Handbook for the Procedure
General notes

This Handbook for the Procedure has been compiled to give readers a quick understanding of “The Procedure for Preparing Application Documents for Designation of Food Additives and Revision of Use Standards for Food Additives,” issued by the Ministry of Health, Labour and Welfare (MHLW).

The Handbook for the Procedure has the following structure:

General notes	Comments for the entire application document
I. Outline of food additives (Japanese only) II. Effectiveness (Japanese only) III. Safety, IV. Daily intake (Japanese only)	Comments for creating an Overview document

Appendices: Information search guide (Japanese only), Concept of food risk assessment (Japanese only), Precautions when conducting new safety tests (Japanese only).

Contents

Background

This Handbook for the Procedure is compiled for the applicant. The handbook is based principally on the Attachment to the "Procedure for Preparing Application Documents for Designation of Food Additives and Revision of Use Standards for Food Additives" (issued by MHLW on September 9, 2014; hereafter, the "**2014 Procedure**").

However, the four guidelines stipulated for food additives by the Food Safety Commission of Japan (FSCJ) were revised in September 2021 **(**hereafter, the "**FSCJ Guidelines**").

Therefore, some parts of this Handbook for the Procedure (particularly, "III. Safety," "IV. Daily intake") provide explanations in accordance with the 2021 Guidelines.

Furthermore, the MHLW's **"Guidelines for the Designation of Food Additives and Revision of Use Standards for Food Additives"** (hereafter, the "**MHLW Guidelines"**) were revised in September 2022.
If the handling differs between the 2014 Procedure and the MHLW Guidelines, the content of the MHLW Guidelines takes precedence. Therefore, some parts of this Handbook for the Procedure provide explanations in accordance with the MHLW Guidelines.

Terms [1/3]

The following abbreviations are used in this Handbook for the Procedure.

General terms

Additives:	Food additives
CAA:	Consumer Affairs Agency
FADCC:	Food Additive Designation Consultation Center
FAO:	Food and Agriculture Organization of the United Nations
FSCJ:	Food Safety Commission of Japan
FSSC:	Food Safety Standards Council
JECFA:	Joint FAO–WHO Expert Committee on Food Additives
JSFA:	Japan's Specifications and Standards for Food Additives
MHLW:	Ministry of Health, Labour and Welfare
PAFSC:	Pharmaceutical Affairs and Food Sanitation Council
WHO:	World Health Organization

Terms [2/3]

The following abbreviations are used in this Handbook for the Procedure.

Terms related to Guidelines and the Procedure

MHLW Guidelines:	Ministry of Health, Labour and Welfare of Japan, *Sei-shoku-hatsu* 0929 No. 3 "Guidelines for the Designation of Food Additives and Revision of Standards for Use of Food Additives" (September 29, 2020)
2014 Procedure:	Ministry of Health, Labour and Welfare of Japan, *Shoku-an-ki-hatsu* 0909 No. 2, Attachment to the "Procedure for Preparing Application Documents for Designation of Food Additives and Revision of Use Standards for Food Additives" (September 9, 2014)
Template:	A prototype published by FADCC for preparing an Overview document, based on Appendix 3 of the 2014 Procedure
FSCJ Guidelines:	Four guidelines stipulated by FSCJ (revised in September 2021), namely: "Guidelines for the Risk Assessment of Food Additives," "Guidelines for the Risk Assessment of Food Additives for Fortification," "Guidelines for the Risk Assessment of Additives (Enzymes) in Foods," and "Guidelines for the Assessment of Flavoring Substances in Foods on Health"

Note: See page 7 for how to use any of the four FSCJ Guidelines.

Terms [3/3]

The following terms are used in this Handbook for the Procedure as types of additives:

Food additives in general:	In the Handbook for the Procedure, “food additives in general” refers to additives other than nutritional-component-related additives, enzymes, and flavoring substances.
Processing aids:	“Processing aids” refers to additives covered by the contents of “Chapter 3 Approach to the risk assessment of processing aids” in the Guidelines for the Risk Assessment of Food Additives.
Additives for breast-milk-substitute foods:	“Breast milk substitutes” refers to additives used in breast-milk-substitute foods for infants up to 4 months old and covered by the special regulations established in the Guidelines for the Risk Assessment of Food Additives.
Flavoring substances:	Additives used for the purpose of imparting aromas to food
Enzymes:	Enzymes used as additives
Food additives for fortification:	“Food additives” used for the purpose of improving nutritional status, such as vitamins and minerals. Vitamins and minerals refer to the substances determined in “Dietary Reference Intakes for Japanese (2025)“, including the related substances (mineral compounds consisting of different base moiety, vitamin derivatives, and metabolites of the target substance).

If you think that the requested product is a processing aid or an additive for breast-milk-substitute foods, please see “About Processing Aids and Additives for breast-milk-substitute foods (in Japanese)” at first.

How to use the Handbook for Procedure I-IV (in Japanese)

When using Handbook for Procedure I-IV, the following four types of additives should be taken into consideration in making your selection.

- Food additives in general (including processing aids and additives for breastmilk substitutes)
- Flavoring Substances
- Enzymes
- Food Additives for Fortification

In addition, please refer to the Handbook for Procedure III. Safety, IV. Daily Intake, please refer to the relevant FSCJ guideline.

Additives	Referenced FSCJ Guidelines
Food additives in general (including processing aids and additives for breast-milk-substitute foods)	Guidelines for the Risk Assessment of Food Additives
Flavoring substances	Guidelines for the Assessment of Flavoring Substances in Foods on Health
Enzymes	Guidelines for the Risk Assessment of Additives (Enzymes) in Foods
Food additives for fortification	Guidelines for the Risk Assessment of Food Additives for Fortification

Chapter 1-1. Flow for designating food additives and revising specifications or standards

(a) Preparation of application documents to request the food additive designation and revision of specifications or standards

FADCC will support applicants by providing advice on preparing application documents and other procedures.

(b) Submission of application documents to CAA

After confirming the contents of the documents, CAA will ask FSCJ to conduct a food risk assessment. It may take some time for the FSCJ to confirm the contents of the documents and to begin deliberations.

(c) Deliberations by FSCJ

After a food risk assessment is conducted, CAA is notified of the results.

(d) Procedures for food additive designation and revision of specifications or standards by CAA

On the basis of the assessment performed by FSCJ, FSSC will discuss whether or not the said additive is to be designated.
On the basis of the deliberation results, procedures for food additive designation and revision of specifications or standards are performed and the substance then becomes available for use as a food additive.

Chapter 1-2. Food additive designation system

The following regulations apply to the use of additives in food:

(a) Additives that are not designated as food additives by the Prime Minister must not be used in foods in Japan.

Note: Additives on the List of Existing Food Additives (published by MHLW in 1996), natural flavoring substances, and Ordinary foods used as food additives are exceptions.

(b) Even if a substance is already designated as a food additive, its use is prohibited if it does not meet the specifications, and it may not be used in a way that does not meet the usage standards.
(Article 13 (2) of Food Sanitation Act)

In the following cases, you must apply to the Prime Minister:

- If you want to use substances that are not designated as food additives.
  ---> Proceed to apply for a new designation.

- If you want to revise existing specifications or standards
  ---> Proceed to apply for the revision of specifications or standards.

