

▶ Agricultural, Forestry and Fisheries Law Practice Team Newsletter

Atsumi & Sakai's Agricultural, Forestry and Fisheries Law Practice Team (AFFL Team) consists of four lawyers and one advisor, each of whom has different strengths and provides a wide variety of high quality legal services in the areas of agriculture, forestry, and fisheries ("AFF") ranging from support for overseas transactions and overseas expansion (or closure), drafting and reviewing agreements for complex purchase and sale transactions, licensing and other intellectual property rights, communications with authorities (such as the Fair Trade Commission), and dispute resolution.



Revisions to the Agricultural Chemicals Control Act

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Japan is currently pursuing a dynamic agricultural reform policy to develop an "aggressive agricultural, forestry, and fisheries industry". As an example, there is a goal to achieve JPY 1,000 billion (USD10 billion) in exports of agricultural, forestry, fishery and food products through industry-specific strategic export capability enhancement. The ratifications of the Japan-Europe EPA and the CPTPP/TPPI I are a positive step in implementing this policy.

Various policies for the aggregation of agricultural land and reduction of agricultural material prices are clearly and closely related to these commercial policies. On the other hand, there are still pressing problems of business continuation in AFF due to the aging of agricultural workers, a problem not easily resolved, and the difficulties of securing an adequate agricultural workforce. Laws relating to AFF include the Civil Code, the Commercial Code, intellectual property laws, laws that apply to the acquisition of agricultural land, laws relating to the study and research of new plant varieties, the purchase of agricultural fertilizers and agricultural chemicals, etc., and domestic and international sales through Japanese agricultural cooperatives ("JA") or non-JA distribution channels; these laws, and related regulations form a complex web. Even the era of Big Data has had an impact on AFF laws, with the Ministry of Agriculture, Forestry and Fisheries having published guidelines in December 2018 for data contracts in the area of agriculture, and effective utilization of agricultural data having become a topic of current study. Our AFFL team will provide information on a regular basis through newsletters addressing noteworthy legal reforms; this first newsletter deals with the revisions to the Agricultural Chemicals Control Act passed by the Diet last year.

1. Background of the Agricultural Chemicals Control Act Revisions

The Agricultural Chemicals Control Act (the "Act") was revised in part on December 1, 2018^[2].

The revisions were intended to rationalize agricultural chemical regulations in order to improve the agricultural chemical registration system by allowing the system to both efficiently and accurately reflect the new insights relating to the safety of agricultural chemicals that have accumulated through scientific development and improvement of assessment methods, as well as to contribute to reduction of the cost of agricultural chemicals.

The revisions fall into four major categories:

- (1) Addition of matters to be registered for an agricultural chemical registration;
- (2) simplification of generic agricultural chemicals registration;
- (3) abolition of the re-registration system of agricultural chemicals and introduction of a reassessment system; and
- (4) enhancement of manufacturer and importer reporting requirements as well as of government reviews of agricultural chemicals safety^[3].

2. Overview of Revisions

- (1) Addition of matters to be registered for an agricultural chemical registration;

It is now required to register:

- concentration of each active ingredient (the "AI");
- types and concentration of components other than the AI of bulk agricultural chemicals;
- name (or company name in the case of a corporation) and address of the manufacturer of AI, and the name and location of where it was manufactured; and
- major manufacturing process of the AI under the Act itself, all of which are required to be entered in the agricultural chemical registration application form.

[1] Please see the website of the Ministry of Agriculture, Forestry and Fisheries for the details of revisions (<http://www.maff.go.jp/j/law/bill/196/houritsu/attach/pdf/index-44.pdf>)

[2] The revision expanding the subject of agricultural chemicals impact assessment from aquatic animals and plants to animals and plants in the living environment (meaning animals and plants that may cause harm to the safety of the human living environment if their habitat or development is obstructed) will come into effect April 1, 2020.

[3] Article 18 of the Enforcement Regulations

(2) Simplification of generic agricultural chemicals registration

When applying for registration of agricultural chemicals that are equivalent to the components and toxicity of registered agricultural chemicals, applicants are now not required to submit certain application documents, thereby eliminating the need for some agrochemical studies (simplification of generic agricultural chemicals registration application).

The context for these revisions is that the penetration rate of generic agricultural chemicals is as low as 5% in Japan while, in contrast, it is 15% to 20 % in Europe and the United States, and the goal of this simplification to enhance the competitiveness of Japanese agricultural products by lowering the costs required for agricultural materials. The revisions also provide for public disclosure of part of the specifications of agricultural chemicals subject to registration as a reference point for development by generic manufacturers, and exempt from submission certain test data on the conditions that (1) the original registered agricultural chemicals and the generic agricultural chemicals which are the subject of the application have equivalent components and safety levels, and (2) 15 years have passed since the date of when the documents were submitted for the registration of the registered agricultural chemicals.^[4]

(3) Abolition of the re-registration system of agricultural chemicals and introduction of a reassessment system

Since the re-registration system has been abolished, a so-called reassessment system has been introduced to reassess the safety, etc. of all agricultural chemicals containing the same AI based on the latest scientific insights approximately every 15 years^[5]. In addition, if the Minister of Agriculture, Forestry and Fisheries publicly designates certain agricultural chemicals as being subject to reassessment, the relevant registrants must submit their test results and undergo reassessment by the designated deadline separately from the periodic reassessment.

