

# **Handout**

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**Fundamental and indispensable knowledges**

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**on current situation of agriculture and food supply**

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**in order to talk about pesticide**

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## Background Knowledge when Considering Pesticides Management

Food is an essential commodity for human existence, and the securing of food is the highest priority in any age. Ever since the development of agriculture, farming has largely been entrusted with securing food for humankind. Looking at human history, the world's population increased dramatically following the Industrial Revolution. Particularly since the start of the 20<sup>th</sup> Century, the rate of population growth has been extreme, and population that stood at roughly 2.5 billion in 1950 more than doubled to exceed 6.0 billion people by 2000, just 50 years later (see Table 1). It is projected that this rapid population growth will continue from now on, and even assuming that the birthrate will continue to decline (medium-level birthrate), the world population by 2050 will be 9.3 billion, and it is projected will exceed 10 billion by the end of the century. Looking over the chronological pattern of population change, the world population exhibited rapid growth that may be described as explosive from the 19<sup>th</sup> Century onwards (see Figure 1). Meanwhile, looking at the global food situation, whereas there are countries that enjoy food satiation, even today 10 years following the turn of the 21<sup>st</sup> Century, approximately 1 billion people do not have sufficient food (they are malnourished), indicating that one in every seven people in the world is in a state of starvation. Furthermore, the Food and Agriculture Organization (FAO) has issued a forecast that it will be necessary to double agricultural production by 2050 in order to feed the world's increasing population.

Table 1 World Population Movements and Estimates: BC to 2050

| Year                               | 100s of 1,000s years' ago | 7000 BC | 600 BC | A.D.1 | 1650  | 1750 | 1800 | 1850  | 1900  | 1950  |
|------------------------------------|---------------------------|---------|--------|-------|-------|------|------|-------|-------|-------|
| Estimated population (100 million) | Emergence of humans       | 0.5     | 1      | 3     | 5.075 | 7.95 | 9.69 | 12.65 | 16.56 | 25.29 |

| Year                               | 1955  | 1960  | 1965  | 1970  | 1975  | 1980  | 1985  | 1990 | 1995  | 2000  |
|------------------------------------|-------|-------|-------|-------|-------|-------|-------|------|-------|-------|
| Estimated population (100 million) | 27.63 | 30.23 | 33.32 | 36.86 | 40.61 | 44.38 | 48.46 | 52.9 | 57.13 | 61.15 |

| Year                               | 2005  | 2010  | 2015  | 2020  | 2025  | 2030  | 2035  | 2040  | 2045  | 2050 |
|------------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|------|
| Estimated population (100 million) | 65.12 | 69.09 | 73.02 | 76.75 | 80.12 | 83.09 | 85.71 | 88.01 | 89.96 | 91.5 |

Source: Figures for 1900 and before are based on the UN, The Determinants and Consequences of Population Trends, Vol.1, 1973. Figures for 1950 onwards are based on the UN, World Population Prospects: The 2008 Revision (medium estimate).

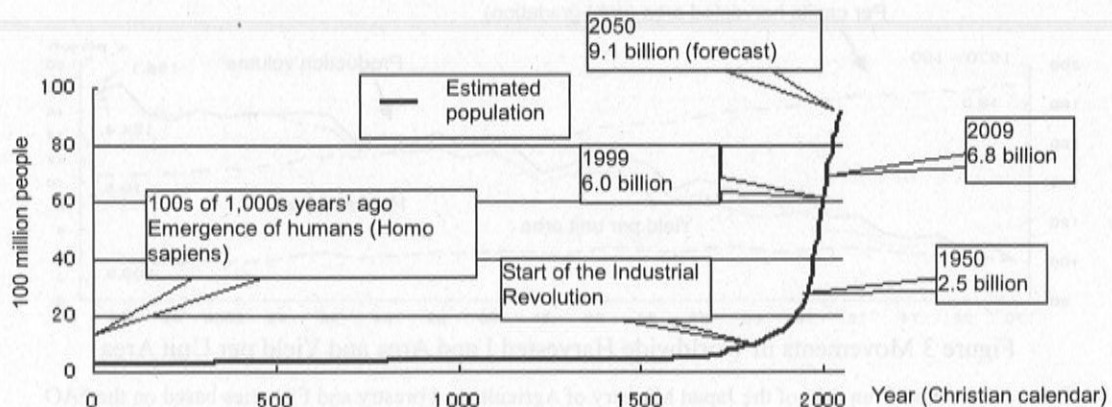


Figure 1 Population Movements from the Christian Era Onwards (prepared using data in Table 1)

Whereas population continues to rapidly grow in developing countries, it has remained more or less the same at around 1.3 billion in the so-called advanced nations (North America, Japan, parts of Europe, Australia, New Zealand), and it is expected to start declining from around 2030. Therefore, almost all the population growth of recent years is taking place in countries other than advanced nations (so-called developing countries and semi-developed countries), and this trend is also expected to continue in the future (see Figure 2).

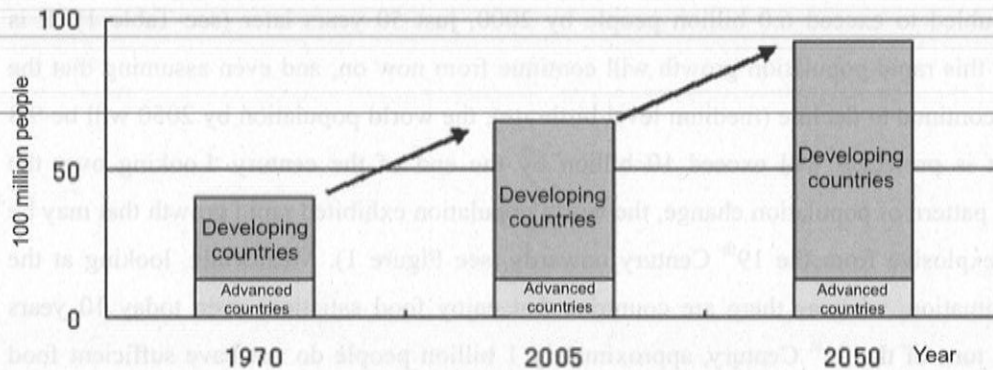


Figure 2 Changes in World Population

Source: Modified from data of the Japan Ministry of Agriculture, Forestry and Fisheries based on the FAO "FAOSTAT" and UN Population Fund (UNFPA) World Population White Paper

Although it is thus forecast that the global population will continue to increase from now on, the total area of harvested land (agricultural land) in the world has remained more or less the same since 1970 (see Figure 3). In other words, the per capita area of agricultural land has been steadily declining (see Figure 3 and Table 2). The only reason why increasing population can be supported under these conditions is that ongoing improvement of crop yields per unit area is being achieved thanks to agricultural modernization. Modern agriculture is built upon the development of agricultural facilities and cultivation technology, the development and utilization of agricultural machinery, the introduction of improved high-yielding varieties, the expansion of a field size (a plot size), and the use of agricultural materials such as chemical fertilizers and pesticides, etc.

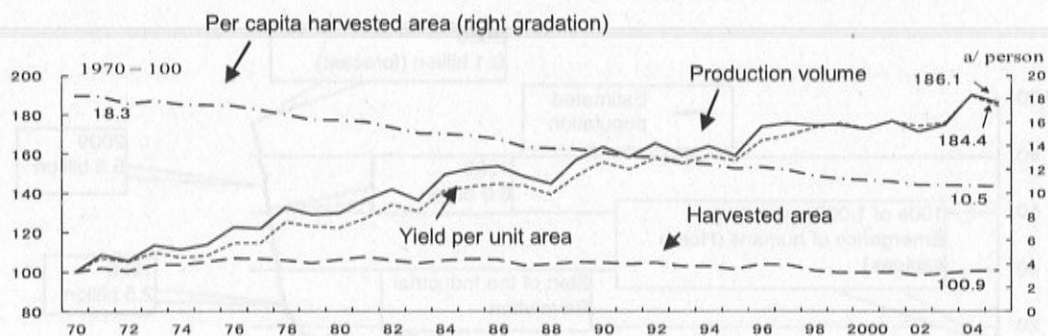


Figure 3 Movements in Worldwide Harvested Land Area and Yield per Unit Area

Source: Modified from data of the Japan Ministry of Agriculture, Forestry and Fisheries based on the FAO "FAOSTAT" and UN Population Fund (UNFPA) World Population White Paper

Table 2 Movements in Worldwide Grain Harvest Area and Production per unit area

|                               | 1961-1963 Yearly Average | 2002-2004 Yearly Average |
|-------------------------------|--------------------------|--------------------------|
| Grain harvest area            | 650 million ha           | 670 million ha           |
| Production per hectare        | 1.4 ton/ha               | 3.2 ton/ha               |
| Population                    | 3.1 billion (1962)       | 6.3 billion (2003)       |
| Per capita grain harvest area | 20.8 a/person (1962)     | 10.7 a/person (2003)     |

Source: Modified from data of the Japan Ministry of Agriculture, Forestry and Fisheries based on the FAO "FAOSTAT" and UN Population Fund (UNFPA) World Population White Paper

## What are pesticides?

### Definition of Pesticides

Pesticides generally refer to Chemical agents that are used to protect crops from pest and disease damage or to control the growth of crops, for example, insecticides, fungicides, herbicides, rodenticides and plant growth regulators, etc. The definition of pesticides differs between countries, however, it is considered desirable to use the following definition given in the FAO International Code of Conduct on the Distribution and Use of Pesticides: "Pesticide means any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or substances which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport."

### History of Pesticides

The history of modern synthetic pesticides dates back to the discovery that dichlorodiphenyl-trichloroethane (DDT) possessed powerful pesticidal ability by Paul Hermann Muller, an engineer of the Swiss pigment maker Geigy, in 1938. This discovery paved the way for the chemical synthetic pesticides we use today. Pesticides are generally categorized according to their purpose of use into the following nine types:

- (1) Insecticides: Chemical agents for controlling pests that damage agricultural crops
- (2) Fungicides: Chemical agents for controlling diseases that damage agricultural crops
- (3) Insect-fungicides: Chemical agents for simultaneously controlling harmful pests and diseases

- |                              |  |
|------------------------------|--|
| (4) Herbicides:              | Chemical agents for controlling weeds  |
| (5) Rodenticides:            | Chemical agents for controlling field rodents that damage agricultural crops               |
| (6) Plant growth regulators: | Chemical agents for accelerating or suppressing growth of agricultural crops               |
| (7) Attractants:             | Chemical agents mainly for attracting harmful pests by odor, etc.                          |
| (8) Repellents:              | Chemical agents for repelling mammals and birds that damage agricultural crops             |
| (9) Spreading agents:        | These are used with other pesticides in order to enhance the adherence of those chemicals. |

Pesticides are processed into Chemical products for distribution and use by adding inert ingredients (surfactants, etc.) to biologically active ingredients (AI). The technology used in the Chemical formulation stage fulfills an important role of effectively eliciting the effects of the active ingredients and mitigating harmful effects. Chemical agents are produced in various forms such as granules, powders, liquids and wettable powders, etc. In recent years, micro capsule agents (fine particles in which the active ingredients are covered by polymer membrane in order to suppress decomposition or loss caused by volatilization; moreover, discharge of active ingredients can be suppressed through adjusting the membrane thickness) and flowable agents (thickened mucus agents in which fine particles of active ingredients are dispersed in water; the suspensibility of active ingredients in the diluted liquid is far superior to that of wettable powders) and so on have been developed, and Chemical production technology has exhibited rapid progress.