Chapter 1-3. Application for designating food additives and revising specifications or standards

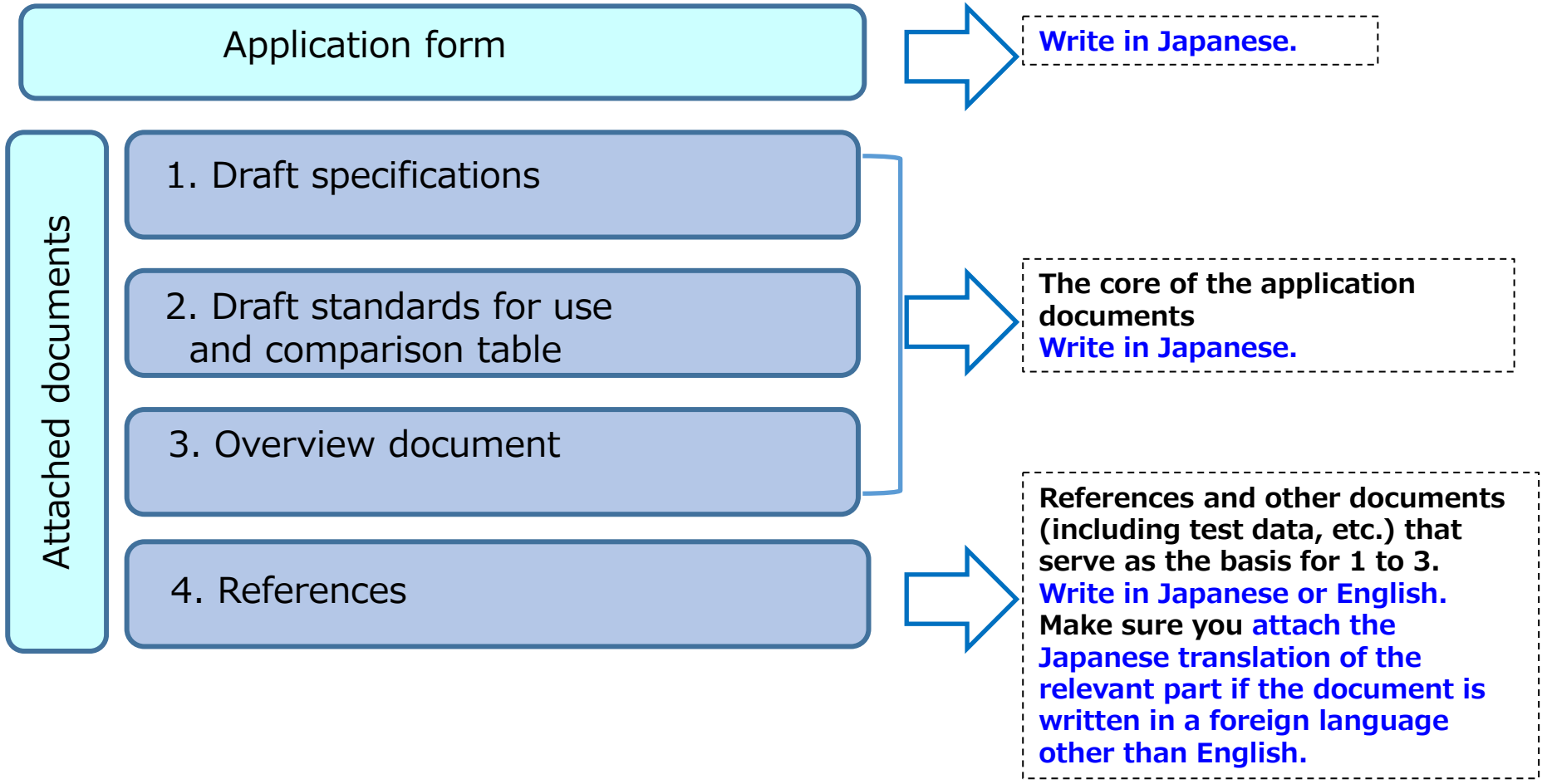
Application procedure and application documents

1. An application form should be submitted to the Prime Minister along with the required attached documents.
   A set of an application form and attached documents is called the "**application documents**".

2. Application documents should be prepared by applicant.
   Applicants are not limited to corporations that manufacture food additives.
   Anybody who, on their own, can collect, examine, and summarize the documents regarding the appropriateness of using the relevant food additives, the safety and effectiveness of the use, and the setting of the specifications is eligible to make an application.

Chapter 2-1. What are the application documents?

These are the contents of the application documents in accordance with the MHLW Guidelines. “3. Overview document” has almost the same content as that of the 2014 Procedure.



Chapter 2-2. What is an application form?

An application form is a document that conveys your wishes for designation of food additives or revision of specifications to the Prime Minister.
The form shall be written in Japanese. The attached form describes the contents of the form in English. (See Appendices 1 and 2 of the MHLW Guidelines.)

Sample (for new designation)

Date

The Prime Minister,

Name: Representative Director of xxx, yyy Co., Ltd.

Address: xxx, yyy City, zzz Prefecture

We apply for designation of the following substance as a food additive that has no risk of harm to human health, according to the provisions of Article 12 of the Food Sanitation Act.

(Product name)

Chapter 2-3. What are attached documents? [1/7]

The contents of the attached documents required by the MHLW Guidelines for the application are almost identical to those in the 2014 Procedure. Therefore, the explanation in this handbook basically follows that in the 2014 Procedure.

However, note that, depending on the type of food additive (food additive in general, nutritional-component-related additive, enzyme, flavoring substance), the necessary description items (e.g., physicochemical characteristics, safety tests) may change. Therefore, this handbook provides explanations according to the FSCJ Guidelines.

Explanations will be given for the same application procedures in the following files:

- **I. Outline of food additives**
- **II. Effectiveness**
- **III. Safety**
- **IV. Daily intake**
- **V. Cited references**

Chapter 2-3. What are attached documents? [2/7]

Attached documents are materials that provide an overview of the food additive for which designation is requested, as well as the basis for its effectiveness and safety. They serve as material for deliberations by FSCJ, the FSSC, and other organizations.

The following is the structure of the attached documents in accordance with the MHLW Guidelines.

1. Draft specifications	To be created when applying for the designation of new food additives and revising the existing specifications. They are a rewrite of the draft specifications in the Overview document in the form of D MONOGRAPHS in the JSFA.
2. Draft standards for use and comparison table	To be created when applying for the designation of new food additives and revising the existing use standards. They are a rewrite of the draft standards for use in the Overview document in the prescribed form.
3. Overview document	Contents are almost the same as in the Overview document of the 2014 Handbook. It consists of items 4 to 11 in the Table on the next slide.
4. References	Documents that support the claims stated in the Overview document should be attached.

Chapter 2-3. What are attached documents? [3/7]

Documents to be attached to the application form for designation of food additives or revision of specifications and standards

Type of document(s)	Designation	Revision of standards for use	Specifications revision
1. Draft specifications	○	-	○
2. Draft standards for use and comparison table	○	○	-
3. Overview documents	○	○	○
4. Document(s) regarding the name and purpose of uses	○	○	△
5. Document(s) regarding the origin or details of development	○	△	△
6. Document(s) regarding the conditions of use overseas	○	○	△
7. Document(s) regarding safety evaluations by international organizations	○	△	△
8. Document(s) regarding physicochemical properties and specifications	○	△	○
9. Documents regarding the draft standards for use	○	○	-
10. Documents on effectiveness			
(1) Effectiveness as a food additive and comparisons of effects with those of other food additives of the same category.	○	○	△
(2) Stability in food	○	△	△
(3) Effects of the food additive on main nutrients in foods	○	△	△
11. Documents for the risk assessment	*	*	*

○: Documents that should be attached; △: Documents that should be attached when there is available knowledge or new knowledge, -: Documents that do not normally need to be attached.
Note: Refer to the FSCJ Guidelines.