(4) Enhancement of the agricultural chemicals safety review^[6]

1.) Improvement of the assessment of the effects of agricultural chemicals on the health of persons using them

A statement of "damage prevention methods to be taken when using" has been added to the matters to be registered and manufacturers or importers must specify it on the package (label); "damage prevention methods to be taken when using" is interpreted as including prevention of not only damage to users of agricultural chemicals but also to people around agricultural land (so-called agricultural chemical drift prevention).^[7]

2.) Enhancement of assessment of an impact on the health of animals and plants

The subjects for an impact assessment have been expanded from aquatic animals and plants to animals and plants in the human living environment^[8], i.e. those having contact with humans.

3.) Introduction of the assessment of the safety of components (AIs and inert ingredients) contained in bulk agricultural chemicals (primary raw materials of agricultural chemicals).

4.) Good Laboratory Practice ("GLP") standards

Certain test results must now be submitted for the registration of agricultural chemicals, and it is now expressly stipulated in the Act that these tests must be "standards conformity tests" which will be aligned with GLP standards. Together with this, the "Administrative Regulation regarding Standards for Securing Specified Test Result and Reliability Thereof" is now being enforced.

5.) Preferential registration examination

Registration reviews for agricultural chemicals that are urgently needed for pest control, etc. and which are very safe when compared to other agricultural chemicals will be given preferential treatment.

6.) Agricultural Materials Council

Applicants for agricultural chemicals registration must be advised by the Agricultural Materials Council in the application process.

[4] Even for generic agricultural chemicals, at the time of the agricultural chemical registration, submission of data on the tests for beneficial effects, harmful effects, and acute toxicity to humans that must be confirmed for each formulation is still required. According to government statements at the 196th Diet session House of Representative Agriculture, Forestry and Fisheries Committee (May 31, 2018), there is a preliminary calculation that by not requiring submission of part of the data, the costs of tests to confirm the safety will be reduced from the previous JPY 1,400,000,000 to JPY 100,000,000.

In addition, until at least 15 years have passed from the day of submission of the documents for the already-registered agricultural chemicals, there will be no exemption from the test data submission requirement.

[5] Under the former Act, the valid term of the registration was three years, and inspection for re-registration was not required. There was a criticism that by not requiring inspection under this system, re-registrations have been made simply by confirming the intention of the registrants to continue sales, with the result that re-registration did not function as a mechanism to ensure safety.

[6] The revisions described in 1.) and 2.) will come into force on April 1, 2020

[7] See government statements at the 196th Diet session House of Representative Agriculture, Forestry and Fisheries Committee (May 31, 2018).

[8] Defined as animals and plants that may cause harm to the safety of the human living environment if their habitat or development is obstructed (Article 3, paragraph 1 of the Act).



3. Conclusion

How these reforms will affect the agricultural chemicals industry, in particular the impact of the simplification of generic agricultural chemicals registration, merits attention because it is likely to result in overseas generic agricultural chemicals manufacturers entering the Japanese market, in particular as although Japanese manufacturers of agricultural chemicals are said to have advanced technical capabilities, they are small in comparison to the leading foreign manufacturers.^[9] As the revisions appear to include some changes that may put significant burdens on small agricultural chemical manufacturers, their effect on the future management of Japanese manufacturers of agricultural chemicals and the number of formulations being registered needs to be monitored to see what trends emerge. Further, as agricultural chemical registration data in Japan now conforms to international standards due to these reforms, test data will become available for “import tolerance” applications, and so these reforms may also affect the export of agricultural products.

[9] Active components developed by Japanese manufacturers account for approximately 40% of the new active components of agricultural chemicals around the world.

Please contact our PR staff to subscribe our newsletter.
E-mail: prcorestaff@aplaw.jp

Author(s) / Contacts



Yasuhiro Usui [First Author]

Partner
Admitted Japan (2007)

Keio University (LL.B., 2004)
University of Pennsylvania (LL.M., 2015)
Atsumi & Sakai (2007-)
Seconded to a seed and pesticide manufacturer (2016-2017)
Seconded to Cool Japan Fund Inc. (2017-January 2018)
E-mail: yasuhiro.usui@aplaw.jp



Hisashi Miyatsuka

Partner
Admitted Japan (1996)

Kyoto University (LL.B., 1994)
Nishimura & Asahi (2007-October 2017)
Atsumi & Sakai (November 2017-)
E-mail: hisashi.miyatsuka@aplaw.jp



Go Fujimoto

Of Counsel
Admitted Japan (2003), New York (2011),
and California (2011, inactive)

The University of Tokyo (LL.B., 1995)
University of Pennsylvania Law School (LL.M., 2010)
Sheng Wo Law Firm (2012-2013)
Dacheng Law Offices, Shanghai Office (2013-2014)
Nishimura & Asahi (April 2014-September 2017)
Atsumi & Sakai (October 2017-)
E-mail: go.fujimoto@aplaw.jp



Fumiko Oikawa

Partner
Admitted Japan (2003) and New York (2017)

Gakushuin University (LL.B., 1997; LL.M., 2000)
University of Michigan Law School (LL.M., 2013)
Atsumi & Sakai (2003-)
Mayer Brown LLP (New York) (September 2013-January 2014)
E-mail: fumiko.oikawa@aplaw.jp

General Inquiries:

Yasuhiro Usui (Agricultural, Forestry and Fisheries Practice Team, Atsumi & Sakai)
Tel: 03-5501-2111 | E-mail: cpg_affl@aplaw.jp



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Atsumi & Sakai Legal Professional Corporation also wholly-owns a subsidiary, Atsumi & Sakai Europe Limited (a company incorporated in England and Wales (No: 09389892); sole director Naoki Kanehisa, a lawyer admitted in Japan), as its London Office. It also has an affiliate office in Frankfurt, Atsumi Sakai Janssen Rechtsanwaltsgesellschaft mbH, a German legal professional corporation (local managing director: Frank Becker, a lawyer admitted in the Federal Republic of Germany).

2. Legal Advice

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