

FAMIC

Incorporated Administrative Agency
*Food and Agricultural Materials
Inspection Center*

2020 ANNUAL REPORT



CONTENTS

03 Fertilizer and Soil Improvement Materials Supervision

- Review of applications for fertilizer registration
- On-site inspections of fertilizer manufacturers
- Setting official fertilizer standards
- On-site inspections of soil improvement materials

06 Agricultural Chemicals Supervision

- Evaluation of agricultural chemicals for registration
- On-site inspections of agricultural chemicals manufacturers
- GLP inspection of test facilities
- Surveys on the current status of use and residue levels of agricultural chemicals at agricultural production sites

09 Feed and Feed Additives Supervision

- On-site inspections of feed and feed additives manufacturers and importers
- Work related to prevention of BSE
- On-site inspections of pet food manufacturers and importers
- Official assay of feed additives
- Confirmation of GMP conformity of feed and feed additives

12 Food Labeling Surveillance

- Food labeling surveillance

14 Contribution to Japanese Agricultural Standards

- Development of JAS (enactment, amendment, confirmation, abolishment)
- Assessment of accredited certification bodies
- FAMIC's Accreditation Service
- Promotion of Export of Agricultural, Forestry and Fishery Products and Food

17 Analysis of Chemical Hazards to Facilitate Food Safety Risk Management

- Analysis for risk management

19 International Relations Work

- National mirror committee for ISO
- International effort on the proper management of agricultural chemicals
- International cooperation
- Collaborating Centre for OIE

22 Others

- Communicating the information of food and agricultural materials
- Ensuring Reliability

Fertilizer and Soil Improvement Materials Supervision

The safety and quality of fertilizers are ensured by “Act on the Quality Control of Fertilizer” in order to provide safe agricultural products stably.

FAMIC implements various operations related to the Act under the directions of Ministry of Agriculture, Forestry and Fisheries (MAFF).



Review of applications for fertilizer registration

The production, imports, and sales of fertilizers are allowed only after the approval of the relevant registration or notification.

FAMIC reviews applications for the registration submitted from manufacturers, and conducts laboratory analyses and field tests on sample fertilizers in order to determine whether they meet the standards required by the Act.

Table 1. Achievement of Fertilizer Registration Application Review

	FY 2020
Number of Fertilizer Registration Application Reviews Reported to MAFF	709
Number of Inquiries Received regarding Change of Raw Materials or Production Processes	1,626

On-site inspections of fertilizer manufacturers

FAMIC conducts on-site inspections of fertilizer manufacturer's facilities such as plants and storehouses to examine their production records and other documents.

We also collect fertilizer samples from manufacturers in order to analyze and determine whether they meet the standards required by the Act.

Table 2. Achievement of Fertilizer Manufacturer On-Site Inspection

	FY 2020
Number of Fertilizer Manufacturer On-Site Inspections	160
out of which Technical Advice was Provided	24
Number of Collected and Analyzed Samples	93



Sampling of fertilizer at on-site inspection

Setting official fertilizer standards

FAMIC confirms the safety and efficacy of fertilizers for providing scientific findings, necessary for establishing new official standards or revising existing ones.

Table 3. Achievement of Surveys Conducted for Establishing Official Fertilizer Standards

	FY 2020
Number of Surveys Conducted for Official Fertilizer Standards	No Request Received from MAFF



Cultivation test

On-site inspections of soil improvement materials

Under the Soil Fertility Enhancement Act, FAMIC conducts on-site inspections of manufacturing sites of soil improvement materials, as well as their products, raw

materials, and account books. FAMIC also confirms if the labeling of soil improvement materials is appropriate.

Table 4. Achievement of On-Site Inspections of Soil Improvement Materials

	FY 2020
Number of On-Site Inspections	26
out of which Technical Advice was Provided	5
Number of Collected and Analyzed Samples	12

Agricultural Chemicals Supervision

Although agricultural chemicals are indispensable for stable agricultural production, chances of their negative impact on human health and the environment cannot be ruled out.

In Japan, agricultural chemicals are regulated by the Agricultural Chemicals Regulation Act so that only those effective on plant pests and diseases and safe for humans and the environment, if applied in accordance with the label instructions, are manufactured, sold and used. FAMIC provides various services related to the Act under the directions of MAFF.



