



**Guiding your products
to regulatory success
in Japan**

Our services for

Plant Protection Products in Japan

First-hand expertise in

Dossier registration / re-evaluation
and Import Tolerance applications

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REGISTRATION OF PLANT PROTECTION PRODUCTS IN JAPAN

Plant protection products in Japan are regulated under the Agricultural Chemicals Regulation Act and approved if deemed safe in line with Good Agriculture Practice (GAP). Plant protection products are authorised strictly in accordance with their intended use, by specifying “application crop”, “application timing” and “application rate”. Farmers are only allowed to use plant protection products under the approved conditions of use.

Registration of plant protection products requires the submission of study data. Based on the data provided, a safety assessment of the plant protection product is conducted by the Ministry of Agriculture, Forestry and Fisheries (MAFF), the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Environment (MOE). The applications for approval are received and managed by the Food and Agricultural Materials Inspection Centre (FAMIC).

The following data needs to be submitted as part of a Japanese registration dossier:

- Human and livestock safety (acute toxicity, chronic toxicity, reproductive toxicity, detoxification method etc.)
- Risk assessments of residues in crop, feed and livestock
- Studies on beneficial organisms in ecosystem (acute toxicity on fish, algae growth inhibition, bee toxicity etc.)
- Environmental exposure assessments (residue in soil, residue in succeeding crop, water pollution, PEC etc.)
- Efficacy and phytotoxicity (efficacy on weed / plant pest, phytotoxicity to applicable crop)

- Impurity evaluation in technical grade active substances (specification and quantification of impurity)
- Physical and chemical properties of active substances and plant protection products (water solubility, soil adsorption, photolysis in water etc.)

Re-evaluation programme for plant protection products

Different to Europe and U.S., plant protection products in Japan up until recently needed to be re-registered every three years. Progress of science, increasingly requires an up-to-date regulatory system able to better adapt itself and accommodate new study data, transition of evaluation methods and agricultural practice and pest control methods. The necessity for a re-evaluation programme of active substances in Japan has become urgent, turning into a heavy burden for applicants, and causing discrepancies between the Japanese requirements and new assessment guidelines implemented as a part of global harmonisation.

Following this, Japan amended its Agricultural Chemicals Regulation Act on December 1st, 2018 by introducing a re-evaluation programme for active substances in the existing plant protection products, to review their safety in accordance with the latest scientific knowledge.

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or contact one of our experts:

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The re-evaluation programme regulates the revision process for new and existing substances by setting out clear timelines:

1. Plant protection products registered after enforcement of the amendment act require re-evaluation approximately every 15 years
2. Existing plant protection products are re-evaluated from 2021 according to a priority order.

The amendment also strengthens the following three areas:

- Risk assessments for applicators
- Ecotoxicological risk assessments
- Introduction of the assessment of technical equivalence

Import tolerance

Import tolerance is a system used to set maximum residue levels (MRL) in agricultural products for plant protection products not registered in Japan and entering the market. Any agricultural product imported to Japan, where non-approved plant protection products have been applied too, needs to meet MRL setting in Japan.

Japan has adopted a positive list system, with MRL being set to 0.01 ppm if there is no specific request for MRL setting from applicants, such as importers, food manufactures and agrochemical companies. Applicants can request setting a specific Japanese MRL based on the “Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals used outside Japan”.

OUR SERVICES

Relying on our accumulated knowledge and first-hand experience in the EU since 1989, our regulatory experts at SCC Japan provide full-scale regulatory and scientific support and qualified registration services for plant protection products in Japan, including handling of all kinds of import tolerance applications and MRL setting.

Data gap analysis

- Evaluating the adaptability of the existing data package to the Japanese guidelines for plant protection products
- Examining the possibilities for read-across of available registration data authorised outside Japan

Study monitoring

- Designing, contracting all necessary studies at contract laboratories in and outside Japan best suited to your needs
- Study monitoring and coordination

Dossier preparation and liaising with authorities

- Preparing and submitting registration dossiers to the Japanese competent authorities
- Compiling and submitting re-evaluation dossiers based on the Japanese “Shoroku” format
- Generating and filing registration / re-evaluation dossiers based on non-Japanese dossier formats (e.g. EU, U.S.)
- Liaising with and handling requests and comments by the Japanese authorities

