(5,6-Dimethyl-1H-benzoimidazol-1-yl)]-Coβ-cyanocobamide

CAS registration number

68-19-9

International numbering system (INS) number

-

E number

-

Other code for substance or specification / standard number

None

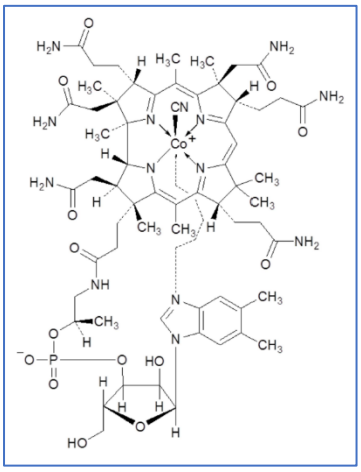
Purpose of use

Fortifier

Information about use (the way in which the additive is applied to food or to the process of food production)

☐ Acquired　☐ Not yet

Structural formula



Molecular formula

$C_{63}H_{88}CoN_{14}O_{14}P$

Molecular weight

Use the atomic weight table in the annex to Japan's Specifications and Standards for Food Additives 10th Edition (or use IUPAC Inorganic Chemistry Division, CIAAW: Standard Atomic Weights Revised. Chem. Int., 29, 18(2007))

1355.37

Description

Cyanocobalamin occurs as dark red crystals or powder.

(4) Draft specifications intended to be established

Describe the preparation status of the specifications for the target substance as comprehensively as possible.

Note: In the case of a new substance designation, draft specifications that guarantee quality must be prepared. In addition, test data, etc. that verify the draft specifications must be submitted.

Specifications

In-house standards	☐ Exist	☐ None
Industrial self-regulation standards	☐ Exist	☐ None

Draft specifications / Draft revision of specifications	☐ Exist	☐ Preparing	☐ Other (please describe below *)
*			
Document for the validation of the draft test method in the draft specification	☐ Obtained	☐ Preparing	☐ Other (please describe below *)
*			
Test Results report on the draft specifications	☐ Obtained	☐ Preparing	☐ Other (please describe below *)
*			
Special note:			

(5) Draft standards for use to be established

Describe the target food, method of use, amount used, etc., of the target substance.

If such standards of use are not to be established, state concisely the reason(s) for not establishing them.

Information on standards for use in Japan and overseas	☐ Exists	☐ None

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For the following Sections 4 to 8, collect the references* on which your application is based, selecting the appropriate status from the choices on the right (Obtained, Not yet obtained).
If you select "Not yet obtained," enter the item number and the reason in the "Additional notes" section below.

* "References" on Check-sheet 1 includes not only printed matter such as research reports published in academic journals and other publications, but also the results of searches of the relevant laws, regulations, and database information on the Web. When listing reports and papers as references, keep in mind that FADCC usually considers the reliability of the sources according to the order below, with (A) as the most reliable. Obtain original papers as far as possible, except in the case of the Risk Assessment Reports issued by the Food Safety Commission of Japan (FSCJ).

(A) Public information, such as reports by specialized public institutions (including on their websites)
(B) Reviewed academic papers in specialized fields
(C) Books in specialized fields
(D) Test data provided by business operators and analytical institutions
(E) Articles published in newspapers and magazines
(F) Web articles other than (A) to (E)

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4. Information on the target substance and related food additives

(1) Origin or details of development	☐ Obtained	☐ Not yet obtained
(2) Condition of use in Japan and overseas	☐ Obtained	☐ Not yet obtained
(3) Methods of manufacturing	☐ Obtained	☐ Not yet obtained
(4) Stability of food additive	☐ Obtained	☐ Not yet obtained
(5) Method of analyzing food additive in food	☐ Obtained	☐ Not yet obtained

Additional notes:

5. Effectiveness

(1) Effectiveness as a food additive and comparisons of effects with other food additives of the same category	☐ Obtained	☐ Not yet obtained
(2) Stability of the food additive in foods	☐ Obtained	☐ Not yet obtained
(3) Effects of the food additive on main nutrients in foods	☐ Obtained	☐ Not yet obtained

Additional notes:

6. Safety evaluations by international organizations, etc.

(Use up-to-date information)

(1) FSCJ (Food Safety Commission of Japan) (Includes evaluation of substances other than food additives)	☐ Obtained	☐ Not yet obtained

(2) JECFA (Joint FAO/WHO Expert Committee on Food Additive)	☐ Obtained	☐ Not yet obtained
(3) EFSA (European Food Safety Authority) and SCF (Scientific Committee on Food)	☐ Obtained	☐ Not yet obtained
(4) US FDA (Food and Drug Administration)	☐ Obtained	☐ Not yet obtained
(5) FSANZ (Food Standards Australia New Zealand)	☐ Obtained	☐ Not yet obtained

Additional notes:

7. Safety

(Refer to FSCJ's Guidelines for the Risk Assessment of Food Additives for Fortification, September 2021, https://www.nihs.go.jp/dfa/FADCC/dfa_e_fadccsite/e_img/e_guidelines_fortification.pdf))

(1) Toxicokinetics	☐ Obtained	☐ Not yet obtained
(2) Findings in humans		
(a) Clinical tests (evidence tables)	☐ Obtained	☐ Not yet obtained
(b) Case reports	☐ Obtained	☐ Not yet obtained
(c) Meta-analysis	☐ Obtained	☐ Not yet obtained
(3) Toxicity		
(a) Genotoxicity	☐ Obtained	☐ Not yet obtained
(b) Repeat dose toxicity	☐ Obtained	☐ Not yet obtained
(i) Subacute toxicity (90 days)	☐ Obtained	☐ Not yet obtained
(ii) Chronic toxicity (12 months or more)	☐ Obtained	☐ Not yet obtained
(c) Carcinogenicity	☐ Obtained	☐ Not yet obtained
(d) Reproductive toxicity	☐ Obtained	☐ Not yet obtained
(e) Developmental toxicity	☐ Obtained	☐ Not yet obtained
(f) Allergenicity	☐ Obtained	☐ Not yet obtained
(g) Others	☐ Obtained	☐ Not yet obtained

Additional notes:

Special notes:

8. Estimation of the daily intake

(1) Estimation of the daily intake	☐ Obtained	☐ Not yet obtained

Additional notes:

9. Other related information

Describe any information to be noted.

10. Submission of test samples of the proposed product to which the target substance is to be added

The Consumer Affairs Agency (CAA) may conducts tests related to the specifications and standards, using specimens as a general rule, to confirm the appropriateness of the respective specifications and standards. At the appropriate time, the CAA will contact the applicant to ask them to provide test samples.

Will samples be provided?	☐ Yes	☐ No
If yes:		
Number of lots you will provide:		
Amount of sample in each lot: g		
Time required for provision of samples: months		
Any additional condition(s) (for) providing samples:		