Evaluation of agricultural chemicals for registration

The manufacture and import of agricultural chemicals are permitted only after the approval for the relevant registration. FAMIC reviews applications for the registration of agricultural chemicals under the Act.

The application data include test results of the efficacy/phyto-toxicity of agricultural chemicals, as well as residues in/on crops, the toxicity to humans and animals, and effects on the environment.

FAMIC also gathers scientific knowledge and information on safety evaluation of agricultural chemicals in order to improve the review process as necessary. All registered agricultural chemicals shall be reassessed at certain intervals in the light of the most up-to-date scientific knowledge and information.

Table 5. Achievement of Registration Application Review of Agricultural Chemicals

		FY 2020
Number of Agricultural Chemicals Registration Application Review	For Reference Value Setting	502
	For Non-Reference Value Setting	1,437
Number of Published Reports of Agricultural Chemicals Registration Application Review		6

On-site inspections of agricultural chemicals manufacturers

FAMIC conducts on-site inspections of manufacturing plants of agricultural chemicals.

We confirm their production records and other related documents. In addition, we also inspect the quality and labels of the products collected from the sites.

Table 6. Achievement of Agricultural Chemicals Manufacturer On-Site Inspection

	FY 2020
Number of On-Site Inspections of Agricultural Chemicals Manufacturers	40
Number of Collected and Analyzed Samples	8



Reception of application for registration of agricultural chemicals



Complete set of application documents and related test results

GLP inspection of test facilities

The Japanese government adheres to the Good Laboratory Practice (GLP) principles established by the Organization for Economic Cooperation and Development (OECD).

FAMIC is the responsible authority for GLP compliance monitoring program of agricultural chemicals in Japan.

Table 7. Achievement of GLP Inspections

	FY 2020
Number of Laboratories Subject to GLP Inspection	22

Surveys on the current status of use and residue levels of agricultural chemicals at agricultural production sites

FAMIC conducts surveys on the current status of agricultural chemical use and their residue level in/on agricultural produce collected at production sites.

Table 8. Details of Surveys on the Use and Residue Levels of Agricultural Chemicals

	FY 2020
Number of Samples Tested for Residue Levels of Agricultural Chemicals	393
Fruit and Vegetables	342
Rice	51



Scene of Residual Agricultural Chemical Analysis

Feed and Feed Additives Supervision

The safety and quality of feed and feed additives are ensured by the Feed Safety Act in order to prevent the production of harmful livestock products that may cause health problems due to the use of unsuitable feed etc.

FAMIC implements various operations related to the Act under the directions of MAFF.



On-site inspections of feed and feed additives manufacturers and importers

FAMIC conducts on-site inspections of feed and feed additives manufacturers and importers, and examines their production / import records and other documents to confirm if they are produced in accordance with the standards and the guidelines

established by MAFF. FAMIC also collects samples of feed and feed additives for laboratory analyses to confirm if the amount of feed additives and harmful substances is kept at the defined level.

Table 9. Number of On-Site Inspections of Feed/Feed Additives Manufacturers/Importers

	FY 2020
Number of On-Site Inspections	244
Number of Collected and Analyzed Samples	299
out of which Technical Advice was Provided	0

Work related to prevention of BSE

FAMIC also conducts on-site inspections of manufacturers of animal-derived feed ingredients for the purpose of preventing Bovine Spongiform Encephalopathy (BSE).

Table 10. Number of BSE-Prevention-Related On-Site Inspections

	FY 2020
Based on MAFF Ordinance	79
Based on MAFF Notification	43

On-site inspections of pet food manufacturers and importers

Under the Pet Food Safety Act, FAMIC conducts on-site inspections of pet food manufacturers and importers to examine their related documents such as production records and import records, and confirms if their products are in conformity with the standards set by MAFF and the Ministry of the Environment.

FAMIC collects samples of pet food to confirm if the amount of additives and harmful substances is kept at the defined level.



