

*Ministry of Foreign Affairs  
Tokyo, Japan*

31 January 2019

Dear Ambassador Flor,

Following the discussions on food additives in the context of Japan-EU EPA negotiations, I have the honour to provide you with attached information on the current procedures for designating food additives in Japan as of 17 July 2018, as a reference to the Food Additive Annex of the SPS Chapter of the Agreement.

Sincerely,

A handwritten signature in black ink, consisting of stylized Japanese characters, likely reading 'Shingo Yamagami'.

Shingo Yamagami  
Director-General  
Economic Affairs Bureau  
Ministry of Foreign Affairs of Japan

Ambassador Patricia Flor  
Head of the Delegation  
of the European Union to Japan

## Attachment

### Information on Procedures for Designating Food Additives in Japan

#### 1) Publication of relevant guidelines

- Information on data requirements for the designation procedures of food additives is available in the current “Guidelines for the Risk Assessment of Food Additives” and “The Procedure for Preparing Application Documents for Designation of Food Additives and Revision of Use Standards for Food Additives”<sup>1</sup>.
- In order to provide further clarity on the data requirements, the Food Safety Commission of Japan (FSC) has established and published guidelines for assessment for enzymes, processing aids and nutrients.
- The Ministry of Health, Labour and Welfare of Japan (MHLW) has also published a relevant notification regarding the data requirements, following the publication of guidelines for assessment by the FSC.
- Regarding those guidelines and notification, the FSC and the MHLW are working towards publishing English translations.

#### 2) Data requirement

- Information requirements are limited to what is necessary for the appropriate designation procedures, and as stipulated in the Annex C, 1(c) of the WTO SPS Agreement.

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#### <sup>1</sup> Published Guidelines:

- Guidelines for the Risk Assessment of Food Additives (Amended Guidelines for Assessment of the Effect of Food on Human Health Regarding Food Additives)  
  
[http://www.fsc.go.jp/english/what\\_we\\_do.data/For\\_HP\\_Guidelines\\_for\\_Food\\_Additives.pdf](http://www.fsc.go.jp/english/what_we_do.data/For_HP_Guidelines_for_Food_Additives.pdf)
- The Procedure for Preparing Application Documents for Designation of Food Additives and Revision of Use Standards for Food Additives  
  
<http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/dl/tenkabutu-hyouka-shishin-english.pdf>

- In this context, the FSC already applies a read across approach by using existing scientific data in its risk assessment on food additives where applicable. For example, when a tested food additive differs only in the base moiety from a food additive already designated, when it is an isomer of a designated additive, or when there are other reasons with scientifically rationale, part of the test can be omitted provided that the reason for doing so is clearly described.
- The risk assessment of the international bodies and the existing international standards on the authorisation of substances are always taken into account whenever available, as required by Guidelines for the Risk Assessment of Food Additives and the Guidelines for the Designation of Food Additives and Revision of Standards for Use of Food Additives, and as also stipulated in the Article 3.1 of the WTO SPS Agreement.

### 3) Timeline

- The standard processing time for Japan's designation process of food additives is set to be two years; one year for the risk assessment by the FSC<sup>a</sup> and another year for approval procedure by the MHLW<sup>b</sup>.
  - a) [http://www.fsc.go.jp/english/RiskAssessment.data/Standard\\_Processing\\_Period.pdf](http://www.fsc.go.jp/english/RiskAssessment.data/Standard_Processing_Period.pdf)
  - b) <http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/dl/tenkabutu-hyoujunjimusyorikikan-english.pdf>
- While Japan does not have a separate standard processing time specifically for extension of use of food additives, the risk assessment procedures would be simplified in cases where the FSC has already conducted a risk assessment on the same substance and no new scientific evidences become available which affect the result of the existing risk assessment.

### 4) Language

- The application and overview documents for approval of food additives should be in Japanese but the reference documents are acceptable in English.
- To support foreign applicants, the Government of Japan allocated additional budget to strengthen the function of the Food Additive Designation Consultation Center (FADCC), which would include consultation by e-mails or telephone calls in English.

- The following guidelines were published in English.
  - a) Guidelines for the Designation of Flavoring Agents (30 November 2016)  
<http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/dl/kor-yo-shiteishishin-english.pdf>
  - b) Guidelines for the Designation of Food Additives and Revision of Standards for Use of Food Additives (30 November 2016)  
<http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/dl/ten-kabutu-shiteikijunkaiseishishin-english.pdf>
  - c) Guidelines for the Assessment of Flavoring Substances in Foods on Health (22 December 2016)  
[http://www.fsc.go.jp/english/index.data/Guidelines\\_for\\_the\\_assessment\\_of\\_flavoring\\_substances\\_in\\_foods\\_on\\_health.pdf](http://www.fsc.go.jp/english/index.data/Guidelines_for_the_assessment_of_flavoring_substances_in_foods_on_health.pdf)
  - d) Guidelines for the Risk Assessment of Food Additives (Amended Guidelines for Assessment of the Effect of Food on Human Health Regarding Food Additives) (14 June 2018)  
[http://www.fsc.go.jp/english/what\\_we\\_do.data/For\\_HP\\_Guidelines\\_for\\_Food\\_Additives.pdf](http://www.fsc.go.jp/english/what_we_do.data/For_HP_Guidelines_for_Food_Additives.pdf)
  - e) Supplement: Approach for the Risk Assessment of Processing Aids (Food Disinfectants and Extractants) (14 June 2018)  
[http://www.fsc.go.jp/english/what\\_we\\_do.data/For\\_HP\\_Supplement\\_Approach\\_for\\_the\\_risk\\_assessment\\_of\\_processing\\_aids.pdf](http://www.fsc.go.jp/english/what_we_do.data/For_HP_Supplement_Approach_for_the_risk_assessment_of_processing_aids.pdf)
  - f) Guidelines for the Risk Assessment of Additives (Enzymes) in Foods (14 June 2018)  
[http://www.fsc.go.jp/english/what\\_we\\_do.data/For\\_HP\\_Guidelines\\_for\\_Enzymes.pdf](http://www.fsc.go.jp/english/what_we_do.data/For_HP_Guidelines_for_Enzymes.pdf)
  - g) Guidelines for the Risk Assessment of Food Additives for Fortification (14 June 2018)  
[http://www.fsc.go.jp/english/what\\_we\\_do.data/For\\_HP\\_Guidelines\\_for\\_FAF.pdf](http://www.fsc.go.jp/english/what_we_do.data/For_HP_Guidelines_for_FAF.pdf)
- The Government of Japan is also continuing effort to make relevant guidelines available in English.