As was mentioned earlier, the history of modern synthetic pesticides dates back to the discovery in 1938 that dichlorodiphenyltrichloroethane (DDT) possessed powerful insecticide pesticidal ability. However, the history of pesticides dates back further than this; for example, in Japan, use of whale oil to control plant hoppers in 1670 was cited as the first instance. In Europe and America, it was already known that the powder of pyrethrum flowers protected crops from pest damage in the 1700s, while lime sulphur and Bordeaux mixture, which were invented and discovered in France, had come to be used for protecting crops by the second half of the 1800s. These products and lead hydrogenarsenate, etc. were introduced to Japan as pesticides at the end of the 19th Century. When talking about modern synthetic pesticides, one cannot forget the insecticide known as parathion (diethyl-p-nitrophenylthiophosphate, product name: Folidol). This is one of the organic phosphorus insecticides that were developed by the German company Bayer in 1944. Said to have been discovered during development of chemical weapons, this agent possesses powerful nerve toxin properties. It was also widely used in Japan at one stage; however, due to a spate of fatal poisoning accidents and murder cases, it was banned from use as a pesticide in 1971.

## Development of Pesticides

The development of new pesticides requires high technical prowess, an extremely long time and huge costs. It generally takes at least 10 years from the discovery of promising new compounds to market launch, and the cost including exploratory research (synthesis and bioactivity testing) and safety testing costs and indirect expenses is estimated somewhere between 10-25 billion yen (see Figures 4 and 5). Around 1975, more than 200,000 compounds were synthesized for pesticides screening around the world, and it was reported that the chances of such compounds being refined into pesticide products was somewhere between 1 in 10,000 and 1 in 20,000 on average. Now, however, as the requirements placed on pesticides become more and more stringent, this probability has decreased to 1 in 50,000 or less.

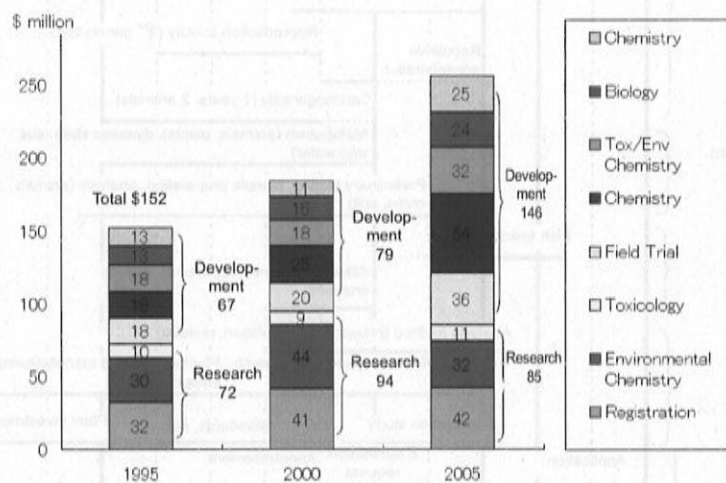


Figure 4 Costs of Exploration and Product Refinement of New Active Ingredients

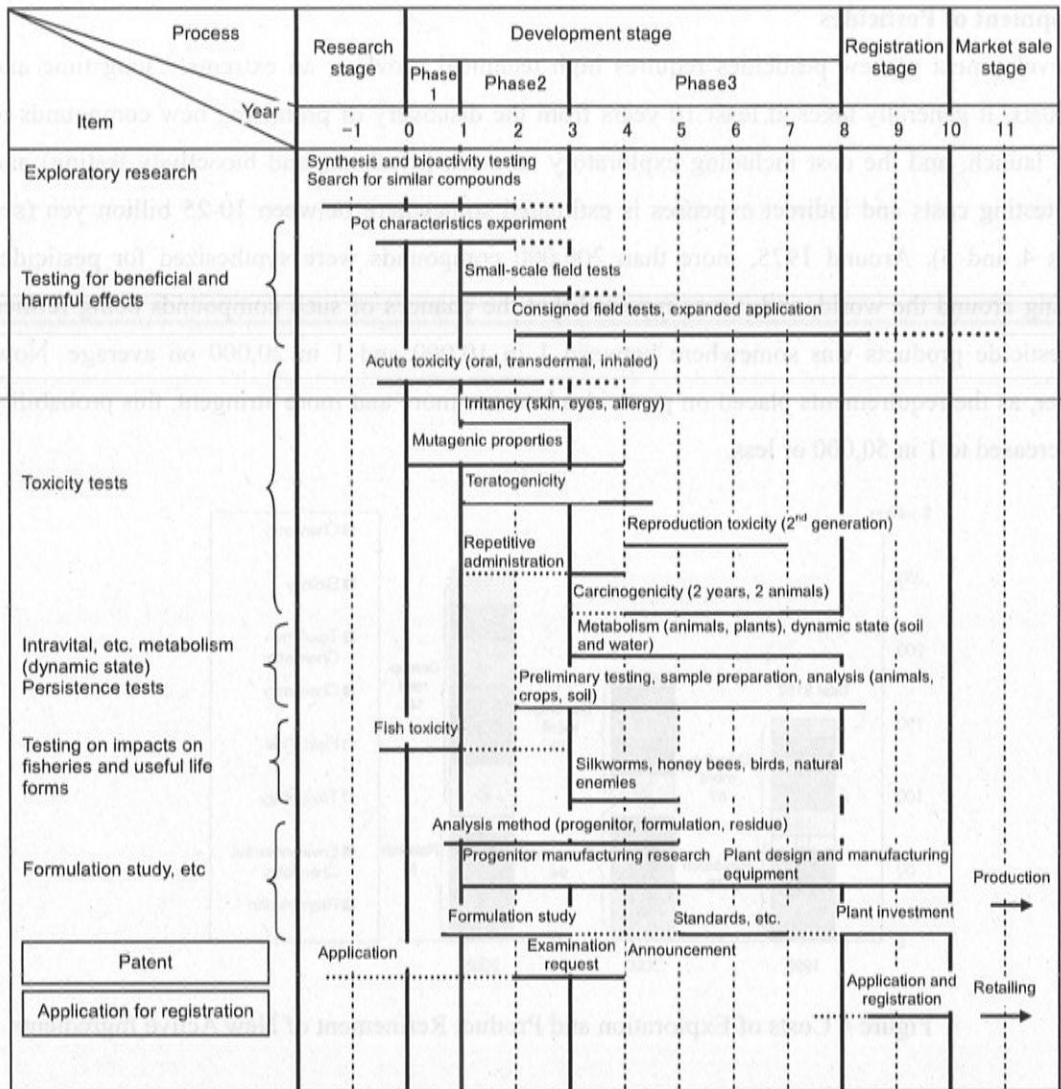


Figure 5 Example of the Timetable of Pesticides Development

### Current Conditions of the Pesticides Industry

It is reported that the global pesticides market in 2005 was worth approximately 35 billion US dollars. Since the world's pharmaceutical market in 2006 was worth 605.1 billion US dollars, the pesticides market is roughly one-seventeenth the size of this. Looking at the comparison of market share between makers, the six top European and American chemicals makers account for more than 70% of the world market, suggesting that the pesticides industry is increasingly becoming an oligopoly dominated by the major manufacturers (see Table 3).



Table 3 Market Share of the Top 9 Companies by Sales (2005)

| Order | Company                              | Sales (million US\$) | Share (%) | Accumulated share (%) |
|-------|--------------------------------------|----------------------|-----------|-----------------------|
| 1     | Syngenta                             | 6307                 | 18        | 18                    |
| 2     | Bayer Holding Ltd.                   | 6929                 | 20        | 38                    |
| 3     | BASF                                 | 4104                 | 12        | 50                    |
| 4     | The Dow Chemical Company             | 3058                 | 9         | 58                    |
| 5     | Monsanto Company                     | 3042                 | 9         | 67                    |
| 6     | E. I. du Pont de Nemours and Company | 2274                 | 6         | 73                    |
| 7     | Makhteshim Agan Industries Ltd       | 1747                 | 5         | 78                    |
| 8     | Sumitomo Chemical Co., Ltd           | 1644                 | 5         | 83                    |
| 9     | Nufarm Limited                       | 1191                 | 3         | 87                    |
| 10    | Others                               | 4704                 | 13        | 100                   |
|       | Total                                | 35000                | 100       |                       |

Looking at the size of the pesticides market by region, North and South America, Western Europe and Japan account for approximately 80% of the total (see Figure 6). Meanwhile, Africa and the former Soviet Union account for 13% and 14% respectively of the world's agricultural land (see Figure 7), and the amount of pesticides use per unit area of agricultural land differs greatly according to country and region. However, these figures pertain to lawfully distributed pesticides, whereas there are no official statistics concerning so-called illegal pesticides that have been unlawfully manufactured and distributed and it is extremely difficult to grasp actual use of pesticides in fields. This factor further exasperates the problems related to pesticides.

Because such high levels of technology and financing are required in order to develop chemically synthetic pesticides, it is practically impossible for entities other than large-scale chemical manufacturers based in advanced countries to compete. Figures 8 and 9 show the country-separate breakdown of applicants for patents in the pesticides and peripheral fields that have been registered with the United States Patent and Trademark Office and European Patent Office. These show that the United States, Germany, Japan, the United Kingdom and Switzerland account for approximately 90% of pesticides patent applications made to the United States Patent and Trademark Office and European Patent Office. This indicates that even among advanced countries, the countries that are capable of developing new chemically synthetic pesticides are limited. Moreover, looking at the breakdown of sales of pesticides by purpose of use, herbicides account for approximately 50% (see Figure 10).