Table 11. Achievement of on-Site Inspections of Pet Food Manufacturers/Importers

	FY 2020
Number of On-Site Inspections	60
Number of Collected and Analyzed Samples	105
out of which Technical Advice was Provided	0

Official assay of feed additives

Manufacturers and importers of specified feed additives such as antibiotics are obliged to take an official assay conducted by FAMIC before they offer their products to the market. They will be exempted from the assay only if their manufacturing facilities have been registered by MAFF.

In response to the applications from feed additives manufacturers, etc., FAMIC conducts lot-based inspections and provides verification stickers to conforming additives.

Table 12. Achievement of Official Assays Conducted for Feed Additives

	FY 2020
Number of Official Assays Conducted for Feed Additives	133

Confirmation of GMP conformity of feed and feed additives

In response to applications from businesses such as feed production, FAMIC confirm the compliance of feeds with GMP guidelines by on-site inspections, and issue confirmation certificates if their conformity is verified.

Table 13. Achievement of GMP Conformity Assessment

	FY 2020
Number of GMP Conformity Assessment	92



On site survey for conformity check

Food Labeling Surveillance

The Food Labeling Act requires that all the food products on sale carry the proper food labeling according to the Food Labeling Standards.

Making use of scientific technology, FAMIC closely monitors food labeling in cooperation with MAFF.



Food labeling surveillance

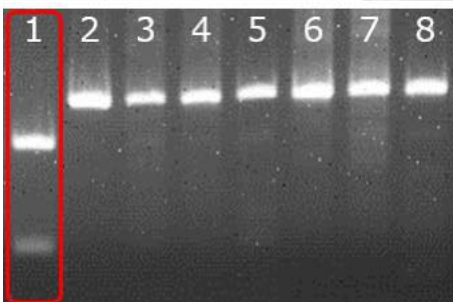
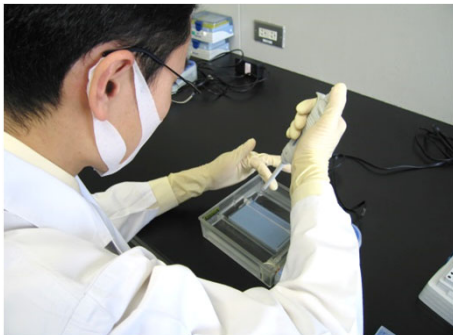
FAMIC conducts scientific inspections on questionable food items, in response to the advice from consumers, to verify the authenticity of descriptions of labeling. The inspection methods include DNA analysis, element analysis, and stable isotope ratio analysis, etc. with reference to the label-described place of origin of food, species and variety of ingredients.

In the case of high possibility of false labeling, on-site inspections will be conducted by FAMIC under the instruction of MAFF.

FAMIC also develops the technologies for determining the geographical origin of ingredients in collaboration with research institutions.

Table 14. Achievement of Food Labeling Surveillance

	FY 2020
Number of On-Site Inspections instructed by MAFF	23
Number of Voluntary On-Site Inspections at the Request of MAFF	3
Number of Scientific Inspections of Food Labeling	5,625
out of which highly dubious cases	86
out of which place-of-origin cases	2,489
out of which GM labeling cases	257

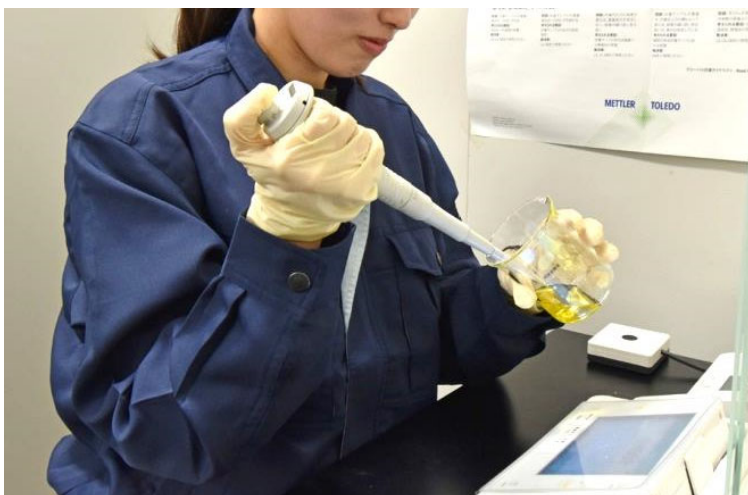


Identifying species of food ingredients using DNA analysis

Contribution to Japanese Agricultural Standards

In the "JAS (Japanese Agricultural Standard) system" based on the JAS Act, JAS marks can be put on agricultural, forestry and fishery products conforming to the JAS.