Chapter 2-3. What are attached documents? [4/7]

The contents of the attached document "1. Draft specifications" are the same as those of the Draft specifications in "3. Overview document." However, The contents of the Overview document are written in table form, whereas those in the attached document are written in the form of the relevant Article in the JSFA. The document shall be written in Japanese. The attached form describes the contents in English.

Sample of Draft specifications

Sodium chlorite

$NaClO_2$ Molecular weight: 90.44
Sodium chlorite [7758-19-2]

Content: This product contains not less than 70.0% of sodium chlorite ($NaClO_2$).

Properties: This product is a white powder with no odor or a slight odor.

Confirmation test 1

Reagents, solutions: Methyl acetate CH_3COOCH_3 [K8382, special grade] [79-20-9]
0.05 mol/L potassium hydroxide solution: Potassium hydroxide (KOH, molecular weight 56.11) g in 1000 mL

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Chapter 2-3. What are attached documents? [5/7]

In "3. Overview document," the draft specifications are written in table form, as shown below. (For more details, refer to “Handbook for the Procedure I-2, Outline of food additives (2).”) Although the document shall be written in Japanese, the attached form describes the contents in English for your consideration.

Sample of draft specifications in table form (excerpted from 2014 Handbook)

Item	Draft specifications	Reference specifications
(a) Name (Japanese)		
(b) Name (English)		

Reference specifications
1:
2:

Chapter 2-3. What are attached documents? [6/7]

"Draft standards for use" in Attached document "2. Draft standards for use and comparison table" has the same content as "Draft standards for use" in "3. Overview document."
If you set standards for use, attach a "Draft standards for use" as shown below.
If you don't set standards for use, use a phrase such as "(Draft standards for use) No use criteria are set for xxx".

Draft standards for use (Example)

(Draft standards for use)

xxx
xxx must not be used in foods other than citrus fruits (excluding unshu orange) and potatoes.
xxx potassium must be used in such a way that no more than 0.010 g will remain in 1 kg of citrus fruits (excluding unshu orange) and no more than 0.007 g will remain in 1 kg of potatoes, in the form of xxx.

Note: xxx is the name of the food additive.

Chapter 2-3. What are attached documents? [7/7]

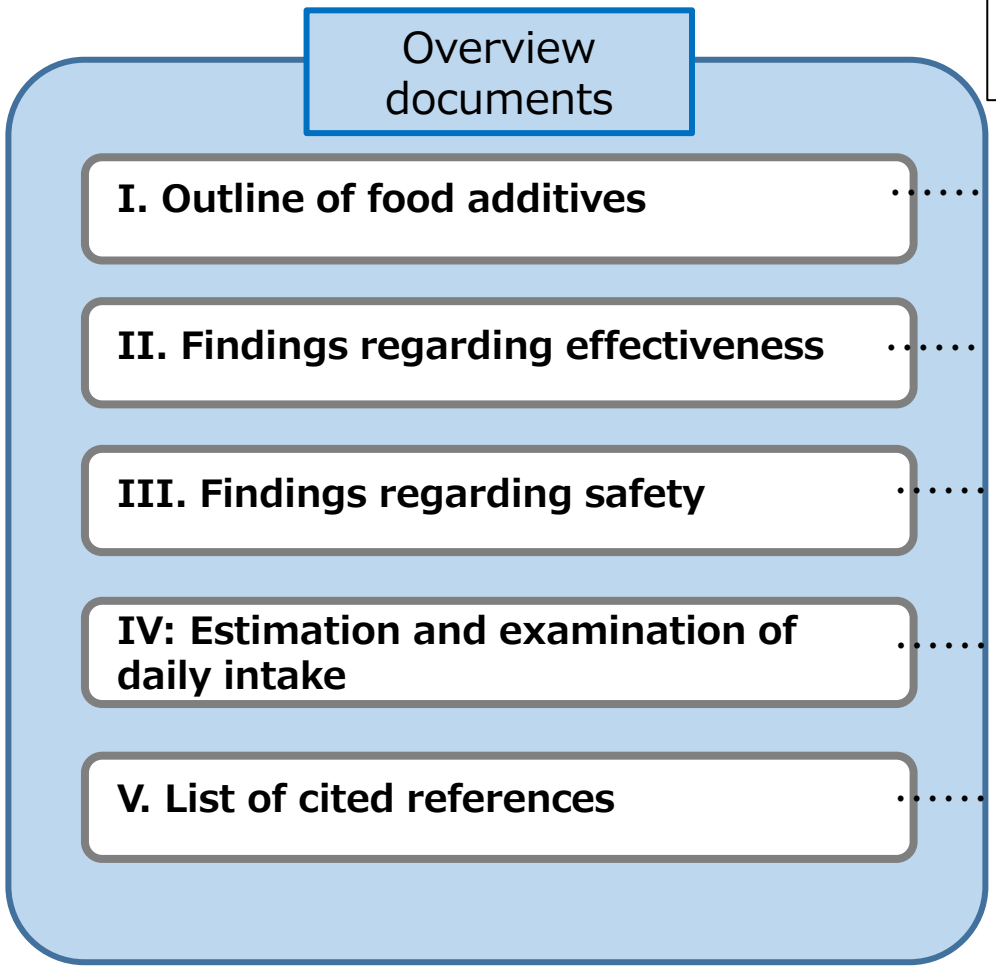
If you apply for a revision of standards for use, attach a comparison table of current standards for use and proposed revision.
(Please underline the changed parts.)
The document shall be written in Japanese. The attached form describes the contents in English.

The comparison table of standards for use (Example)

Proposals	**Curreent**
xxx Xxx must not be used in foods other than citrus fruits (excluding mandarin oranges) and potatoes. Xxx potassium must be used in such a way that no more than 0.010 g will remain in 1 kg of citrus fruits (excluding mandarin oranges) and no more than 0.007 g will remain in 1 kg of potatoes, in the form of xxx.	xxx Xxx must not be used in foods other than citrus fruits (excluding mandarin oranges). Xxx must be used in such a way that no more than 0.010 g will remain in 1 kg of citrus fruits (excluding mandarin oranges), in the form of xxx. **Note: xxx is the name of the food additive.**

Chapter 3-1. What is an Overview document? [1/2]

The attached document “3. Overview document” consists of the five parts shown on the left.
It is to be prepared in accordance with the 2014 Procedure; however, III and IV are to be written in accordance with the FSCJ Guidelines.



Items 4 to 9 of the MHLW Guidelines

Item 10 of the MHLW Guidelines

Item 11 of the MHLW Guidelines (FSCJ Guidelines)

List of cited references

Chapter 3-1. What is an Overview document? [2/2]

1. **The applicant is responsible for preparing** the Overview document.