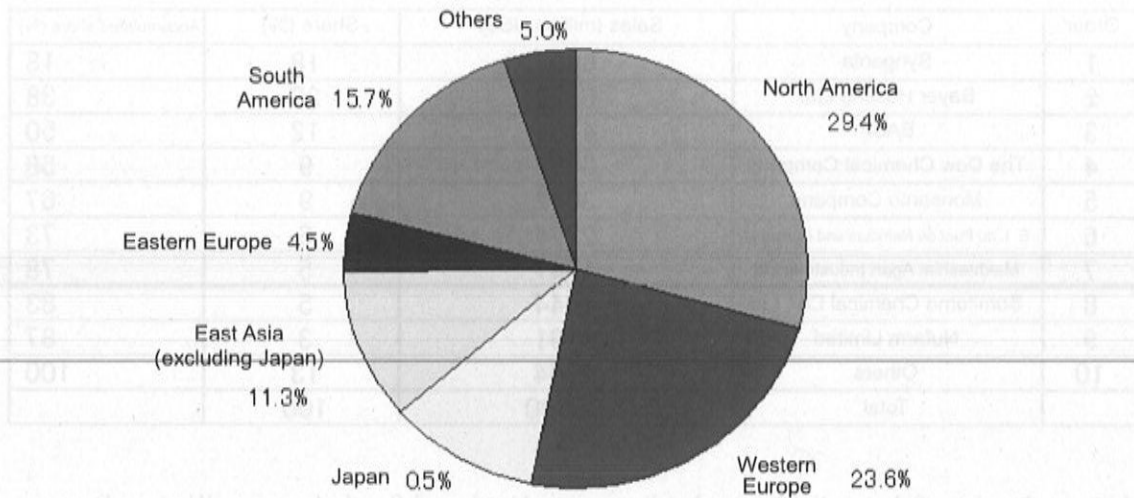


Figure 6 Regional Distribution of the Pesticides Market in 2003 (Phillips McDougall, 2004)

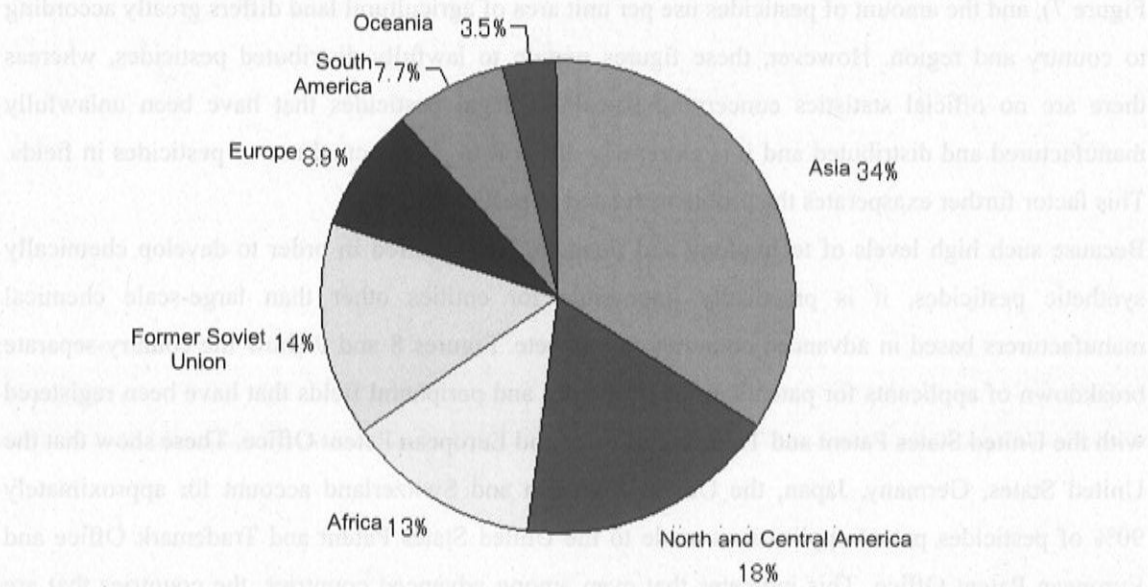


Figure 7 Distribution of Agricultural Land Area in the World in FY 1999 (FAO Statistical Databases)

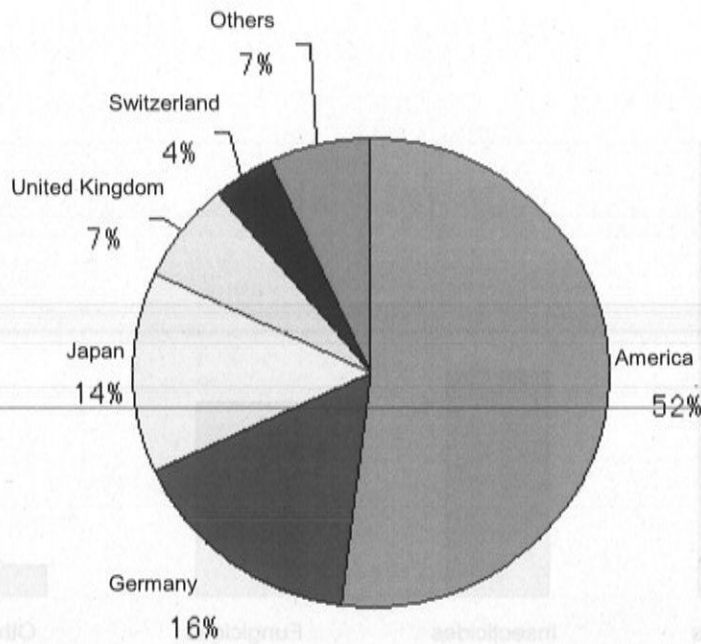


Figure 8 Number of Patents in the Pesticides and Peripheral Fields Registered with the United States Patent and Trademark Office between 1978 and 2000

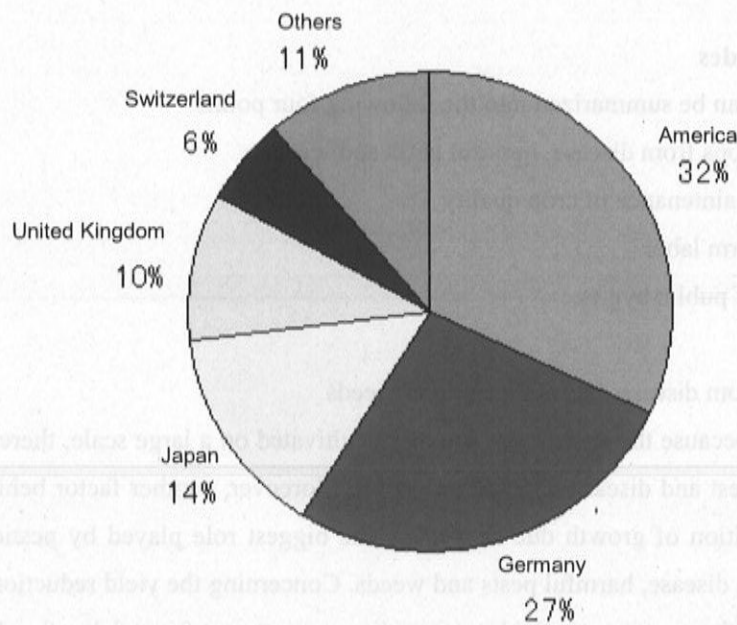


Figure 9 Number of Patents in the Pesticides and Peripheral Fields Registered with the European Patent Office between 1978 and 2000

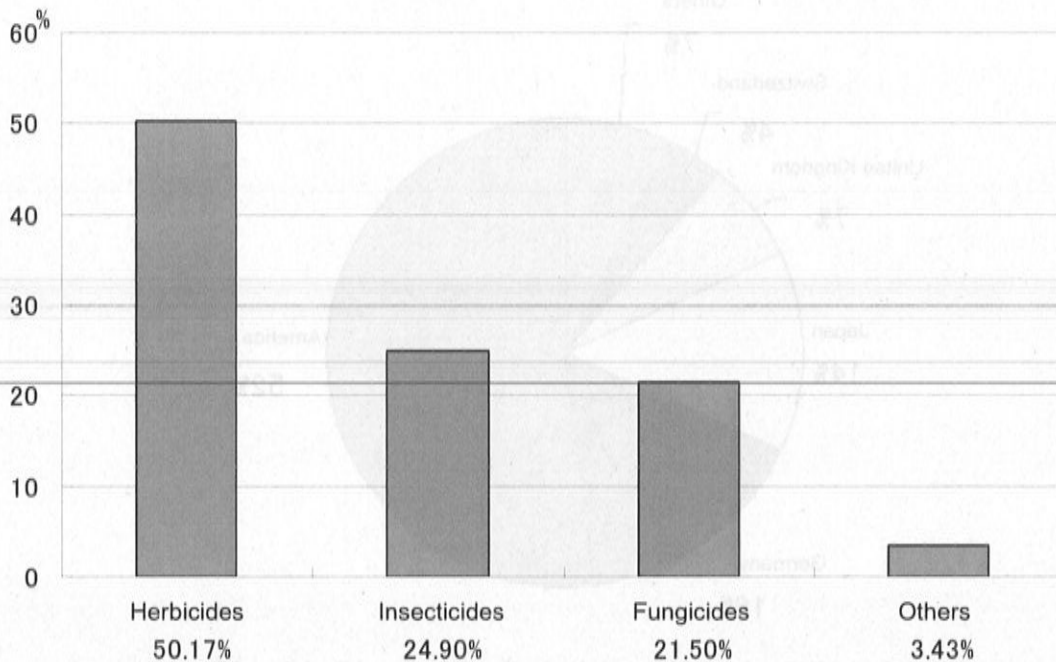


Figure 10 Breakdown of World Pesticides Sales by Purpose of Use in 2003  
(Phillips McDougall, 2004)

### **Roles Played by Pesticides**

The roles of pesticides can be summarized into the following four points:

- (1) Protection of crops from disease, harmful pests and weeds
- (2) Improvement/maintenance of crop quality
- (3) Mitigation of farm labor
- (4) Improvement of public hygiene

#### **1) Protection of crops from disease, harmful pests and weeds**

In modern agriculture, because the same crops are often cultivated on a large scale, there is a higher chance of widespread pest and disease damage occurring. Moreover, another factor behind reduced crop yields is the inhibition of growth due to weeds. The biggest role played by pesticides is the protection of crops from disease, harmful pests and weeds. Concerning the yield reduction rate when crops are cultivated without using pesticides, according to tests performed by the Japan Plant Protection Association, the rate of reduction can reach as high as 100% in crops such as peaches and so on (see Table 4). This indicates that attempts to cultivate crops without using pesticides can result in reduced yields, inferior quality and, in the worst case scenario, zero income for producers.

Table 4 Decline in Revenue when Not Using Pesticides  
 ("Food Safety and Environment," Kazuki Matsunaga, p. 37)  
 (Survey by the Japan Plant Protection Association, 1990-2006)

| Crop (number of surveyed cases) | Decline in Revenue (%) |         |      | Decline in Profit |         |      |
|---------------------------------|------------------------|---------|------|-------------------|---------|------|
|                                 | Minimum                | Maximum | Mean | Minimum           | Maximum | Mean |
| Rice (14)                       | 0                      | 100     | 24   | 5                 | 100     | 30   |
| Wheat (4)                       | 18                     | 56      | 36   | 18                | 93      | 66   |
| Soybeans (8)                    | 7                      | 49      | 30   | 18                | 63      | 34   |
| Apples (8)                      | 90                     | 100     | 97   | 95                | 100     | 99   |
| Peaches (4)                     | 37                     | 100     | 70   | 48                | 100     | 80   |
| Cabbages (20)                   | 10                     | 100     | 67   | 18                | 100     | 69   |
| Radish (12)                     | 4                      | 100     | 39   | 18                | 100     | 60   |
| Cucumbers (5)                   | 11                     | 88      | 61   | 11                | 86      | 60   |
| Tomatoes (7)                    | 14                     | 93      | 36   | 13                | 92      | 37   |
| Potatoes (2)                    | 22                     | 44      | 33   | 22                | 64      | 43   |
| Eggplants (2)                   | 21                     | 75      | 48   | 22                | 78      | 50   |

In the entire world, compared to the maximum agricultural crop yield estimated in the case of ideal cultivation, between 26-40% of agricultural products are lost due to disease, pests and weeds in the pre-harvest stage. If control using pesticides is not carried out, it is possible that losses will be double this amount. Furthermore, post-harvest losses caused by disease and pests account for another 20%. In terms of the financial value, crop losses account for 145.2 billion US\$ in Asia or approximately 60% of the world total (see Figure 11). In terms of loss rate, Africa is top (see Figure 12).