Businesses that want to display the JAS mark must obtain confirmation from accredited certification bodies that they comply with the standard. Producers and manufacturers can propose standards related to their business to MAFF in the system. In addition to the spread of JAS system, FAMIC conducts various tasks related to the system.



Development of JAS (enactment, amendment, confirmation, abolishment)

FAMIC encourages producers and manufacturers to propose ideas for JAS. The JAS are to be reviewed within five years after their enactment or previous

review in order to meet the changing needs of society.

FAMIC conducts researches and studies related to review of the standards.

Table 15. Contribution to JAS

	FY 2020
Cases where FAMIC Drafted New or Revised Version of JAS Standards	16
Participation in Organic Equivalency Discussions	4 Countries

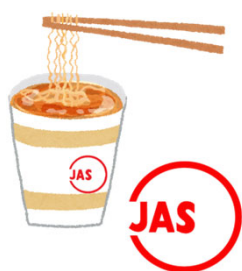
Assessments of accredited certification bodies

FAMIC conducts assessments of applications submitted from domestic and overseas organizations seeking for accreditation as certification bodies, and reassessments of accredited certification bodies.

In addition, FAMIC audits their post-accreditation performance. The assessments and audits (e.g. document assessments, witnessing, on-site assessments) are conducted based on the requirements of ISO/IEC 17011.

Table 16. Achievement of Inspections of JAS Accredited Certification Bodies

		FY 2020
Number of Surveys for Accreditation of Certification Bodies	Accreditation & Renewal Survey	6
	Survey for Changes	318
Number of Inspections Based on JAS Law	Number of On-Site Surveys for Accredited Certification Bodies	68
	Number of Surveys for Accredited Certification Bodies in Foreign Countries	8
	Number of Competence Surveys for Accredited Certification Bodies	460



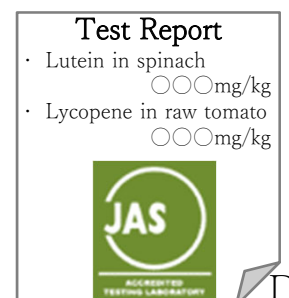
A



B



C



D

Types of JAS Marks:

(A) General JAS (B) Organic JAS (C) Specific JAS (D) Testing Method JAS

FAMIC's Accreditation Service

Japan Accreditation Service for agriculture, forestry and fisheries (JASaff) accredits certification bodies and testing laboratories in the field of agriculture, forestry and fisheries complying with ISO/IEC 17011.



Table 17. Achievement of JASaff Accreditation

	FY 2020
Number of Accreditation of Certification Bodies or Testing Organizations	4

Promotion of Export of Agricultural, Forestry and Fishery Products and Food

The Act on Facilitating the Export of Agricultural, Forestry, and Fishery Products and Food plays a key role in the export of those products from Japan.

Based on the Act, FAMIC assesses (evaluates) applications submitted from organizations that seek for accreditation and their renewal.

In addition, FAMIC audits their post-accreditation performance through document assessments, witnessing and on-site inspection.

Table 18. Achievement of Inspection of Registered Certifying Bodies under Act on Facilitating the Export of Agricultural, Forestry, and Fishery Products and Food

		FY 2020
Number of Surveys for Accreditation of Certifying Bodies	Accreditation & Renewal Survey	5
	Survey for Changes	3



Analysis of Chemical Hazards to Facilitate Food Safety Risk Management

Risk management here is an approach taken by MAFF to prevent issues and accidents arising from harmful chemical substances and/or microorganisms in food.

As an accredited testing laboratory under ISO/IEC 17025 for chemical hazard analysis, FAMIC conducts internationally reliable analytical tests and report the results to MAFF.