2. The Overview document must be written in **Japanese**.

3. When preparing an Overview document, basically follow the 2014 Handbook.

4. However, among the items listed in the Overview document, those related to safety should be written in accordance with the FSCJ Guidelines.
   The items and the arrangement may differ partly, depending on the type of food additive (food additive in general, food additive for fortification, enzyme, or flavoring substance).

5. The documents listed in the list of cited references in the Overview document shall be attached as they are, as long as they are written in Japanese or English. For documents written in other languages, **make sure you translate the referenced parts into Japanese** and attach them to the relevant document.

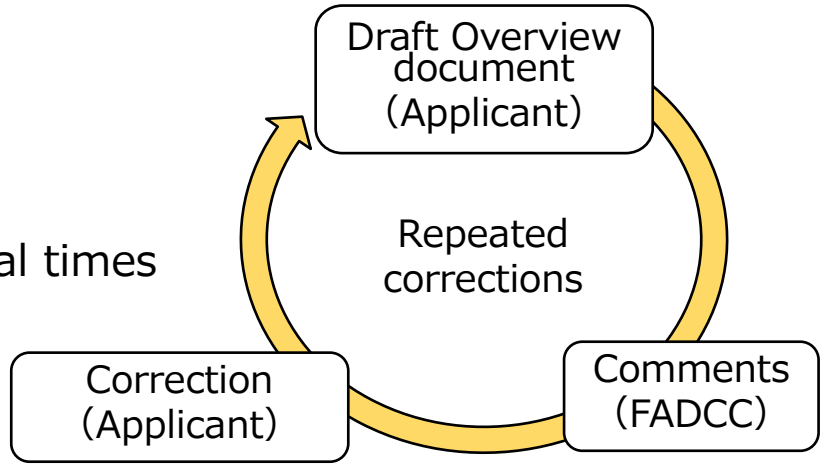
Chapter 3-2. Points to note when creating an Overview document [1/2]

Preparing an Overview document requires knowledge of the chemistry, toxicology, etc., related to food additives.
In addition, to make the Overview document meet the requirements of FSCJ and CAA, applicants need to devise ways to explain and present information.

FADCC will advise you so that you can prepare the draft Overview document appropriately. Specifically, it comments on the scientific accuracy and appropriateness of the specifications in the Overview document so that applicants can make the necessary corrections.

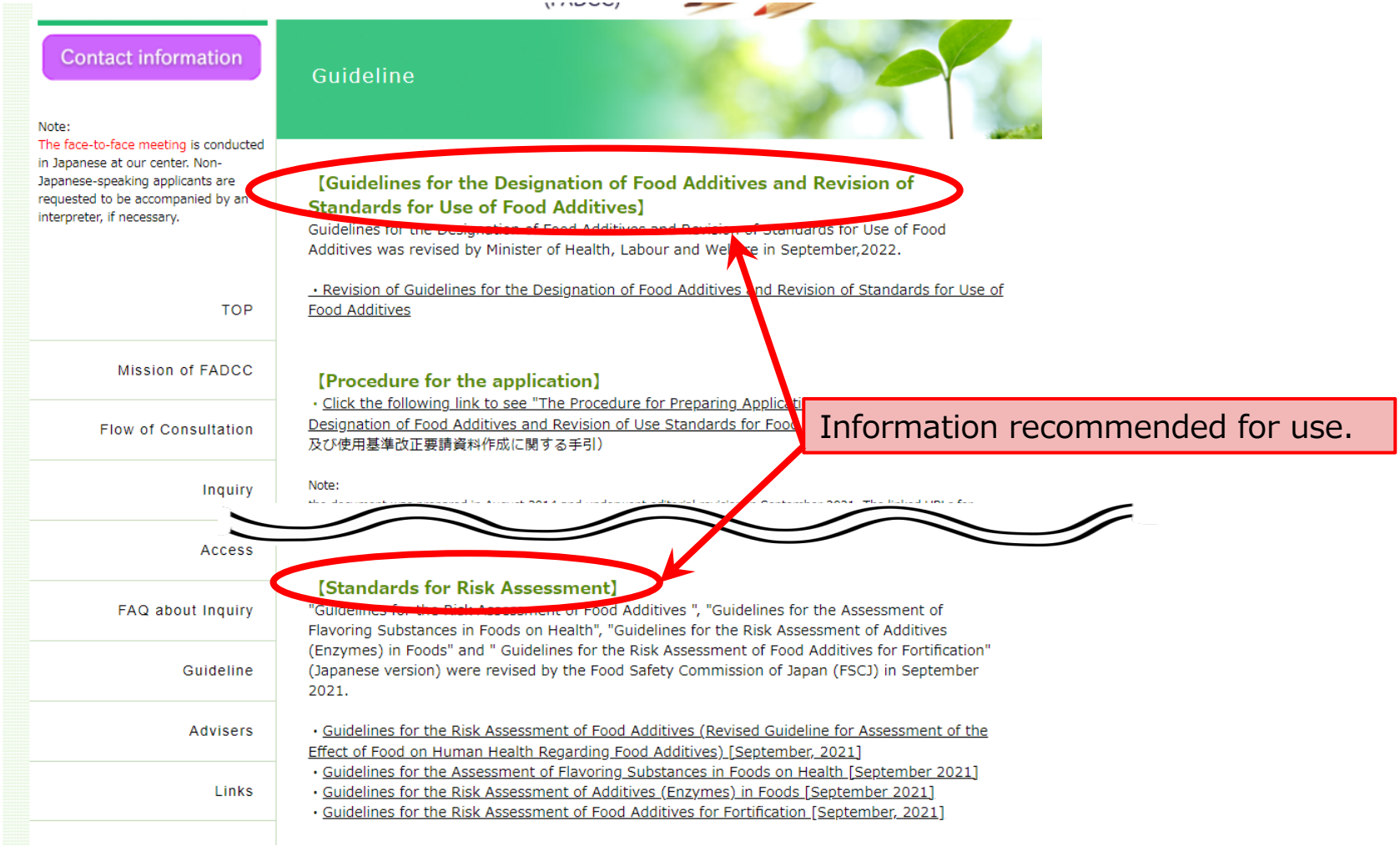
Note that such a document is called a "draft Overview document" until it is completed.

Applicants are required **to correct** the draft several times in accordance with the comments made by FADCC, **aiming for completion**.



Chapter 3-2. Points to note when creating an Overview document [2/2]

Recommendations for the items to be included in your Overview document are available on FADCC's website. You can download them for your reference.



Chapter 3-3. Points to note regarding descriptions [1/5]

The description in the Overview document shall be written on the basis of objective evidence so that the natural properties and benefits of the substance for which food additive designation is sought can be understood in deliberations by FSCJ or FSSC.

(a) Clearly state what you want the readers to understand about the application substance.
(b) Clearly explain the background and the basis of why the description is appropriate.

For example, to explain effectiveness, refer to the following sentence structures:

(a) Using xxx (substance name) shortens the time of *** in the food manufacturing process and can prevent the deterioration of raw materials.

(b) This is due to the ** property of xxx, and this ability is superior to that of conventional food additives in improving @@@.
The data underlying this fact are shown below. ――――――
Compared with similar food additives, it delivers higher values in terms of **. ――

Chapter 3-3. Points to note regarding descriptions [2/5]

1. Make sure you indicate the basis for the details given in the Overview document by using cited references.
   Especially when writing numerical values, check the original and cite the values accurately.