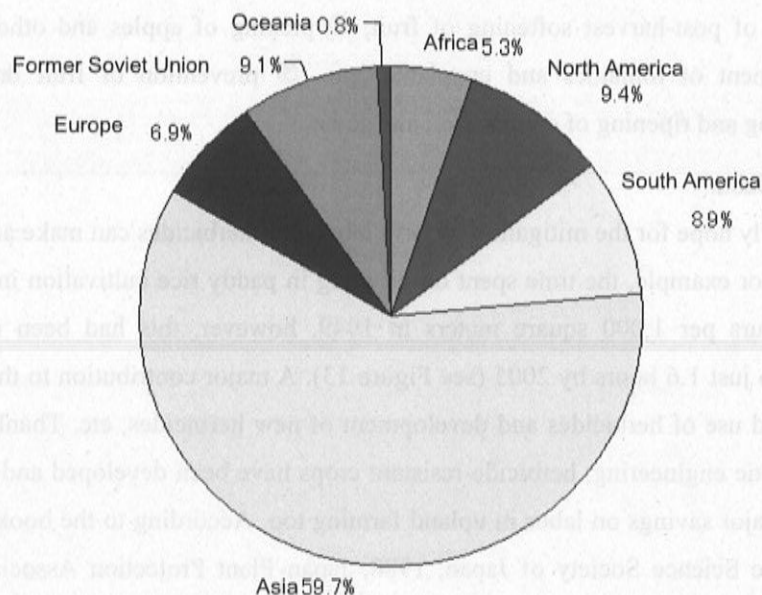


Figure 11 Value of Crop Losses Caused by Pest and Disease Damage and Weeds (US\$ billion)

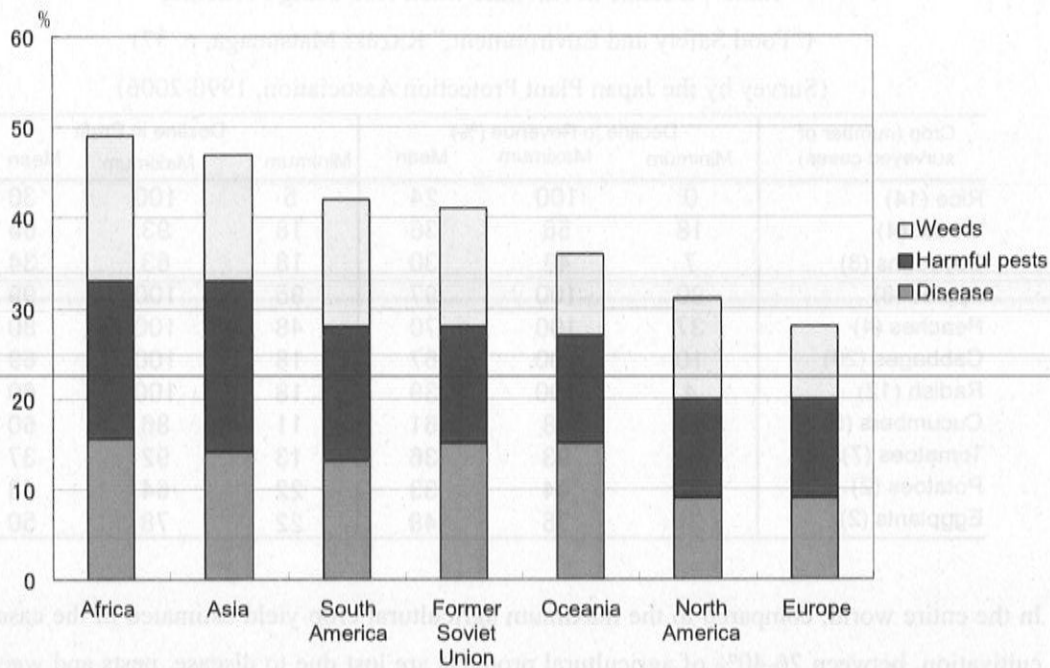


Figure 12 Loss Rate of Crops Due to Disease, Pests and Weeds

## 2) Improvement/maintenance of crop quality

Concerning improvement/maintenance of crop quality, a typical example is the cultivation of seedless fruits through utilizing plant hormones. Other uses of pesticides in this category are: ① prevention of rind puffing that causes skin to separate from fruit in Citrus unshiu oranges, ② long-term prevention of post-harvest softening of fruit, ③ picking of apples and other fruits, ④ bearing and enlargement of tomatoes and eggplants, etc., ⑤ prevention of fruit dropping, ⑥ acceleration of coloring and ripening of apples, etc., and so on.

## 3) Mitigation of farm labor

All farm workers dearly hope for the mitigation of farm labor, and herbicides can make an important contribution to this. For example, the time spent on weeding in paddy rice cultivation in Japan was approximately 50 hours per 1,000 square meters in 1949, however, this had been reduced by approximately 97% to just 1.6 hours by 2005 (see Figure 13). A major contribution to this has been made by the expanded use of herbicides and development of new herbicides, etc. Thanks to recent developments in genetic engineering, herbicide-resistant crops have been developed and have made it possible to make major savings on labor in upland farming too. According to the book “What are pesticides?” (Pesticide Science Society of Japan, 1988, Japan Plant Protection Association), it is estimated that labor costs would increase by approximately 900 billion yen (equivalent to more than 30% of the total value of rice production) in the case where all weeding in Japan’s paddy fields is conducted manually without the use of herbicides. In order to manually weed 2 million hectares of paddy fields in Japan, assuming 8 hours of labor per day, it would require 120 million man-days of

labor. If this work were to be completed in two months (60 days), it would be necessary for 2 million people to pick weeds in the summer heat every day (roughly 60 man-days per hectare). Therefore, for Japan, where the agricultural working population is now less than 3 million people, it is impossible to produce rice without the use of herbicides.

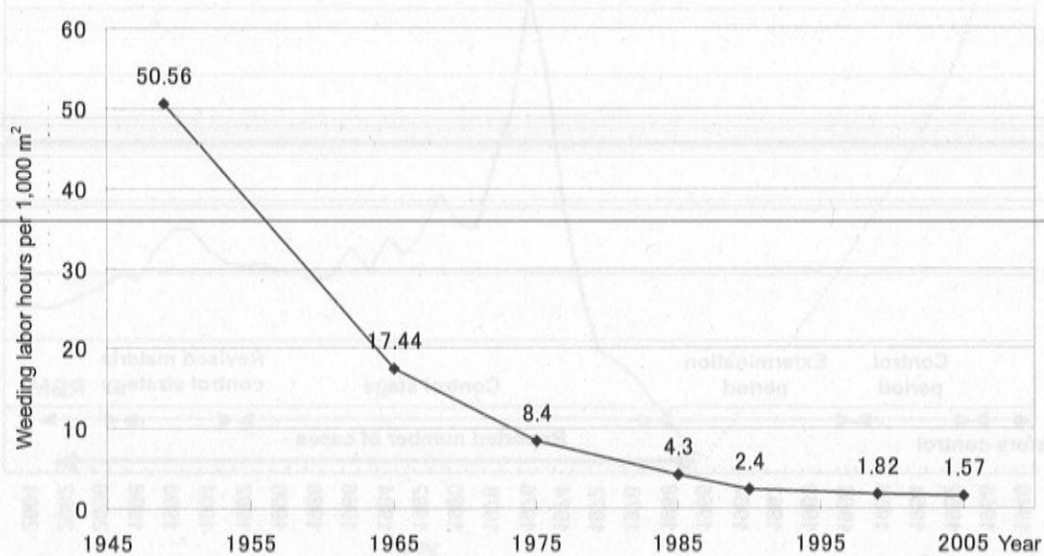


Figure 13 Mitigation of Labor through Use of Herbicides in Paddy Rice Cultivation

#### 4) Improvement of public hygiene

Pesticides also play an important role in the improvement of public hygiene. There are many diseases in the world that are transmitted through insects. Typical examples are malaria and dengue fever that are carried through certain types of mosquitoes. There are also numerous insects such as flies and lice that are undesirable in terms of human hygiene, but again damage has been greatly reduced thanks to the development of chemically synthesized pesticides (see Figure 14). For example, in Sri Lanka, thanks to the periodic spraying of DDT between 1948 and 1962, the number of malaria patients was reduced from approximately 2.8 million people per year to 17 people in 1963. As another instance, in Italy, DDT was used from 1947 with the objective of eradicating malaria, resulting in the country being declared free of the disease by the World Health Organization (WHO) in 1970. In Japan, phthiriasis was prevalent in the years following World War II, however, thanks to thorough prevention measures using DDT and so on, the public hygiene situation was greatly improved.

In Sri Lanka, the number of malaria patients rebounded after DDT was banned from use, and the WHO made an announcement in September 2006 that it “recommends the indoor residual spraying of organochlorine insecticide DDT in order to eliminate malaria.” This was a case where control of malaria through use of DDT was deemed to be more important than the risks placed on people and the environment. From the above it can thus be seen that pesticides have made a major contribution to the welfare of humankind from the viewpoint of improving public hygiene.

