Outline of the Act Partially Amending the Agricultural Chemicals Regulation Act

Background

O Improvement of the Safety of Agricultural Chemicals

It is necessary to make improvements in the agricultural chemical registration system so that it will be able to efficiently and reliably reflect new knowledge and advances in evaluation methods concerning agricultural chemical safety that has been accumulated through scientific developments.

○ To contribute to the realization of even more efficient agriculture

In order to contribute to the realization of more efficient, low-cost agriculture by providing high quality and inexpensive agricultural chemicals, it is necessary to rationalize the regulations regarding agricultural chemicals.

Note: in addition, in the Act on the Support for Strengthening Agricultural Competitiveness as well, regarding the regulations concerning agricultural chemicals, reevaluation is taking place from the standpoints of safety improvement, harmonization with international standards, and rationalization of the regulations based on the latest scientific evidence.

From the standpoint of **the people**, further improvement in the safety of agricultural chemicals



From the standpoint of **farmers**: (1) improvement of the safety of farmwork; (2) reduction in production costs; (3) promotion of exports of agricultural products

From the standpoint of manufacturers of agricultural chemicals: promotion of international marketing of agricultural chemicals originating in Japan

Outline of the Act

1.Introduction of a Reevaluation System

Regarding agricultural chemicals containing the same active ingredients, together on a regular basis, <u>reevaluation of safety, etc. in light of the latest scientific evidence</u> will be conducted. Also, by taking measures such as <u>requiring reports</u> from manufacturers of agricultural chemicals <u>on an annual basis</u>, registrations will be reviewed when necessary, and efforts will be made to realize <u>the further improvement of agricultural chemical safety</u>. In addition, the current reregistration system will be abolished.

(Article 8, Article 9, Article 15, Article 29, former Article 5)

2. Revision of Agricultural Chemical Screening Procedures

- 1) Strengthening the Safety Screening of Agricultural Chemicals
 - (1) strengthen the evaluation of the impact of agricultural chemicals on their users
 - (2) strengthen the evaluation of the impact of agricultural chemicals on animals or plants
 - (3) introduce the evaluation of the ingredients (active ingredients and impurities) that the technical grade active ingredients (the main materials of agricultural chemicals) contain (Article 3, paragraph (2))
- 2) Simplification of the Application Process for Generic Agricultural Chemicals In the <u>application process for generic agricultural chemicals</u>, if the ingredients and safety of the brand name agricultural chemicals and the technical grade active ingredients are equivalent, <u>a portion of the test data that is required to be submitted</u> may be <u>omitted</u>. (Article 3, paragraph (3))

Effective date: within 6 months of the date of promulgation (provided, however, that for 2. 1), (1) and (2) within 2 years of the date of promulgation)

農薬取締法の一部を改正する法律の概要

背景

○ 農薬の安全性の向上

科学の発展により蓄積される、農薬の安全性に関する新たな知見や評価法の発達を 効率的かつ的確に反映できる農薬登録制度への改善が必要

○ より効率的な農業への貢献

良質かつ低廉な農薬の供給等により、より効率的で低コストな農業に貢献するため、 農薬に係る規制の合理化が必要

※ なお、農業競争力強化支援法においても、農薬に係る規制を、安全性の向上、国際的な標準との 調和、最新の科学的根拠に基づく規制の合理化、の観点から見直すこととされている。



国民にとって、農薬の安全性の一層の向上

農家にとって、①農作業の安全性向上、②生産コストの引下げ、

③農産物の輸出促進

農薬メーカーにとって、日本発の農薬の海外展開の促進

法律の概要

1 再評価制度の導入

同一の有効成分を含む農薬について、一括して定期的に、<u>最新の科学的根拠に 照らして安全性等の再評価</u>を行う。また、農薬製造者から<u>毎年報告を求める</u>こと 等で、必要な場合には、随時登録の見直しを行い、<u>農薬の安全性の一層の向上</u>を 図る。なお、現行の再登録は廃止する。 (第8条、第9条、第15条、第29条、旧第5条)

2 農薬の登録審査の見直し

- (1) 農薬の安全性に関する審査の充実
 - ① 農薬使用者に対する影響評価の充実
 - ② <u>動植物に対する影響評価</u>の充実
 - ③ <u>農薬原体</u>(農薬の主たる原料) <u>が含有する成分(有効成分及び不純物)</u> の評価の導入 (第3条第2項)

(2) ジェネリック農薬の申請の簡素化

<u>ジェネリック農薬の登録申請</u>において、先発農薬と農薬原体の成分・安全性が同等であれば提出すべき試験データの一部を免除できることとする。

(第3条第3項)

施行期日:公布日から6月以内(ただし、2(1)①及び②については、公布日から2年以内)