



	e.g., Add this product to wine, etc., mix, and remove by filtration.
Classification related to the FSCJ's* <sup>1</sup> Guideline for Risk Assessment of the Food Additives	<u>Please check the box if any of the followings apply to your item.</u> <input type="checkbox"/> Flavoring substances <input type="checkbox"/> Enzymes <input type="checkbox"/> Fortification <input type="checkbox"/> None of the above
Summary of your proposal for designation/amendment Please provide a brief description of the problem to be solved by and the benefits to Japanese consumer with your item in 200-300 words. Please also explain why you think your item needs to be newly designated, as well as the reason why the standard for use or the specification to be revised.	
Details of consultation  Please also submit materials that provide a general description of the food additive (e.g., outline of the components, usage in or outside Japan, etc.) with this application.	

\*<sup>1</sup> FSCJ: Food Safety Commission of Japan

### 3. Pre-checklist of this inquiry

Please also check the following points with respect to the items listed in the "Summary of your proposal for designation/amendment" section.

#### 3-1 Verification of exemption from the "Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (PMD Act)"

Have you verified with the officer in the public health center whether your item and its use do not fall under the category of pharmaceuticals, quasi-drugs or etc. as defined in the PMD Act? If so, you are required to follow the procedures under the PMD Act.

Yes, I did (PMD Act not applicable)       No

Other (reason: \_\_\_\_\_ )

#### 3-2 Verification of applicability of the food additive

Have you verified with the health center that your item and its use is an additive \* as defined in the Food Sanitation Act (FSA)?

\* The term "additives" as used in this Act means substances which are used by being added, mixed or infiltrated into food or by other methods in the process of producing food or for the purpose of processing or preserving food.

Yes, I did (FSA applicable)       No

Other (reason: \_\_\_\_\_ )

e.g. Because of revision of standards for use of a food additive which have already been specified )

#### 3-3 Verification regarding imported food or food additives

If it is a case related to the importation of your item or food products using your item, have you verified with the food monitoring section of the quarantine whether the importation is allowed or not?

Yes, I did (compliant with the FSA)       Yes, I did (not compliant with the FSA)       No

Other (reason: \_\_\_\_\_ )

#### 3-4 Verification regarding Genetically Modified Organisms

Does your item fall under the category of the one produced using Genetically Modified Organisms?

Yes

No

Not sure

Note

The consultation is provided in Japanese at the FADCC. You bring interpreter(s) with you at the consultation if you need.