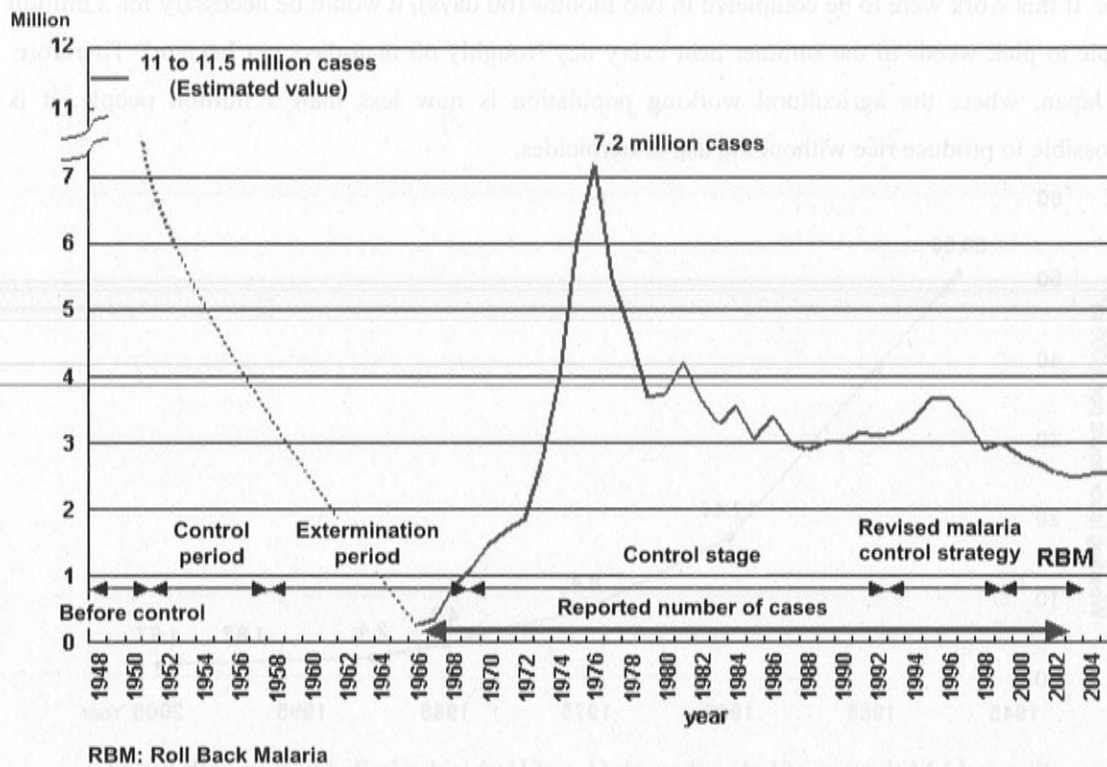


Figure 14 Malaria Countermeasures and Number of Infected Persons in Southeast Asia since 1948

### Problems with Pesticides

Although pesticides play an important role in securing agricultural crop yields and improving public hygiene and so on, there are many NGOs (Non-Governmental Organizations) that are opposed to their use throughout the world. The Pesticide Action Network (PAN), which has its headquarters in the United States, conducts vigorous anti-pesticide campaigns in more than 90 countries. When chemically synthesized pesticides were first being developed, there were many cases of poisoning caused by use of organophosphorous insecticides with high degrees of acute toxicity. One of the most well-known examples was parathion poisoning. This compound was first synthesized in Germany in 1944. However, the allied nations acquired the patent for it and widely used it as an insecticide following the end of World War II. Possessing good insecticidal activity, this compound was widely used particularly in Japan for controlling rice stem borers on rice and codling moth larva on fruit trees (the compound was registered as an pesticide in Japan from January 1952 to February 1971). However, the compound parathion had extremely high human toxicity with a median lethal dose ( $LD_{50}$ ) of 13mg/kg. Now, parathion is categorized as the most dangerous Class Ia (Extremely hazardous) in the WHO's risk classification of pesticides. There have been numerous poisoning accidents during use of parathion and it is currently banned from use in many countries (in Japan, parathion is designated as a specified toxic substance under the Poisonous and Deleterious



Substances Control Act, and its handling is prohibited except by specially authorized researchers of toxic substances. In advanced countries today, the ratio of registered pesticides with acute toxicity (detrimental effects arising from single administration (exposure) or multiple administrations over 24 hours) has been greatly reduced.

It is easy to image cases of harm arising out of the mistaken ingestion or other forms of direct consumption of pesticides, however, pesticides can indirectly impart damage to humans and ecosystems in the shape of residue. The book *Silent Spring*, which raised warning over this, was written by Rachel Carson in 1962. This work suggested that using compounds that do not decompose in the natural environment as pesticides may lead to accumulation and non-foreseeable harms in the environment. This was a revolutionary work for bringing to light issues that had hitherto not been considered, for example, bioaccumulation, chronic toxicity (negative impacts of even small quantities when ingested over the long term) and the negative impacts of pesticides on the environment and ecosystems. This book was groundbreaking for stating that ongoing ingestion of small quantities could manifest toxicity and that the bioaccumulation of nondegradable compounds in the food chain could have negative impacts in higher levels of the food chain, and it played a part behind the formation of the United States Environmental Protection Agency (USEPA) in 1970. In Japan too, mass death of fish caused by the paddy field herbicide PCP (Pentachlorophenol) in 1961 was a major issue that triggered a debate into the effects of pesticides on the natural environment. This led to major revision of the Agricultural Chemicals Control Act and establishment of Ministry of the Environment in 1971, marking the beginning in earnest of controls on residual pesticides and their environmental impacts. DDT and BHC (benzene hexachloride), which were introduced to Japan after World War II and made a major contribution to improve public hygiene and expand agricultural production, were banned from use in 1971. Looking back, the period around 1970 marked a major turning point regarding control of pesticides in countries that possessed effective control systems and enforcement setups.

The number of fatalities caused by pesticide poisoning in Japan was on average over 40 per year in the 1950s, but this figure was greatly reduced in line with the strengthening of controls (see Table 5). This indicates that the strengthening of controls led to major improvement in the safety of pesticide users. However, looking at the world overall, pesticide poisoning cases are still a critical problem. According to FAO and WHO, between 1 and 5 million cases of serious pesticide poisoning occur every year and it is estimated that these cause tens of thousands of fatalities. Furthermore, according to the FAO, even though the amount of pesticide usage in developing countries accounts for approximately 25% of the global production of pesticides, 99% of the world's fatal pesticide poisoning accidents occur in these countries.

The accident that occurred in the Philippines in 2005, when more than 100 elementary children suffered from poisoning and 28 died, is a typical example of pesticide poisoning in developing

countries. This accident occurred in March 2005 in the town of Mabini on Bohol Island, the Philippines. The elementary school children who experienced symptoms of poisoning had eaten confectionery made from cassava flour sold at a store next to the school. The Philippine authorities investigating the accident detected traces of the organophosphorous pesticide Coumaphos (phosphorothioic acid O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl)O,O -diethyl) from residue in a frying pan in the home of the storekeeper who had prepared the confectionery and from the blood and stomach contents of two of the dead children. The said pesticide was found in a container similar to the container used to store flour in the storekeeper's house, and it is thought that the pesticide was mistakenly used instead of the flour. Incidentally, Coumaphos is also used as an insecticide for controlling hygiene pests, although it has not been registered in Japan.

Table 5 Pesticide Poisoning Cases in Japan

| Year              | Fatalities (figures in parentheses indicate during spraying) | Poisoning (figures in parentheses indicate during spraying) |
|-------------------|--|---|
| 1957-1960 average | 45   | 681   |
| 1961-1965 average | 38 (20)  | 322 (296)   |
| 1966-1970 average | 39 (15)  | 276 (252)   |
| 1971-1975 average | 21 (4)   | 233 (216)   |
| 1976-1980 average | 17 (6)   | 158 (147)   |
| 1981-1985 average | 12 (3)   | 68 (59)   |
| 1986-1990 average | 6 (3)  | 54 (45)   |
| 1991-1995 average | 4 (1)  | 20 (13)   |
| 1996              | 2 (0)  | 66 (60)   |
| 1997              | 4 (0)  | 43 (29)   |
| 1998              | 3 (1)  | 50 (44)   |
| 1999              | 0 (0)  | 57 (41)   |
| 2000              | 0 (0)  | 42 (30)   |
| 2001              | 2 (1)  | 144 (132)   |
| 2002              | 2 (0)  | 56 (48)   |
| 2003              | 6 (1)  | 28 (25)   |
| 2004              | 2 (1)  | 54 (39)   |
| 2005              | 6 (0)  | 38 (26)   |
| 2006              | 6 (1)  | 28 (11)   |
| 2007              | 0 (0)  | 35 (26)   |

Figures (not including suicides and homicides) for the period 1957 to 1975 are acquired from survey by the Monitoring and Guidance Section of the Pharmaceutical Affairs Bureau, the Ministry of Health, Labour and Welfare, and those for 1976 onwards are acquired from survey by the Plant Protection Division of the Agricultural Production Bureau, the Ministry of Agriculture, Forestry and Fisheries

In many developing countries, the sale and advertisement of pesticides are not managed or are conducted illegally. In Cambodia, FAO/UNEP/WHO newsletters have reported that pesticides are sold at roadside stands in unlabeled soft drink bottles and so on.

### **Differences between Pesticides and Pharmaceuticals and Off-patent Active Ingredient Drug Products (Generic Products)**

Pesticides and pharmaceuticals are similar in that they are both basically chemical substances that possess high activity with respect to living organisms, however, they differ greatly in terms of economy and their tolerance levels for harmful effects (side effects). Since pharmaceuticals are used with the objectives of curing diseases, mitigating symptoms and saving lives through their medicinal properties, the obtained effects are important and there is a certain tolerance level with respect to side effects. Moreover, in cases where such pharmaceuticals are directly concerned with human life, economy can be disregarded. Meanwhile, in the case of pesticides, cost effectiveness is the primary concern and the occurrence of harmful incidents (harmful effects or environmental pollution, etc.) is basically not tolerated.

The discovery and development via fine chemistry of new active ingredients used in pesticides, etc. is almost exclusively limited to corporations based in advanced nations. Newly discovered and developed active ingredients are protected by the patent system, by which patent holders are given monopolistic rights to use such ingredients for a certain period, however, third parties are also allowed to use them once the said protected period comes to an end. Pesticides and pharmaceuticals that are manufactured by third parties using these active ingredients for which the protected period has expired (patent-free ingredients) are known as generic products. Because generic products can be cheaply supplied without incurring the huge costs of invention and development, they far surpass original products in terms of price competitiveness. Accordingly, the ratio of use of generic pesticides in developing countries is far higher than in advanced countries. For example, generic pesticides account for 75% of all the pesticides used in China. Meanwhile, in Japan, stringent controls are also placed on generic pesticides so the registration and distribution of generic pesticides is strictly controlled. Although generic pesticides have the same active ingredient compounds as original products, because they adopt different synthesizing techniques and use different plants, etc. in synthesis, the types and quantities of impurities generated during synthesis differ; moreover, pharmaceutical formulation (the types and quantities of auxiliary ingredients added in order to bring out the effects of the active ingredients; because the qualitative and quantitative formula of original products is a corporate secret, its nondisclosure is recognized) also differs. Accordingly, in countries that don't have solid or effective regulation systems or controls, a problem is that generic products are distributed and used without undergoing sufficient evaluation of safety and effectiveness.

Table 6 shows the number of generic pesticides makers according to region. More than 60% of the

top 100 companies are based in China and India, showing that both countries are the giants of generic pesticide manufacturing. Moreover, looking at the makers of generic pesticides in terms of sales value, first-placed Makhteshim Agan Industries Ltd and second-placed Nufarm Limited stand out from the rest (see Table 7). Makhteshim Agan Industries Ltd and Nufarm Limited are generic pesticides makers, but they are also on a par with new pesticide developers and enter the top ten companies in terms of pesticide sales (see Table 3). Makhteshim Agan Industries Ltd is based in Israel, while Nufarm Limited is an Australian company. Both Israel and Australia are members of the OECD and are thought to have superiority over developing countries in terms of production technology, etc. Moreover, both companies have cleared stringent regulations to obtain official registration for generic products and advance the generic pesticides business in advanced Western countries too. On comparing sales of Makhteshim Agan Industries Ltd and Nufarm Limited with sales of generic pesticides makers in China and India, the Chinese and Indian makers are numerous but have small sales per company, indicating that many of them are small and medium enterprises.