Photo from MAFF

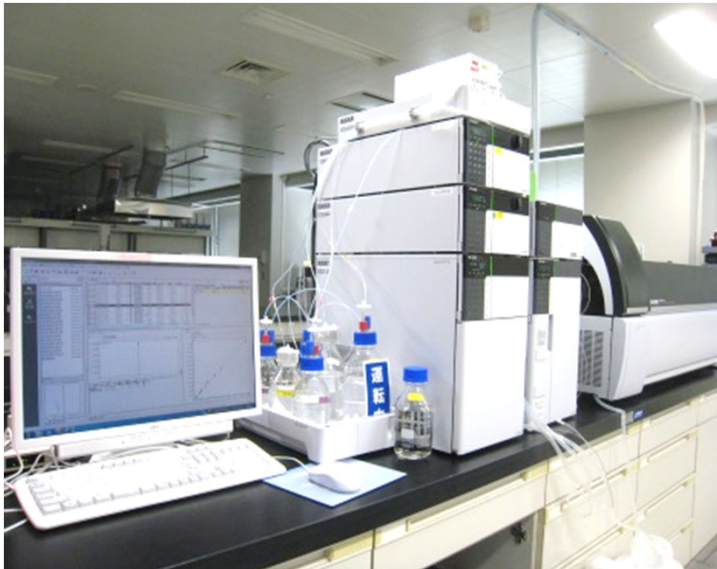
Analysis for risk management

Based on the “Surveillance and Monitoring Plan” of MAFF, we conduct analytical tests of traces of harmful substances such as heavy metals and mycotoxins in agricultural

products and feed for their risk management, and report the results to MAFF.

Table 19. Analytical Tests Conducted for Surveillance and Monitoring

		FY 2020
Number of Tested Items		896
	Mycotoxin in Wheat, Barley and Rye	896



Analysis by using LC-MS-MS



Job's tear

Created the Standard Procedure for Aflatoxin Analysis in Job's tear



**Asteraceae Plant
(Japanese Butterbur & Butterbur Scape)**



**Asteraceae Plant
(Echinacea Herb Tea)**

Created the Standard Procedure for Pyrrolizidine Alkaloids Analysis

International Relations Work

FAMIC serves as a national mirror committee for International Organization for Standardization (ISO). We implement operations related to international harmonization of registration systems for agricultural chemicals.

Furthermore, we provide international cooperation to foreign countries.



National mirror committee for ISO

As a national mirror committee for the Technical Committees (TC) and Sub Committees (SC) of ISO shown in the table, FAMIC incorporates Japanese perspective and comments to have them reflected to ISO standards. We also attend meetings as a part of the Japanese delegation.

ISO/TC34	Food Products
ISO/TC34/SC10	Animal Feeding Stuffs
ISO/TC34/SC12	Sensory Analysis
ISO/TC34/SC16	Horizontal Methods for Molecular Biomarker Analysis
ISO/TC34/SC17	Management Systems for Food Safety
ISO/TC89/SC3	Plywood
ISO/TC218	Timber

Table 20. Achievement in International- Standard-Related Activities

	FY 2020
Number of ISO Japanese Mirror Committee Meetings Convened	1
Number of ISO Projects FAMIC is Participating in Their Development and/or Revision	41
out of which Already Published as ISO Documents	19
Number of Participated ISO Meetings (incl. Web Meetings)	20 Times
Participation in CODEX Japanese Meeting	3 Times

International effort on the proper management of agricultural chemicals

FAMIC participates in OECD meetings and contributes to the international harmonization of registration systems for agricultural chemicals.

We also take part in the Codex Committee on Pesticide Residue (CCPR) to work on the establishment of maximum residue limits (MRLs) of pesticides in foods and animal feed.



Meeting of OECD Working Group on GLP

FY 2020
<ul style="list-style-type: none"> · FAMIC reviewed the draft of OECD Guidance Document on Agricultural Chemicals from the technical viewpoint, and forwarded the result to MAFF in FY 2020. · FAMIC fielded a staff to discuss the alteration of OECD GLP on-site inspection schedule that had been necessitated by the COVID-19 pandemic. · Another FAMIC staff participated in a meeting to consider the international harmonization of biological pesticide testing requirements in OECD Expert Group of Bio-Pesticide (EGBP).