   Example: The substance xxx has the property of *** (Reference 1), and it has already been used as a food additive overseas (Reference 2).

2. If you cite several parts from the same document, include the page number of the citation in the main text of the Overview document so that it can be easily identified.

   Example: “It is ...” (Reference 15, page 72)

3. If you cannot find the information you need after searching the Internet, don’t just write “No information” or similar in the main text; instead, give evidence of your search.

   For example, convert a document containing the search engine's name, search terms, search date, and a screenshot of the search results into a PDF and submit it as a cited reference.

Chapter 3-3. Points to note regarding descriptions [3/5]

4. Many reports by international organizations, such as JECFA, are based on literature reviews. However, please obtain the original and provide a concise explanation based on it, instead of just citing the necessary part of an organization's report. If you can't get the original, explain this in the main text of the Overview document.

5. When citing the assessment document prepared by FSCJ, transcribe the said part without any corrections or omissions. Also, specify the beginning and end of the citation.

   Examples: (Start of citation) 『 ～quoted text～ 』(End of citation)

Chapter 3-3. Points to note regarding descriptions [4/5]

6. When citing a reference in the main text, write the corresponding reference number immediately after the citation so that the reader can quickly identify the corresponding reference.

Example of favorable description:

The origin of the target substance is substance B (Reference 2), obtained by adding various chemical modifications to substance A extracted from a plant named xx (Reference 1).

Example of unfavorable description:

The origin of the target substance is substance B, obtained by adding various chemical modifications to substance A extracted from a plant named xx (Reference 1, Reference 2).

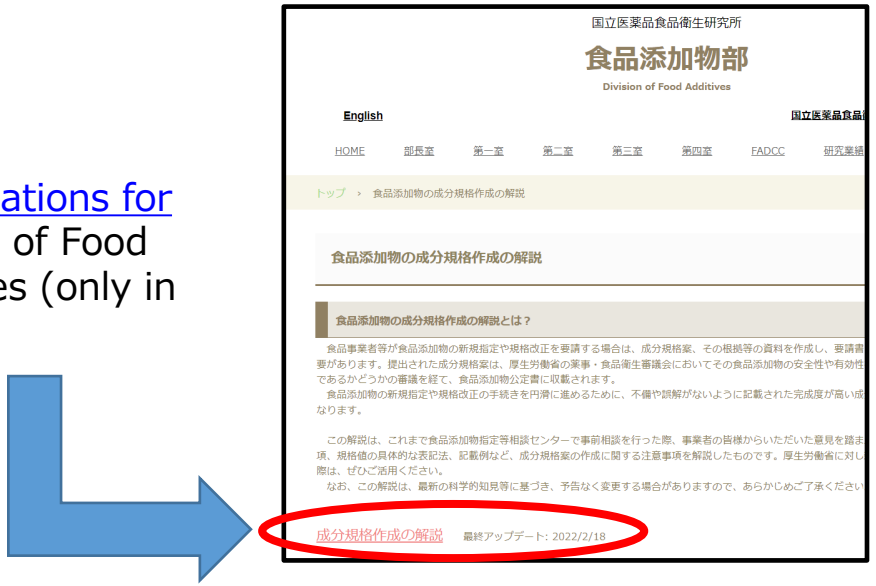
Chapter 3-3. Points to note regarding descriptions [5/5]

7. For the development of the draft specifications there are detailed rules regarding the names of reagent chemicals and the way in which test methods are described.

Example:
- Reagent names and test methods, in principle, conform with Japan's Specifications and Standards for Food Additives (JSFA).
- Pay attention to spelling and terminology: e.g.,「および→及び」「そのほか→その他」
  「ろうと→漏斗」「攪拌→かくはん」

– Units:
e.g., milliliters: → not ml but mL

National Institute of Health Sciences
Refer to the "Explanation for creating specifications for food additives" on the website of the Division of Food Additives, National Institute of Health Sciences (only in Japanese).



8. Each figure and table should be numbered consecutively in a series of Arabic numerals.

Chapter 3-4. Structure of an Overview document [1/2]

Template for creating an Overview document

The structure of an Overview document follows the content in Appendix 3 of the 2014 Handbook. However, in accordance with the changes in the items and arrangement due to revisions of the MHLW Guidelines, FADCC has made templates for creating an Overview document. It will provide templates for each type of food additive, namely food additives in general (including processing aids and breast-milk substitutes), nutritional-component-related additives, enzymes, and flavoring substances.

- The templates are posted on the FADCC website and will be updated occasionally. Please check them as necessary.

- When it comes time to write a draft of the Overview document, FADCC will send the latest template to you. Please use it.

- As a general rule, don't change the items written on the template.
- You can avoid leaving out or misspelling items by using the template.

Chapter 3-4. Structure of an Overview document [2/2]

An example of items in the first part of a template is as follows.
Please prepare your Overview document by using the template sent by FADCC.

I. Outline of the food additive
Introduction*
1. Name and purpose of use
(1) Name
(2) CAS registry number, etc.
(3) Purpose of use
(4) Method of use*
2. Origin or details of development
3. Actual situation of use in Japan and overseas
(1) Japan
(2) Codex
= = <Omitted below> = =

It is essential to state the history, purpose, and merits of use of the substance as a new food additive. Therefore, establish an "Introduction" section at the beginning of the Overview document and explain the purpose of the request in a few simple lines.

Describe clearly how the substance is expected to be used as a food additive.
In the items under "1. Name and purpose of use," make a sub-item "(4) Method of use" after sub-item "(3) Purpose of use."

***Note**: The template has been created based on Appendix 3 of the 2014 Procedure.
In the 2014 Handbook, there are no items called "(Purpose of application)" and "Method of use." However, they are added to the template because such information is essential.

The following pages provide templates for Food additives in general, Flavoring substances, Enzymes and Food additives for fortification.

The following template is used to describe the items to be included in the Overview document.

Template in Japanese : Food additives in general

Ⅰ. 添加物の概要
序
1．名称及び用途
2．起源又は発見の経緯
3．国内外における使用状況
4．国際機関等における安全性評価
5．物理化学的性質
（1）構造式等
（2）製造方法
（3）成分規格
（4）食品添加物の安定性
（5）食品中の食品添加物の分析法
6．使用基準案
7．その他

Ⅱ. 有効性に関する知見
1．食品添加物としての有効性及び他の同種の添加物との効果の比較
2．食品中での安定性
3．食品中の主要な栄養成分に及ぼす影響

Ⅲ. 安全性に関する知見
1．体内動態試験
2．毒性試験
（1）遺伝毒性試験
（2）反復投与毒性試験
（3）発がん性試験
（4）生殖毒性試験
（5）発生毒性試験
（6）アレルゲン性試験
（7）その他の試験
3．ヒトにおける知見

Ⅳ. 一日摂取量の推計及び考察

Ⅴ. 引用文献一覧

Please note that the templates are posted on the FADCC website and are updated as needed. When you are ready to write your Overview document, FADCC will send you the latest template, so please use that one.

The following template is used to describe the items to be included in the Overview document.