Table 6 Regional Breakdown of Generic Pesticides Makers  
(Top 100 Firms in Terms of Sales)

| Region                            | Number of Companies |
|-----------------------------------|---------------------|
| China                             | 41                  |
| India                             | 20                  |
| Europe (incl. Turkey and Israel)  | 19                  |
| South-east Asia (incl. Australia) | 9                   |
| South America                     | 7                   |
| North America                     | 4                   |
| Total                             | 100                 |

Table 7 Generic Pesticides Makers in the World (Top 30 Companies with Sales)

| Company                        | Country   | Annual Sales<br>(million US\$) | Fiscal Year |
|--------------------------------|-----------|--------------------------------|-------------|
| 1 Makhteshim-Agan              | Israel    | 1581                           | 2006        |
| 2 Nufarm                       | Australia | 1253                           | 2006        |
| 3 Cheminova                    | Denmark   | 680                            | 2006        |
| 4 Sipcam-Oxon                  | Italy     | 378                            | 2005        |
| 5 United Phosphorus            | India     | 350                            | 2006        |
| 6 Cerexagri                    | US        | 270                            | Unknown     |
| 7 Agripec                      | Brazil    | 198                            | Unknown     |
| 8 Isagro                       | Italy     | 196                            | 2006        |
| 9 Amvac                        | US        | 194                            | 2006        |
| 10 Red Sun                     | China     | 153                            | 2005        |
| 11 Xinan Chemical              | China     | 138                            | 2005        |
| 12 Rallis                      | India     | 133                            | 2006        |
| 13 Sanonda                     | China     | 120                            | 2005        |
| 14 Taminco                     | Belgium   | 119                            | 2006        |
| 15 Meghmani Organics           | India     | 105                            | 2007        |
| 16 Huaxing Chemical            | China     | 100                            | Unknown     |
| 17 Rotam                       | Hong Kong | 100                            | Unknown     |
| 18 Excel Crop Care             | India     | 93                             | 2007        |
| 19 Jiangshan Agrochemical      | China     | 90                             | Unknown     |
| 20 AH Marks                    | UK        | 84                             | Unknown     |
| 21 Nagarjuna                   | India     | 80                             | 2006        |
| 22 Sabero Organics             | India     | 75                             | Unknown     |
| 23 Indofil                     | India     | 70                             | Unknown     |
| 24 Jiangsu Suhua Group         | China     | 70                             | Unknown     |
| 25 Shenghua Biok               | China     | 70                             | Unknown     |
| 26 Changxing Zhongshan         | China     | 60                             | Unknown     |
| 27 Jingma Chemicals            | China     | 60                             | Unknown     |
| 28 Punjab Chemicals            | India     | 60                             | 2006        |
| 29 Shandong Qiaochang Chemical | China     | 60                             | Unknown     |
| 30 IQV                         | Spain     | 58                             | 2004        |

### Imitation Products and Illegal Pesticides

In developing countries, as with other legislation, patent-related legislation had not made much progress until a few years ago. Accordingly, new active ingredients that were protected by law in advanced countries were not protected in developing countries due to the absence or inadequacy of legislation. (Even today, in countries that don't belong to the World Trade Organization (WTO) and are not bound by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), patent-related legislation is not far advanced and a similar situation is continuing). As a result, manufacture of imitation products has not been controlled. For example, in India, which together with China is home to many generic pesticides makers, the patent system did not target pesticides and pharmaceuticals up until 2005. Pesticides finally became targets for the patent system following review of the patent law in 2005. This resulted from the fact that the TRIPs agreement that came into

effect in 1995 made it obligatory for developing countries to introduce the substance patent system (the obligation to implement the TRIPs agreement became valid for least developing countries from 2006). Because of these deficiencies of the patent system in developing countries, it was legal to manufacture and distribute not only generic pesticides using patent-free active ingredients for which the protected period under the patent system had expired, but also imitation products using active ingredients that were still protected under the patent systems of advanced countries.

If patent systems are established, it becomes illegal to manufacture and distribute imitation products, however, in developing countries, because the efficacy of controls isn't guaranteed, numerous imitation products continue to be manufactured and distributed. For example, according to the Report on the Survey of Imitation Product Suppression Activities Utilizing Trade Fairs in the Pesticide Industry, 2009 staged by JETRO Shanghai Center, in China, "the trade marks/trade names of original products continue to be unlawfully used on the labels of generic products and imitation products, and there are even cases where the labels of original products are forged (dead copies) and affixed to imitation products for sale." It goes on to say that, "the goods that carry such false labels contain zero or less than the displayed amount of pesticide components or even different pesticide components than displayed, and are imparting huge economic loss and detrimental impacts on the original products." These products are in violation of Chinese laws, Pesticide Control Ordinances, Product Mass Law, Trademark Law, Unfair Competition Prevention Act, Industrial Production Certificate Control Ordinance and numerous other regulations. Moreover, according to the Report on Trends and Analysis of Sophistication of Imitation Product Displays, 2010, which is the report on illegal pesticides issued by JETRO Shanghai Center, "In line with the globalization of the world economy, imitation products are now being distributed on the world scale." Clarifying the criteria of lawful pesticides in order to understand what illegal pesticides are, lawful pesticides have obtained the official registration permit (or equivalent) following review under the pesticide registration system of the country concerned and there are no inaccuracies regarding quality (the qualitative and quantitative formula and content of active ingredients, etc.), label contents and container. Accordingly, any products that don't satisfy any one of these criteria are illegal pesticides. In developing countries that don't have functioning pesticide registration systems, there are places where the majority of used pesticides are illegal. Additionally, products where the chemical structure of active ingredients has been modified in order to ensure equivalent or better effectiveness than pre-existing products are referred to as "Me-too products." If the proper procedures were followed, such products could be newly registered as new compounds and would differ from imitation products.

The situation regarding illegal pesticides in developing countries is unthinkable seen from the common viewpoint of advanced countries. For example, an article in the Brazilian newspaper Varol on December 8, 2008 reported that the pesticide-smuggling mafia had taken over the Midwestern

region of Brazil. Reporting on conditions far removed from common practices in advanced countries, the article reported as follows: "The mafia is a massive organization that owns marine transportation companies, aircraft and private airports, and it regularly bribes customs employees in order to smuggle pesticides, drugs and arms. Almost all the smuggled pesticides are generic products from China that are very cheap and have unreliable quality. Not only is it a crime to sell smuggled agricultural chemicals, but because such products have no quality guarantee, they carry risk of harming the environment and human health. In the Midwest, 10% of pesticides are imported official products, while 90% are smuggled. The 10% of original products are used for shop displays, however, in reality the smuggled products are handed over in sales. The bags that contain pesticides obtained through official routes carry official stamps and are supposed to be returned to the authorities after use, however, because they can be sold for high price, this rule isn't upheld." When considering the pesticides management system, it is necessary to realize this reality in many developing countries where illegal pesticides are smuggled by organized crime groups on a major scale.

## **Pesticide Management System and Reality in Japan**

### **Overview of Japan**

Area: 377,915 square kilometers

Population: 127,368,088 (estimate as of July 2012)

Literacy rate: 99%

Land usage (2005):

Farmland: 11.64%

Perennial crops: 0.9%

Others: 87.46%

Type of government: Parliamentary cabinet system with constitutional monarchy

Gross domestic product:

\$ 5,458,873 million (2010 nominal GDP)

Per capita nominal GDP: \$ 43,140.9 (2010)

Sector-separate GDP:

Agriculture: 1.2%

Industry: 27.3%

Services: 71.6% (estimate as of 2011)

Sector-separate breakdown of employment:

Agriculture: 3.9%

Industry: 26.2%

Services: 69.8% (estimate as of 2010)

Main agricultural products:

Rice, beets, vegetables, fruits, pork, chicken, beef

WTO membership: Member since founding (1995)

## **Pesticides Management System and Mechanism of Pesticides Registration in Japan**

### **Pesticides Management System in Japan**

In Japan, pesticides are managed under the Agricultural Chemicals Control Act, which was promulgated in July 1948. Prior to that, in 1947, the Agricultural Chemicals Inspection Center (the current Agricultural Chemicals Inspection Station of the Food and Agricultural Chemicals Inspection Center) of the Ministry of Agriculture and Forestry was established in 1947. According to Article 1-2 of the Agricultural Chemicals Control Act, "For the purpose of this law, the term "Agricultural Chemicals" (pesticides) shall mean fungicides, insecticides, and other substances used to control fungi, nematodes, mites, insects, and rodents or other plants and animals, or viruses (hereinafter generically called "diseases and insect pests") that may damage crops (including trees and



agricultural and forestry products, and hereinafter called “Crops, etc.”), and also refers to other substances (including those, specified by government ordinances, that are used as raw materials or materials to control the diseases and insects pests) and agents such as growth accelerators and germination suppressors, etc. used to promote or suppress the physiological functions of crops, etc.” The law also regards natural enemies that are used to prevent and control diseases and insect pests in crops as pesticides. The definition of pesticides differs between countries. For example, in Japan, a chemical substance is a pesticide when used in the cultivation of agricultural crops, however, if the same chemical substance is used for exterminating hygiene pests (mosquitoes, cockroaches, termites, etc.), it is no longer an pesticide but rather a “quasi-drug” no longer subject to control under the Agricultural Chemicals Control Act. The focal point of pesticides management is the registration system. In Japan, only pesticide manufacturers that have been registered by the Minister of Agriculture, Forestry and Fisheries can manufacture, import and sell pesticides. Violations of the law are subject to criminal punishment. The Ministry of Agriculture, Forestry and Fisheries, Ministry of the Environment, Ministry of Health, Labour and Welfare and Cabinet Office (Food Safety Commission) are involved in the registration of pesticides. Registration is effective for three years, and renewed registration must be applied for every three years in order to maintain registered status. The Agricultural Chemicals Law is under the joint jurisdiction of the Ministry of Agriculture, Forestry and Fisheries and the Ministry of the Environment, while the Minister of the Environment sets criteria that pertain to impacts on the environment and ecosystems. Meanwhile, the Ministry of Health, Labour and Welfare has jurisdiction over the management of residual pesticides in foods. In addition to setting maximum residue levels (MRL), it monitors residual pesticides in foods under the setup shown in Figure 15. Japan switched from the negative list system to the positive list system in May 2006, resulting in all residual pesticides criteria becoming applicable to all foods. When the new system was enforced in 2006, maximum residue levels (MRL) were established for 799 active ingredients.

