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Japan Established Food Additive Designation Consultation Center

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Sanitary/Phytosanitary/Food Safety

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Report Highlights:

In June 2014, Japan's Ministry of Health, Labor, and Welfare (MHLW) established the Food Additive Designation Consultation Center (FADCC) to assist companies with applications for food additive use in Japan. The FADCC is now in operation and is accepting requests for consultations from potential applicants. FAS/Japan will monitor the FADCC and its success in improving the efficiency of Japan's food additive approval process.

General Information:

In June 2014, the Government of Japan (GOJ) announced the creation of the FADCC, which will assist companies in preparing applications for allowed use of food additives. Currently, Japan requires all applications for food additives, either as a new designation or for an expansion for use in target foods, to go through a lengthy regulatory review by MHLW and the Food Safety Commission (FSC) that can take up to several years before approval is granted. Japan also requires a number of chemicals that are outside the U.S. definition of “food additives”, such as post-harvest fungicides, to also go through this review process. As Japan’s regulatory review has been slow and cumbersome, the United States and other countries have pressed Japan for years to try to improve its approval process. Japan hopes that the FADCC will help companies in preparing more complete applications, as providing a dossier that is “satisfactory” and acceptable to MHLW and FSC is one of the most difficult parts of the whole process for food additive approval. The GOJ expects that the FADCC will especially be useful for companies with limited experience with Japan’s regulatory review process. As the FADCC has only operated for a few months, FAS/Japan will monitor the center’s effectiveness closely.

Overview of the Pre-Application Consultation on the Designation of Food Additives

Summary

Article 10 of Japan’s Food Sanitation Act stipulates that:

“...food additives shall not be used or marketed without authorization (designation) by the Minister of Health, Labor, and Welfare (hereinafter referred as ‘the Minister’). In addition, when specifications or standards are established for food additives based on Article 11 of the act and stipulated in MHLW (Ministry of Health and Welfare Notification No. 370, 1959), those additives shall not be used or marketed unless they meet the standards or specifications. Any person who wishes to use a food additive that is not designated by the Minister or wishes to use a designated additive in products in which the additive is not permitted, shall file an application with the Minister. The applicant needs to submit required documents along with an application form. The documents include information showing a description, effectiveness, and safety of the additive and data quoted in the information.”

Food additive applications must first be submitted to MHLW for an extensive review of the document and its supporting information. Once MHLW feels that an application is complete, it then submits the dossier to the FSC for a formal review. During the approval process, both MHLW and the FSC may have a number of follow-up questions, before and during the review, which requires an extensive amount of interaction with applicants. This long “back and forth” process can significantly extend the time for the preliminary consultation prior to formal acceptance of the application, as well as the FSC’s review before approval is granted. For more information on Japan’s additive review process, please consult the annual USDA/FAS [“FAIRS Country Report Food and Agricultural Import Regulations and Standards – Narrative.”](#)

Given Japan’s strict review process, companies are now contacting MHLW with questions on their applications before formally submitting their products for approval. Additionally, USG and other countries have requested MHLW to improve the efficiency of Japan’s food additive approval

procedures. As a result of these recent developments, MHLW conducted a survey to identify the steps in which applicants face the most technical difficulty during the process of seeking a food additive approval. Based on the survey, MHLW found that the preparation of an acceptable dossier is the most time-consuming process, especially for applicants with limited regulatory experience, and therefore concluded that providing for a pre-application consultation period with its experts was an effective way to expedite the process. In June 2014, MHLW established the Food Additive Designation Consultation Center in the National Institute of Health Sciences, with the intention to assist companies with their food additive applications by providing guidance for and review of applications. The FADCC mostly consists of former food additive regulatory specialists, including previous members of the FSC Expert Committee (the section of the FSC that performs risk assessments). GOJ hopes that by allowing for this consultation in advance, the FADCC will help companies ensure that their applications will be complete in advance of the formal submission to MHLW and the FSC, thereby ensuring a smoother and quicker review process for food additive approval. The FADCC began accepting applications for assistance in July.

Note:

The FADCC conducts its consultations only in Japanese and on a face-to-face basis. The FADCC requests that non-Japanese applicants be accompanied by an interpreter if necessary.