Template in Japanese ： Flavoring substances

Ⅰ．添加物の概要
序
１．名称及び用途
２．起源又は発見の経緯
３．国内外における使用状況
４．国際機関等における安全性評価
５．物理化学的性質
（１）構造式等
（２）製造方法
（３）成分規格
（４）食品添加物の安定性
（５）食品中の食品添加物の分析法
６．使用基準案
７．その他

Ⅱ．有効性に関する知見
１．食品添加物としての有効性
２．食品中での安定性
３．食品中の主要な栄養成分に及ぼす影響

Ⅲ．安全性に関する知見
１．遺伝毒性
２．一般毒性
３．一日摂取量の推計及び考察

Ⅳ．引用文献一覧

Please note that the templates are posted on the FADCC website and are updated as needed.
When you are ready to write your Overview document, FADCC will send you the latest template, so please use that one.

The following template is used to describe the items to be included in the Overview document.

Template in Japanese ： Enzymes

Ⅰ．添加物の概要

序
1．名称及び用途
2．起源又は発見の経緯
3．国内外における使用状況
4．国際機関等における安全性評価
5．物理化学的性質
（1）基原生物
（2）製造方法
（3）成分
（4）性状
（5）成分規格
（6）食品添加物の安定性
（7）食品中の食品添加物の分析法
6．使用基準案
7．その他

Ⅱ．有効性に関する知見

1．酵素としての有効性及び他の同種の酵素との効果の比較
2．食品中での安定性
3．食品中の主要な栄養成分に及ぼす影響

Ⅲ．安全性に関する知見

1．基原生物の安全性
（1）病原性及び有害物質の産生性に関する事項
（2）寄生性及び定着性に関する事項
（3）病原性の外来因子に関する事項
2．酵素の消化管内での分解性に関連する事項
（1）消化管内での易分解性
（2）消化管内での分解に関わる主要な因子
（3）酵素又はその分解物の吸収及び他の栄養成分の吸収への影響
（4）酵素の主要な成分の過剰摂取の問題
（5）未分解物又は部分分解物の排泄及び蓄積
3．酵素の毒性
（1）90日間反復投与毒性試験
（2）遺伝毒性試験
（3）アレルゲン性
4．酵素の消化管内での分解性及びアレルゲン性に係る試験

Ⅳ．一日摂取量の推計及び考察

Ⅴ．引用文献一覧

Please note that the templates are posted on the FADCC website and are updated as needed.
When you are ready to write your Overview document, FADCC will send you the latest template, so please use that one.

The following template is used to describe the items to be included in the Overview document.

Template in Japanese ： Food additives for fortification

Ⅰ．添加物の概要
序
１．名称及び用途
２．起源又は発見の経緯
３．国内外における使用状況
４．国際機関等における安全性評価
５．物理化学的性質
（１）構造式等
（２）製造方法
（３）成分規格
（４）食品添加物の安定性
（５）食品中の食品添加物の分析法
６．使用基準案
７．その他

Ⅱ．有効性に関する知見
１．食品添加物としての有効性及び他の同種の添加物との効果の比較
２．食品中での安定性
３．食品中の主要な栄養成分に及ぼす影響

Ⅲ．安全性に関する知見
１．体内動態試験
２．ヒトにおける知見
（１）臨床試験
（２）症例報告
（３）メタアナリシス
（４）ヒトにおける知見に係る判断について
３．毒性試験
（１）遺伝毒性試験
（２）反復投与毒性試験
（３）発がん性試験
（４）生殖毒性試験
（５）発生毒性試験
（６）アレルゲン性試験
（７）その他の試験

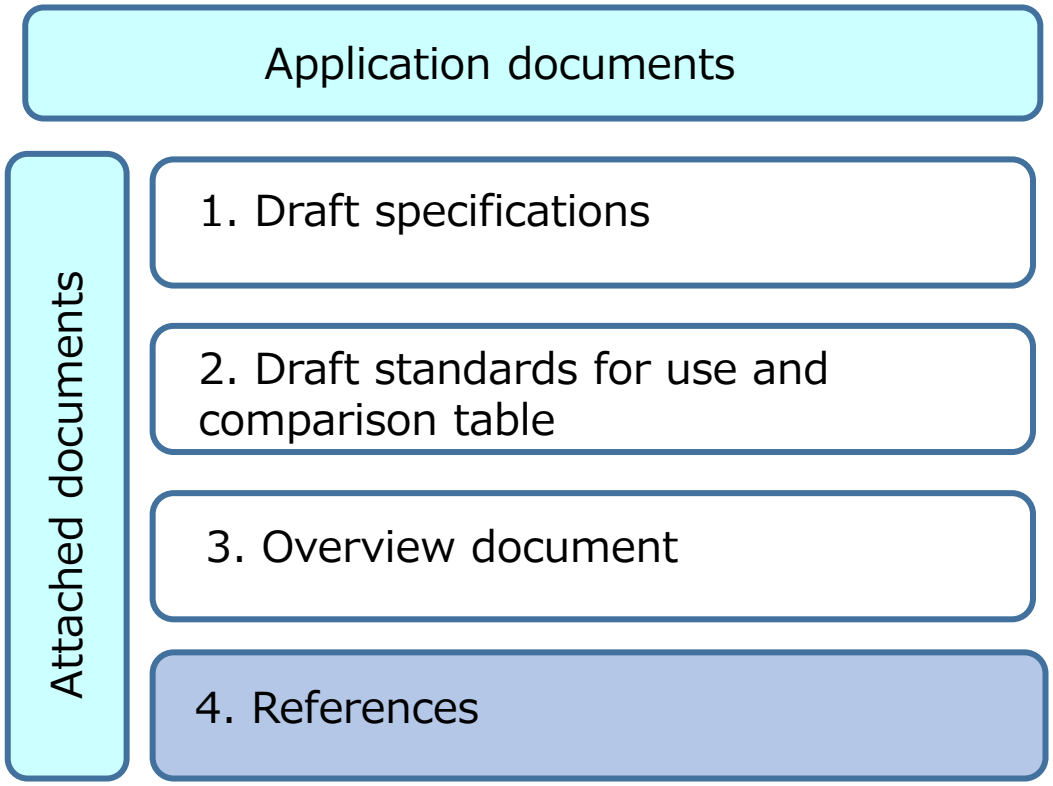
Ⅳ．一日摂取量の推計及び考察

Ⅴ．引用文献一覧

Please note that the templates are posted on the FADCC website and are updated as needed.
When you are ready to write your Overview document, FADCC will send you the latest template, so please use that one.

Chapter 4-1. Regarding cited references [1/10]

Make a list of cited references at the end of the Overview document, and submit the full reference documents as separate files (PDF file, etc.) from the Overview document.



PDF file of the reference documents.
If the reference document was written other than in Japanese or English, submit a Japanese translation of the relevant part (cited part) together with the original version in PDF form.

Chapter 4-1. Regarding cited references [2/10]

1 Not only printed materials such as books, papers, and reports, but also information published online can be used in PDF form. However, there is much uncertain information on the Internet, so if you want to use this information as a reference, check its veracity yourself. You may wish to include:

(a) Public information, such as reports from specialized public organizations (including web postings)
(b) Academic papers in specialized fields
(c) Books in specialized fields
(d) Measurement data from in-house tests and analytical institutions
(e) Articles published in newspapers and magazines
(f) Articles on the web other than (a) to (e)

FADCC believes that reliability is highest to lowest in numerical order from (a) to (f).