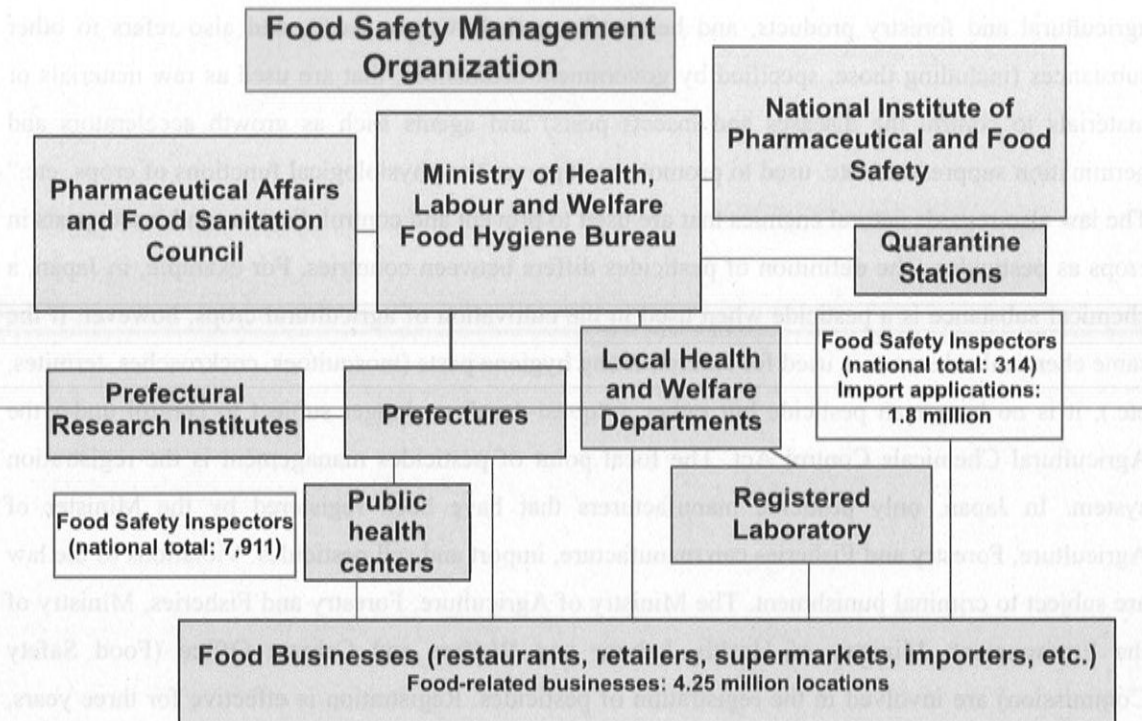


Figure 15 Pesticides Residue Monitoring System in Japan

In Japan, penal regulations were bolstered based on revision of the Agricultural Chemicals Control Act in 2002. As a result, penalties were extended to cover the manufacture, import (including import agency), sale and use of unregistered pesticides. In addition, users of pesticides were required to comply with the following four requirements: ① to only use pesticides on applicable crops, ② to use pesticides according to prescribed quantities and concentrations, ③ to uphold the prescribed period of use, and ④ to use within the prescribed total frequency of use, and penalties of imprisonment of up to 3 years or fine of up to 1,000,000 yen were imposed on violations. Moreover, although not subject to penalties, users were required to make efforts in the following areas: ① not to use pesticides for which the final valid date on the container has expired, ② to strive to prevent dispersion of pesticides when using in residential areas, ③ to keep a record of the date and place of use of pesticides, the used crops, the types and names of pesticides, the amount of pesticide used per unit area or the degree of dilution, ④ to strive to prevent runoff of pesticides when using in paddy fields that require water sealing, and ⑤ to strive to prevent sublimation of pesticides when using pesticides that require covering. Moreover, in cases of violations concerning the manufacture, import or sale of unregistered pesticides, penalties of imprisonment of up to 3 years or fine of up to 1,000,000 yen are imposed on individuals, and fines of up to 100 million yen are imposed on corporations. This revision was prompted by a major incident concerning the sale and use of unregistered pesticides in 2002. This case came to light when Yamagata Prefectural Police arrested a

retailer for selling unregistered pesticides. Subsequent investigations by the Ministry of Agriculture, Forestry and Fisheries found that more than 4,600 households had purchased the unregistered pesticides.

### **Mechanism of Pesticide Registration in Japan**

#### **(1) Mechanism of pesticide registration in Japan**

Parties (manufacturers or importers) who wish to acquire pesticide registration must make an application to the Minister of Agriculture, Forestry and Fisheries attached with an application form stating the types and content of active ingredients, the targeted diseases and pests, method of use and other required items, the results of tests concerning the pesticide quality, beneficial effects, harmful effects to crops, toxicity for humans and livestock, behavior and persistence in the environment, and also a sample of the pesticide in question. Applications are processed through the Agricultural Chemicals Inspection Station which is the former Agricultural Chemicals Inspection Station (ACIS) of the Food and Agricultural Chemicals Inspection Center (hereinafter referred to as FAMIC). When the Ministry of Agriculture, Forestry and Fisheries receives an application, the Minister instructs FAMIC to conduct inspections. FAMIC then conducts various tests on the quality, beneficial effects, harmful effects, and safety, etc. of the pesticide, determines whether or not the application contents satisfy crop residue criteria, etc. stipulated by the Ministry of the Environment and Ministry of Health, Labour and Welfare, and reports its findings to the Ministry of Agriculture, Forestry and Fisheries. If the application is deemed successful as a result of the tests, the Minister of Agriculture, Forestry and Fisheries approves the registration, and the registration certificate is issued to the applicant via FAMIC. Figure 16 shows the flow of pesticide registration. Incidentally, the data protection period for registered pesticides in Japan is 15 years.



Figure 16 Flow of Pesticide Registration in Japan

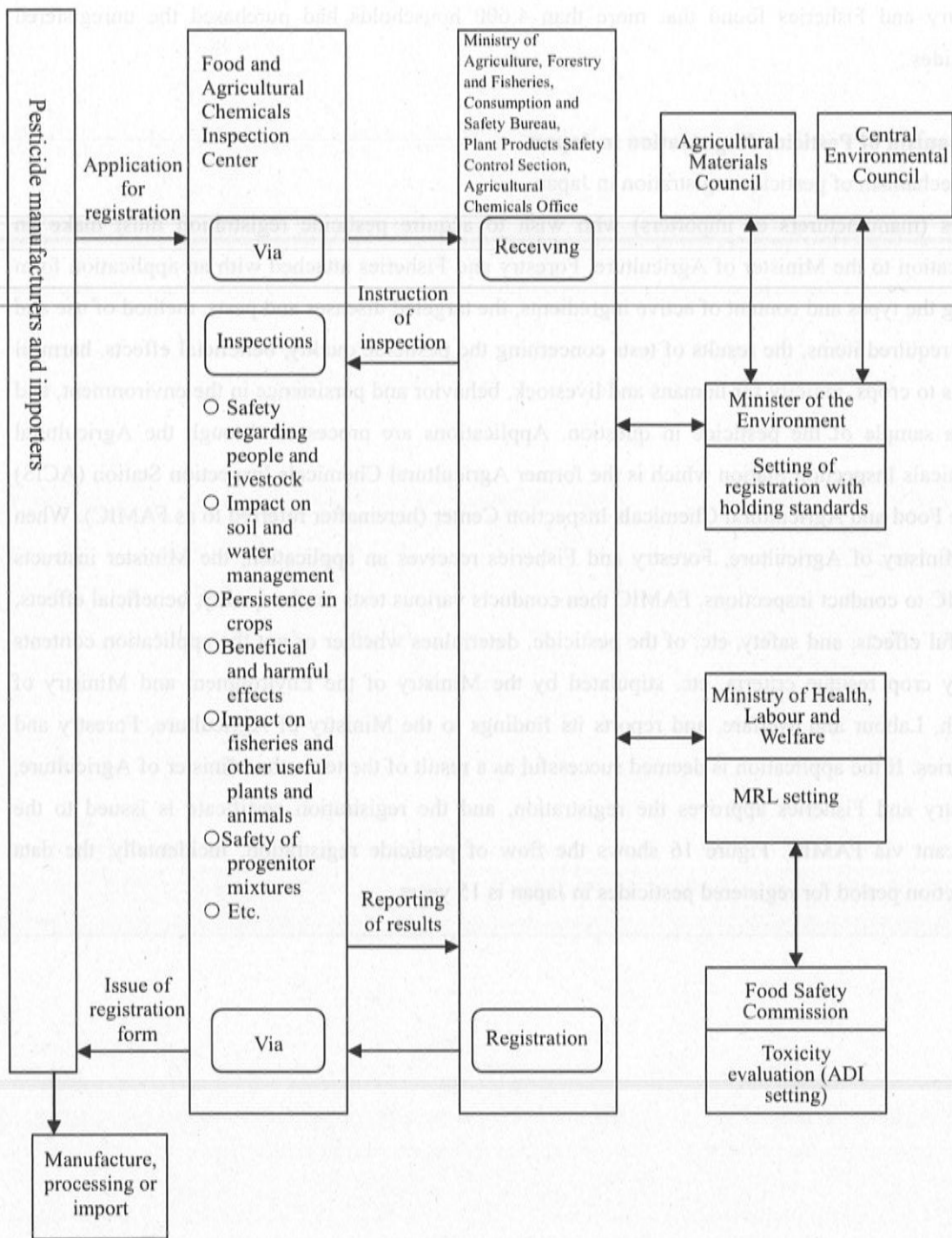


Figure 16 Flow of Pesticide Registration in Japan

(2) Changes in Registration Inspection Items, etc. for Pesticides in Japan

Registration inspections for pesticides in Japan have undergone repeated changes reflecting the social background and scientific progress of the age (see Table 8). The Agricultural Chemicals Inspection Center, responsible for overseeing the registration of pesticides in Japan, was established in 1947 as the Ministry of Agriculture and Forestry Agricultural Chemicals Inspection Center. At the time of establishment, it only had two divisions – the biological division and chemical division – other than the General Affairs Department. Between 1967 and 1990, the Pesticide Residue Section, the Technical Research Section, the Planning and Coordination Section, the Aquatic Organisms Safety Section, the Coordination Guidance Officer, the Toxicity Section, the Pesticide Inspection Officer and the Environment Section were successively established. The Agricultural Chemicals Inspection Station Law was enacted in 2000, and the Agricultural Chemicals Inspection Center became the Pesticides Inspection Station following the reorganization that ensued administrative reform in April 2001 (at the same time, the Planning and Evaluation Office was established, the Technical Research Section became the Survey and Research Section, and the Planning and Coordination Section became the Inspection Coordination Section). Furthermore, in 2007, the Food Quality, Labeling and Consumer Services and Fertilizer and Feed Inspection Services were integrated to form the Food and Agricultural Chemicals Inspection Center Agricultural Chemicals Inspection Station.