International cooperation



In response to the requests from MAFF, etc., FAMIC sends its staff overseas as technical experts, and receives trainees from foreign countries.

Technical support for agricultural chemicals residue analysis in Ethiopia

	FY 2020
Requests from MAFF or other organizations to assign FAMIC staff or receive trainees from foreign countries	No Requests Received

Note : FAMIC, received two requests from international organizations for lending digital video materials to introduce FAMIC activities in online lectures to overseas participants, to which FAMIC consented.

Collaborating Centre for OIE

FAMIC has been designated as the world's first Collaborating Centre of the World Organization for Animal Health (OIE) in the field of feed safety and analysis, and has been contributing to their activities through the provision of expertise, and supporting the development of standards in the field of animal feed safety and analysis.



FY 2020
<ul style="list-style-type: none"> · Two English articles, Summary of “Research Report of Animal Feed” and “General Tests for Feed Additives”, have been posted on FAMIC website since Nov. 2020 and March 2021 each. In addition, provisional English translation of MAFF Ordinance on Specifications and Standards of Ingredients for Feed and Feed Additives has been posted on FAMIC website. · FAMIC prepared and submitted the Annual Report 2020 to OIE headquarters. FAMIC also replied to inquiries from OIE regarding the FAMIC's Five Year Activity Plan 2020-2024 as OIE-Collaborating Centre, which had been previously submitted. · FAMIC carried out a questionnaire survey to collect the feedback on the FAMIC-hosted technical workshop from the participated Lab Network countries, aiming at improved feed quality and safety in Asian region. · FAMIC participated in the 3rd Regional Meeting for OIE Reference Centres in Asia and the Pacific (Feb 24-25, 2021), and made presentations on Lab Network development.

Others



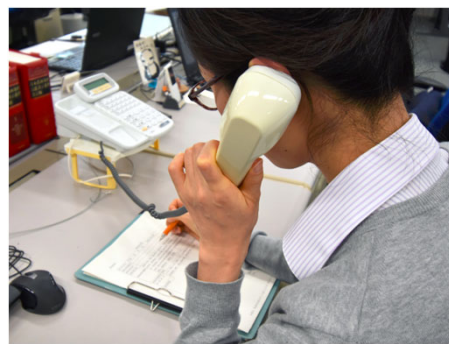
Communicating the information of food and agricultural materials

FAMIC provides the information of food, fertilizers, agricultural chemicals and feed via seminar, website, telephone consultation, public relations magazine and mail magazine.

We also accept facility tours throughout the year and introduce FAMIC's work outlines and inspection facilities.

Table 21. Information Service

	FY 2020
Information Provision through Website, etc.	462,524 Accesses
Assignment of Lecturers in Response to Requests from Businesses, etc.	42 Assignments
Organization of Seminars, etc.	24 Times



Ensuring Reliability

Based on the concept of ISO/IEC 17025, FAMIC adheres to the inspection and technical management conformed to the standard documents. FAMIC establishes the quality assurance system appropriate for the purpose of each analysis work.

Furthermore, in order to ensure the viability of such system, FAMIC has been working on the application for the third party accreditation of ISO/IEC 17025 and the self-declaration of conformity by FAMIC itself.

Table 22. Ensuring FAMIC's Inspection and Analysis Reliability

	FY 2020
Participation in External Proficiency Tests	12 Times

FAMIC maintained the following laboratory accreditation in FY 2020:

- LC-MS/MS-Based Quantification Test of Fusarium Toxins in Wheat and Barley
- Qualitative Test of Recombinant DNA in Soybeans and Soybean-Processed Products
- Quantitative Test of Mycotoxins (16 Varieties) in Corn by LC-MS/MS
- Detection Test of Mammal-Derived DNA, Ruminant-Derived DNA, Bovine-Derived DNA, Cervid-Derived DNA in Feed using Thermal Cycler based on Chapter 16 of Feed Analysis Standard

FAMIC Poster Children

Close trio from Saitama City

FAM **AMI** **MIC**

They represent the image of FAMIC that ensures food safety and consumers' reliance.