2 Check that the publication is the latest.
Note that reports from public institutions are updated from time to time.

Chapter 4-1. Regarding cited references [3/10]

3 Number the documents in the reference list of the Overview document in citation order (order of appearance). Mark, or highlight, the parts of the reference that you referenced in the Overview document.
Use of a marker with about 50% opacity is recommended so that the highlighted text can be read without problem.

4 If you need to indicate a citation from a reference hundreds of pages long, consider the convenience of readers when preparing the document. For example, extract only the necessary parts and convert the extract to a PDF together with the front page of the reference (publisher's information in the case of books) and the table of contents.

5 Make sure you follow the necessary procedures so that no problems arise regarding the copyright of the references.

Chapter 4-1. Regarding cited references [4/10]

6 It is not appropriate to cite other references when attempting to use a document prepared by the applicant as a citation.

7 To use searched content on the Internet as a reference, it is convenient to convert the contents into a PDF file which includes the search-site name, search date, search words (search formula), and search results.

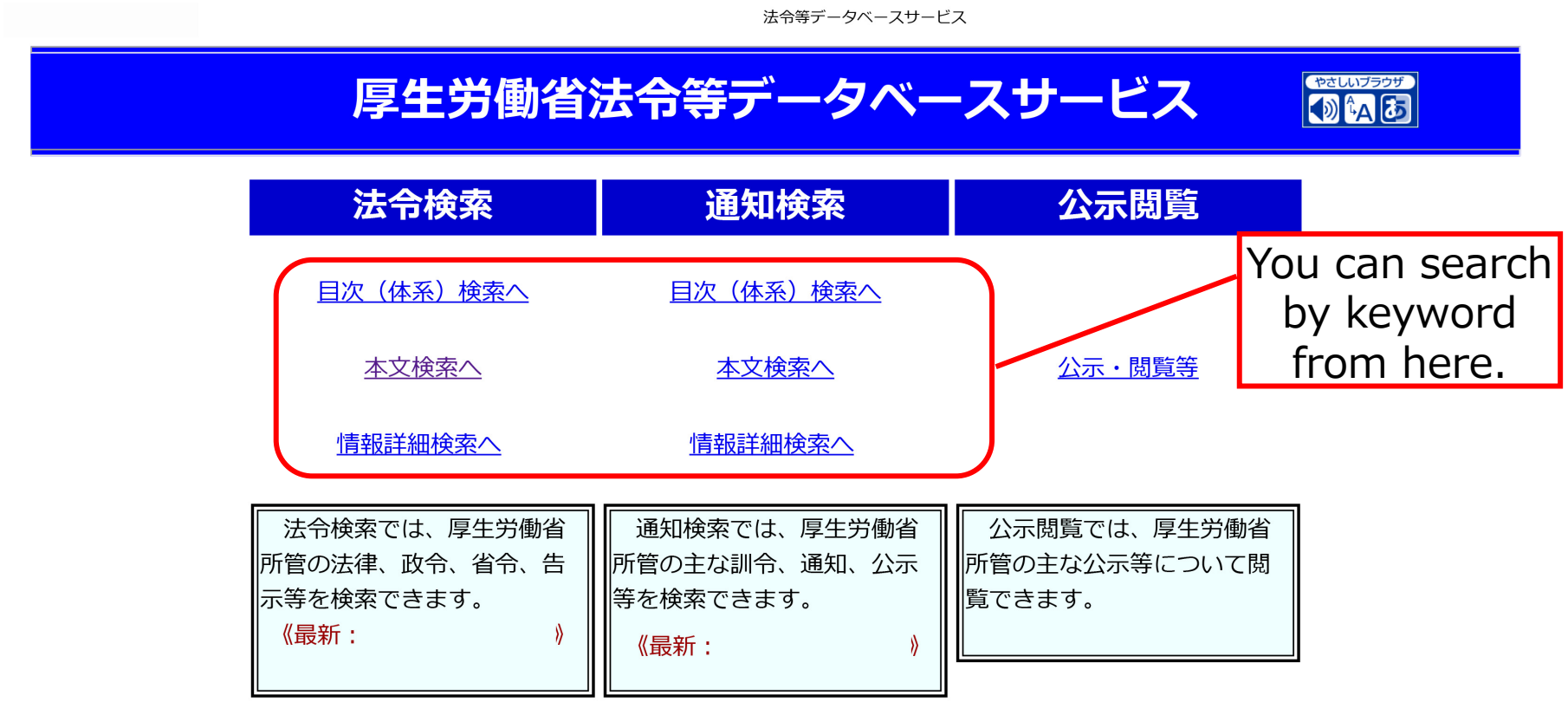
8 Regarding 1.(a) Public information, such as reports from specialized public organizations (including web postings), you can download the legal notification information online and convert it into a PDF for use as a cited reference.

In such a case, download the required information from the government website that issued the notification.

Note: You can search for the laws, regulations, and notifications.
・the MHLW regulations
MHLW Database for laws and regulations (Japanese only)
・the CAA regulations
CAA regulations (Japanese only)

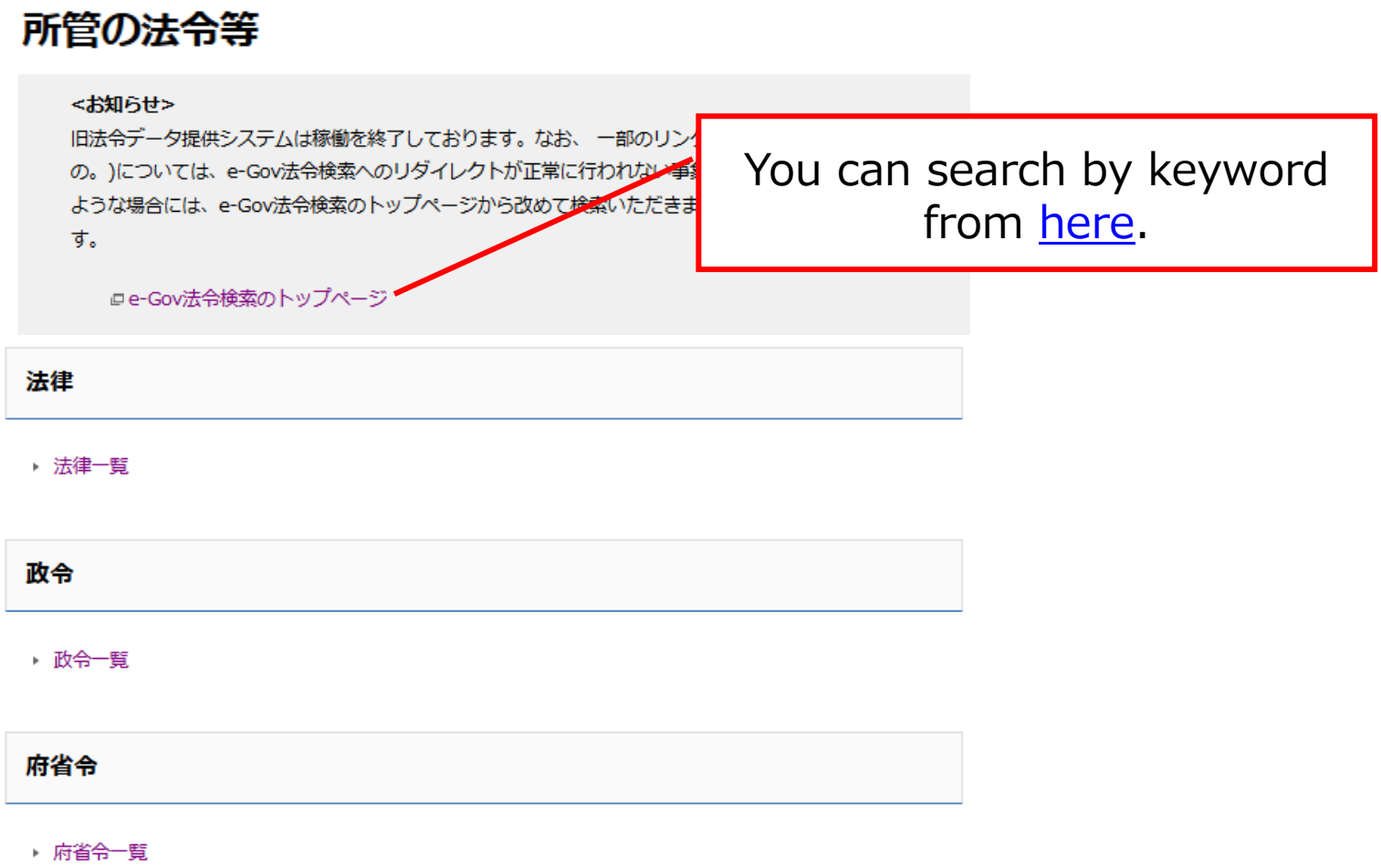
Chapter 4-1. Regarding cited references [5/10]