Information on the Food Additive Designation Consultation

Location of Food Additive Designation Consultation Center (FADCC)

Zip code: 154-0015

Address: 2-31-5, Sakurashinmachi, Setagaya-ku, Tokyo
(Toshiba Sakurashinmachi Building 3F)

Tel/Fax: 03-6432-6013

Email: fadcc@nihs.go.jp

Office hours: Monday –Friday, 10:00–12:00 and 13:00–16:30

(Excluding national holidays and year-end and New Year holidays)

Website: http://www.nihs.go.jp/dfa/fadcc_e_aboutus.html

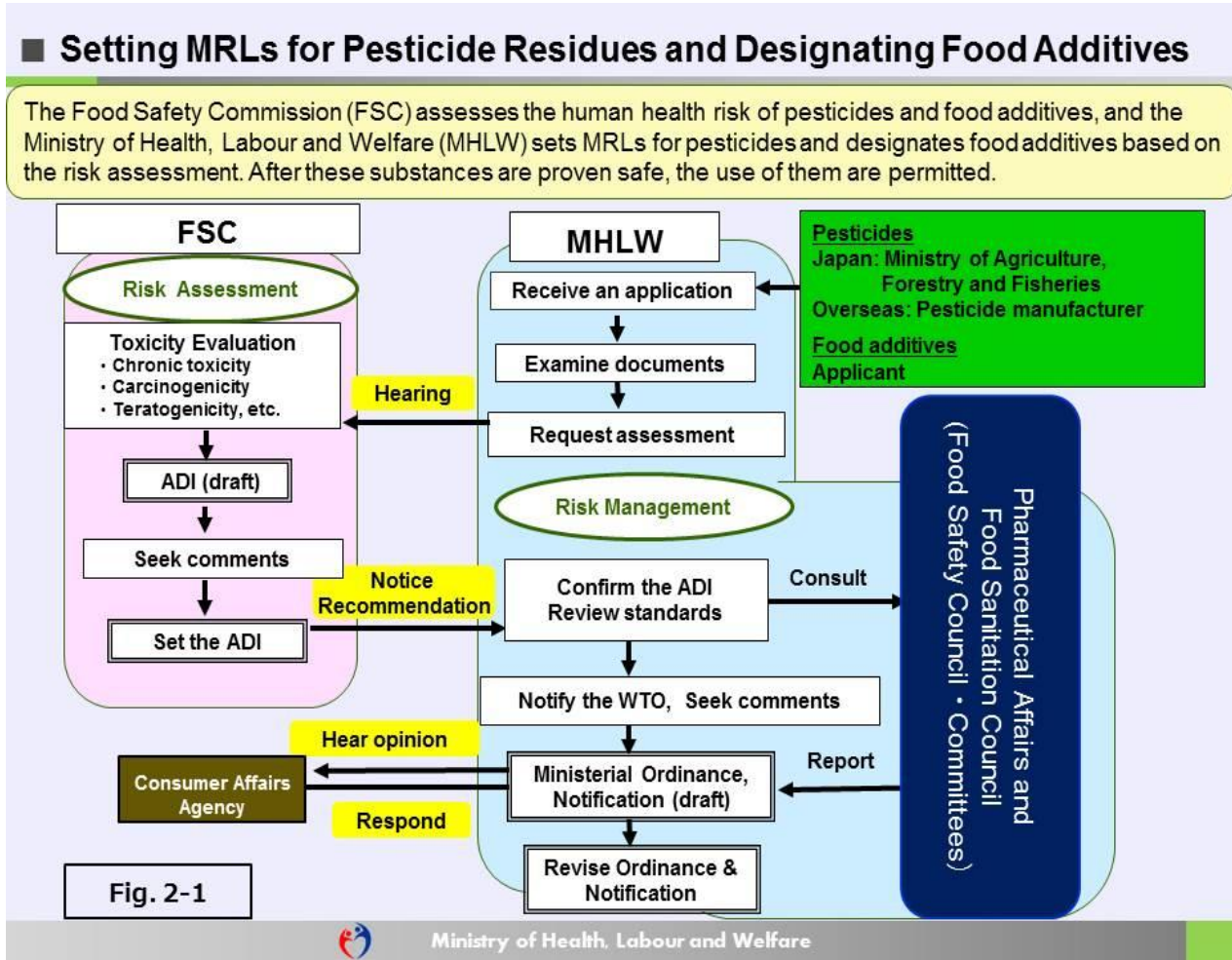
Prior to a submission to MHLW, the FADCC will consult on applications for either the designation of a new food additive or the revision of existing use standards for a designated food additive to expand use.

The FADCC will offer advice on:

- How to prepare/compile documents on the following information:
 - Sources/history/background of discovery/creation of the food additive
 - Physicochemical characteristics and compositional specifications
 - Effectiveness
 - Safety
 - Standards for use
 - Other general matters concerning application for designation
 - Confirmation on whether drafted documents are correctly organized and referenced information is accurate.

- Also, when additional information is required by the FSC during its risk assessment review, the FADCC will advise on how to collect and compile requested information.
- Finally, MHLW notes that the FADCC bases its advice for applications on actual cases and experience. Please note that interaction with the FADCC does not guarantee that MHLW or the FSC will not request additional information during their respective reviews due to a number of issues, such as the publishing of new findings on safety.

For information on the FADCC, go to http://www.nihs.go.jp/dfa/fadcc_e_aboutus.html



General Food Additive Review Process in Japan

■ Role of Food Additive Designation Consultation Center

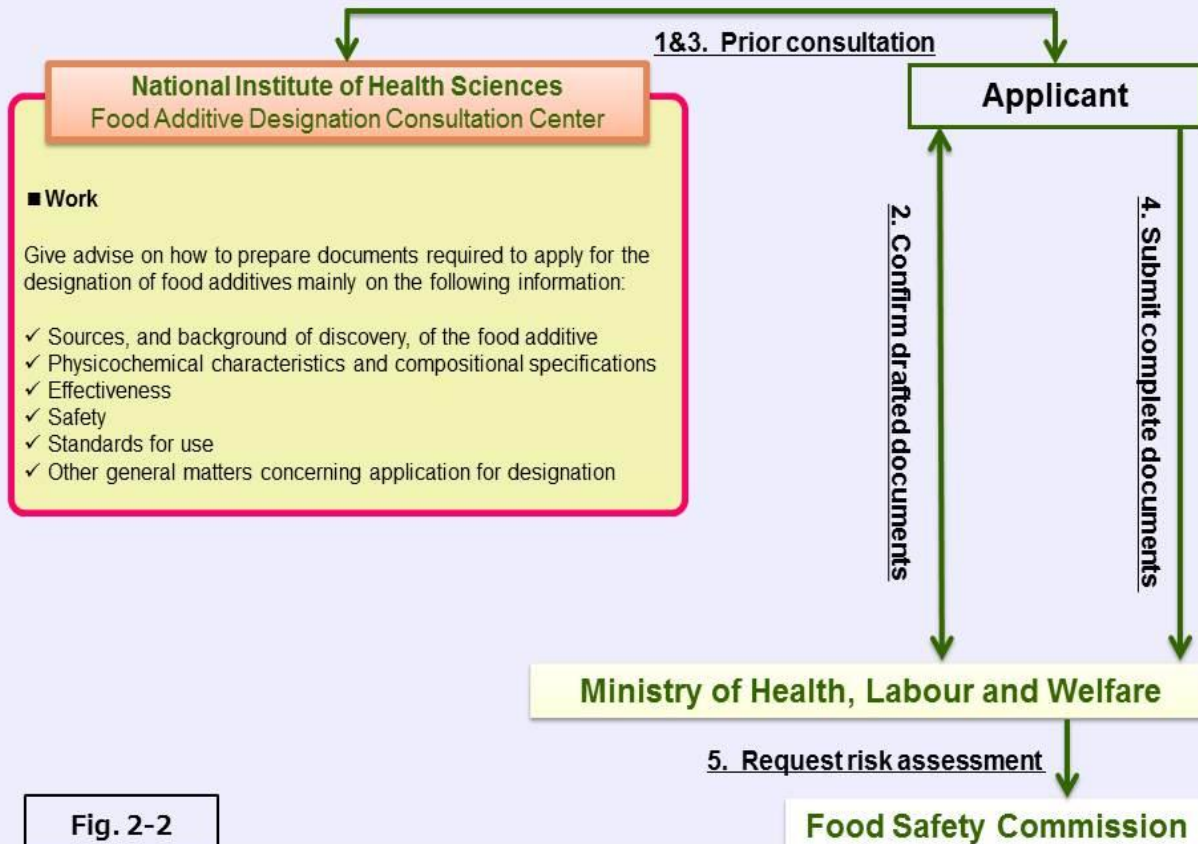


Fig. 2-2