MHLW Database for laws and regulations (Japanese only)



Chapter 4-1. Regarding cited references [6/10]

CAA regulations (Japanese only)



Chapter 4-1. Regarding cited references [7/10]

9 Followings are describing examples for cited papers, articles to be listed in the "list of cited references"

- For Papers: (Author name, paper title, journal name, year of publication, volume number, page numbers (start–end))

01 Morikawa R, Kubota N, Amemiya S, Nishijima T, Kita I: Interaction between intensity and duration of acute exercise on neuronal activity associated with depression-related behavior in rats. The Journal of Physiological Sciences 2021;71(1):1

02 鈴木一平，熊井康人，多田敦子他：日本食品標準成分表2015年版（七訂）分析マニュアルに基づく加工食品中のビタミンD類分析法の改良と検証．食品衛生学雑誌 2020;61:53-7. doi: https://doi.org/10.3358/shokueishi.61.53

- For Books: (author (or editor) name: names of chapter, section, or item. “book title”, publisher, year of publication; page numbers)

03 田島慶三: 不規則性単条有機ポリマーの構造基礎命名法. “コンパクト化合物命名法入門”, 東京化学同人, 2020; 59-87

04 日本医薬品添加剤協会編集：コハク酸. “医薬品添加物事典 2021”, 薬事日報社，2021; 201

05 Rowe RC, Sheskey PJ, Quinn ME: Polyvinyl alcohol. “Handbook of Pharmaceutical Excipients, 6th ed.”, American Pharmaceutical Association, 2009; 564-5

Chapter 4-1. Regarding cited references [8/10]

- For Japan's Specifications and Standards for Food Additives：（CCA： Name of test methods or monographs. version of JSFA, year of publication）

06 消費者庁: 33. 鉛試験法（原子吸光光度法）, 40. ヒ素試験法. 第10版食品添加物公定書, 2024 https://www.caa.go.jp/policies/policy/standards_evaluation/food_additives/official_documents_002/assets/001208056.pdf（アクセス日：2025/1/16）

07 消費者庁: L －ロイシン. 第10版食品添加物公定書, 2024 https://www.caa.go.jp/policies/policy/standards_evaluation/food_additives/official_documents_002/assets/001208056.pdf（アクセス日：2025/1/16）

- For FSCJ Evaluation documents：（FSCJ：Title of the report. YYYY/MM）

08 食品安全委員会：添加物評価書「二炭酸ジメチル」. 2019 年１月

- For Notices: (Issuer: Title of Notification. Date of issue and Notification number, Issued year)

09 消費者庁食品衛生基準審査課長：「食品添加物の指定及び使用基準改正要請資料作成に関する手引」の一部改正について. 令和7年3月24日消食基第209号, 2025

- For Patent：(Name of inventor: Title of the invention. Patent document number, Patent granting agency (ex. JPO). Date of Publication of Patent Gazette)

10 ○○：××を含む食品組成物. 特許第7566414号, 日本国特許庁, 令和6年10月17日

Chapter 4-1. Regarding cited references [9/10]

- For Internal reports (documents): (Company name: Report (documents) title. Company internal report (document), year of creation)

11 ○○：××報告書．社内報告書，2025

- For Websites: (Website name: Title of relevant page, source URL (Date of access : YYYY/MM/DD)

12 EFSA (European Food Safety Authority): Food additives
https://www.efsa.europa.eu/en/topics/topic/food-additives（ アクセス日：2025/3/25）

13 消費者庁：食品添加物 https://www.mhlw.go.jp/content/001435384.pdf（ アクセス日：2025/3/25）

- For US CFR 21:（Web site name : Section # & title URL（Date of access : YYYY/MM/DD）

14 Code of Federal Regulations Title 21: Sec. 177.1670 Polyvinyl alcohol film https://www.ecfr.gov/current/title-21 （ アクセス日：2025/3/25）

- For CODEX Guidelines:（Responsible body : Name of Guidelines and code, revised year; pages URL（Date of access : YYYY/MM/DD）

15 CAC: Class names and the international numbering system for Food additives CXG 36-1989, 2024; 1-5, 45 https://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/tr/ （ アクセス日：2025/3/25）

Chapter 4-1. Regarding cited references [10/10]

- For WHO Food Additives Series: (JECFA: Substance. Meeting #, Meeting term, Publication #, year; pages)

16 JECFA: Metatartaric acid. 84th JECFA, 6-15 June 2017, FAS75, 2019, 145-163

- For WHO Technical Report Series: (JECFA: Substance. Meeting #, Meeting term, Publicaton #, year; pages)

17 JECFA: Metatartaric acid. 84th JECFA, 6-15 June 2017, TRS1007, 2017; 43-49

- For FAO/WHO Compendium of Food Additive Specifications:
  (JECFA: Substance. Monographs #, JECFA Meeting #, published year; page(s)); or
  (JECFA: Substance. Monographs # (Published year), URL (Date of Access: YYYY/MM/DD)

18 JECFA: Magnesium stearate. Monographs 17, JECFA 80th meeting, 2015; 27-30

19 JECFA : Triethyl Citrate. Monograph 7 (2009)
https://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph7/additive-477-m7.pdf (アクセス日 : 2025/3/25)

This is the end of the General notes.

Next, see the following notes:

I. Outline of food additives (Japanese only)
II. Effectiveness (Japanese only)
III. Safety, IV. Daily intake (Japanese only)

For I to Ⅳ, a Handbook for the Procedure suitable for each section has been provided according to the type of food additive, namely food additives in general (processing aids, breast-milk substitutes), enzymes, food additive for fortification, or flavoring substances, and the content of the application (new designation, revision of standards for use, revision of specifications).

If you think the target substance may fall under processing aids or breast-milk substitutes, please refer to "Regarding of processing aids and breast-milk substitutes (Japanese only)".

Also, when seeking information, refer to the Information search guide.