Table 8 Changes in Registration Inspection Items, etc. for Pesticides in Japan

| Fiscal Year | Changes in Inspection Items, etc.   | Inspection Setup, Background to Revision of Legislation, etc.   |
|-------------|---|---|
| 1947        |   | Establishment of the Agricultural Chemicals Inspection station (biology section and chemistry section)  |
| 1948-1970   | <ul style="list-style-type: none"> <li>• Ingredients (active ingredients)</li> <li>• Properties (physical and chemical)</li> <li>• Beneficial effects</li> <li>• Acute toxicity (oral and transdermal)</li> <li>• Analytical method (formulation)</li> <li>• Fish toxicity</li> </ul> | 1948: Establishment of the Agricultural Chemicals Regulation Law<br>1967: Establishment of the Agricultural Chemicals Inspection Station (Pesticide Residue Section)  |
| 1971-1972   | <ul style="list-style-type: none"> <li>• Chronic toxicity (subacute)</li> <li>• Crop residue</li> <li>• Soil residue</li> <li>• Impact on silkworms</li> <li>• Harmful effects (surrounding crop, adjacent spraying, growth damage, secondary harmful effects)</li> </ul>             | 1971: Strengthening of registration inspections in line with revision of the Agricultural Chemicals regulation law (following strong social requests for better safety concerning toxicity and persistence) |

|           |  |  |
|-----------|--|--|
|           | <ul style="list-style-type: none"> <li>• Accumulation in animal bodies</li> <li>• Residual analysis method</li> <li>• Conditions for safe use</li> <li>• Fish toxicity (crustaceans)</li> </ul>  | <p>Establishment of the Agricultural Chemicals Inspection Center (Pesticides Residue Inspection Section)</p> <p>Establishment of Ministry of Environment</p>   |
| 1973-1977 | <ul style="list-style-type: none"> <li>• Chronic toxicity (long-term, 2 years)</li> <li>• Genetic safety</li> <li>• Progenitor synthesis method, hazardous effects of</li> </ul>   | <p>Ministry of Health, Labour and Welfare: request for genetic safety inspections</p> <p>1976: Establishment of the Agricultural</p>   |
|           | <ul style="list-style-type: none"> <li>sub-ingredients and auxiliary ingredients</li> <li>• Toxicity of mixed agents</li> <li>• Impacts on honey bees</li> <li>• Fish toxicity (deformed and anemic fish)</li> </ul>   | <p>Chemicals Inspection Center (Planning and Coordination Section)</p>   |
| 1978-1982 | <ul style="list-style-type: none"> <li>• Physical properties (flotation index)</li> <li>• Drug resistance</li> </ul>   | <p>Responding to advances made in toxicology,</p> <p>1979: Establishment of the Agricultural Chemicals Inspection Center (Aquatic Organisms Safety Section, Toxicity Section)</p>  |
| 1983-1987 | <ul style="list-style-type: none"> <li>• GLP system</li> <li>• Safety in use</li> <li>• Impacts on useful animal (terrestrial life forms, aquatic plants, fish and shellfish)</li> <li>• Inspection of mixed items in registered pesticide progenitors</li> <li>• Toxicity testing (eye and skin irritancy)</li> </ul> | <p>Controls on distribution of illegal pesticides</p> <p>Spate of accidents caused by use of Agricultural Chemicals for other than the intended purposes</p> <p>Problems of residual pesticides in the environment (river water and groundwater)</p> <p>Setting of new guidelines on toxicity testing</p> <p>Setting of GLP criteria</p> |
| 1988-1991 | <ul style="list-style-type: none"> <li>• Pesticide concentrations in river water and groundwater</li> <li>• Behavior of pesticides in the atmosphere</li> </ul>  | <p>Problems regarding safety of imported agricultural products</p> <p>Problems concerning use of pesticides on golf courses</p> <p>Setting of residual pesticide target values in potable water</p>  |

|           |  |  |
|-----------|--|--|
|           |  | 1990: Establishment of the Pesticides Inspection Center (Environment Section)  |
| 1992-1994 | <ul style="list-style-type: none"> <li>• Impacts on life forms in aqueous environments</li> <li>• Water contamination inspections</li> </ul>   | Start of the setting of registration reservation criteria concerning water quality<br>Additional setting of soil environmental criteria<br>Additional setting of water quality criteria in tap water |
| 1995-     | <ul style="list-style-type: none"> <li>• Changes in cautionary items accompanying enforcement of the Product Liability Act</li> <li>• International harmonization of the pesticides registration system discussed in OECD, etc.</li> </ul> | Enforcement of the Product Liability Act   |
| 2000      | <ul style="list-style-type: none"> <li>• Neural toxicity test</li> <li>• Water flea acute swimming inhibition test</li> <li>• Algae growth inhibition test</li> </ul>  |  |
| 2002      | <ul style="list-style-type: none"> <li>• Introduction of penalties for users of pesticides</li> </ul>  | Discovery of problems concerning use of unregistered pesticides<br>Revision of the Agricultural Chemicals Control Act  |
| 2003      | <ul style="list-style-type: none"> <li>• Strengthening of controls on unregistered pesticides</li> </ul>   | Revision of the Food Hygiene Law<br>Enactment of the Food Safety Basic Law<br>Establishment of the Food Safety Commission  |
| 2005      | <ul style="list-style-type: none"> <li>• Introduction of fisheries PEC</li> </ul>  | Enforcement of revised registration reservation criteria concerning aquatic plants and animals   |
| 2006      | <ul style="list-style-type: none"> <li>• Introduction of water pollution PEC</li> <li>• Revision of the registration reservation criteria concerning soil residues</li> <li>• Enforcement of the positive list system</li> </ul>           | Enforcement of revised registration reservation criteria concerning water pollution and soil residue<br>Enforcement of the revised Food Hygiene Law  |

Modified by the author from “Chemical Substances Ecological Risk Assessment and Controls – Pesticides,” issued on November 30, 2006, the Japanese Society of Environmental Toxicology, published by IPC Ltd.

(3) Test results, etc. that need to be submitted for registration

As of 2008, the following test results need to be submitted when making applications for pesticide registration in Japan.

- 1) Test results concerning beneficial effects  
Test results concerning beneficial effects on the applicable diseases and pests  
(Test results concerning beneficial effects on the applicable crops, etc. in cases of pesticides used for enhancement or suppression of crop physiological functions)
- 2) Test results concerning chemical hazard
  - a Test results concerning chemical hazard on applicable crops
  - b Test results concerning chemical hazard on peripheral crops
  - c Test results concerning chemical hazard on succeeding crops
- 3) Test results concerning toxicity  
Tests to investigate acute toxicity
  - a Test results concerning acute oral toxicity
  - b Test results concerning acute transdermal toxicity
  - c Test results concerning acute inhalation toxicity
  - d Test results concerning skin irritancy
  - e Test results concerning eye irritancy
  - f Test results concerning skin sensitization
  - g Test results concerning acute neural toxicity
  - h Test results concerning acute delayed neural toxicityTests to investigate medium to long-term effects
  - i Results from the 90-day repeated oral administration toxicity test
  - j Results from the 21-day repeated dermal administration toxicity test
  - k Results from the 90-day repeated inhalation toxicity test
  - l Results from the repeated oral administration neural toxicity test
  - m Results from the 28-day repeated administration delayed neural toxicity test
  - n Results from the 1-year repeated oral administration toxicity test
  - o Test results concerning carcinogenicity
  - p Test results concerning reproductive toxicity
  - q Test results concerning teratogenic potency
  - r Test results concerning mutagenic propertiesTests for acquiring useful information for considering steps to counter acute toxic symptoms
  - s Test results concerning impact on vital functionsTests for grasping information on the pesticide decomposition paths inside flora and fauna



and the structure of decomposed substances, etc.

- t Test results concerning fate inside animal bodies
  - u Test results concerning fate inside plant bodies
    - Tests to assess environmental impacts
  - v Test results concerning fate in soil
  - w Test results concerning fate in water
  - x Test results concerning impacts on aquatic plants and animals
  - y Test results concerning impacts on useful living organisms other than aquatic plants and animals
  - z Test results concerning properties, stability and degradability, etc. of active ingredients
  - al Test results concerning calculation of predicted environment concentration.
- 4) Test results concerning residual persistence
- a Test results concerning residual persistence in crops
  - b Test results concerning residual persistence in soil

In Japan, the GLP system was introduced to pesticide registration scheme in 1984, making it necessary to conduct stringent quality assurance with respect to test results.

### **Situation regarding Registered Pesticides in Japan**

#### **Situation regarding Registered Pesticides and Distribution, etc. in Japan**

Registration of pesticides is to be carried out according to each brand, and even if ingredients are the same, it is necessary to conduct separate registrations if the form of pesticide (powder or emulsion, etc.), contained quantities of active ingredients or manufactures and/or retailer are different. As of the end of December 2012, 172 companies had acquired pesticide registration. The number of registered cases was 4,332, and the number of registered active ingredients was 545. The number of registered pesticides has been decreasing each year after reaching a peak in 1990 (see Tables 9, 10 and 11). Moreover, whereas the registered numbers of insecticides and fungicides are decreasing, the registered number of herbicides is on the increase (see Figure 17). The industrial group for the pesticides sector in Japan is the Japan Crop Protection Association, which was established in 1946 and assumed its present form in 1953. This association is composed of 40 full-time members and 34 supporting members, and it is a member of the Asian Crop Protection Association (Croplife Asia) and the world Crop Protection Association (Croplife International). In Japan, because stringent controls continue to be imposed on off-patent active ingredients, there are very few generic pesticides. Indeed, generic pesticides don't even account for 1% of all registered pesticides.

Table 9 Changes in the Number of Registered Pesticides in Japan

| Pesticide year                                | 1987 | 1988 | 1989 | 1990 | 1991 | 1992 |
|---|------|------|------|------|------|------|
| Insecticide                                   | 2662 | 2603 | 2705 | 2680 | 2567 | 2438 |
| Fungicide                                     | 1216 | 1219 | 1236 | 1242 | 1225 | 1241 |
| Pesticide-fungicide                           | 1015 | 1071 | 1099 | 1118 | 1100 | 1074 |
| Herbicide                                     | 757  | 788  | 795  | 823  | 844  | 839  |
| Chemical fertilizer                           | 1    | 3    | 7    | 13   | 16   | 22   |
| Rodenticide                                   | 87   | 85   | 85   | 82   | 78   | 61   |
| Plant growth regulator                        | 82   | 82   | 102  | 106  | 115  | 114  |
| Pesticide-fungicide<br>plant growth regulator |      |      |      |      |      | 11   |
| Others  | 238  | 233  | 245  | 235  | 252  | 248  |
| Total   | 6018 | 6084 | 6274 | 6299 | 6197 | 6037 |

Table 10 Changes in the Number of Registered Pesticides in Japan

| Pesticide year                                | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 |
|---|------|------|------|------|------|------|------|------|
| Insecticide                                   | 2371 | 2261 | 2168 | 2087 | 1997 | 1913 | 1882 | 1830 |
| Fungicide                                     | 1242 | 1253 | 1233 | 1194 | 1222 | 1204 | 1293 | 1280 |
| Pesticide-fungicide                           | 1021 | 940  | 823  | 744  | 691  | 621  | 489  | 475  |
| Herbicide                                     | 811  | 901  | 931  | 975  | 1098 | 1199 | 1232 | 1310 |
| Chemical fertilizer                           | 26   | 31   | 41   | 43   | 43   | 48   | 48   | 44   |
| Rodenticide                                   | 50   | 47   | 47   | 47   | 48   | 47   | 45   | 44   |
| Plant growth regulator                        | 118  | 110  | 111  | 109  | 111  | 109  | 113  | 117  |
| Pesticide-fungicide<br>plant growth regulator | 13   | 13   | 16   | 17   | 17   | 17   | 17   | 15   |
| Others  | 230  | 224  | 219  | 218  | 212  | 211  | 204  | 194  |
| Total   | 5882 | 5780 | 5589 | 5434 | 5439 | 5369 | 5323 | 5309 |

Table 11 Changes in the Number of Registered Pesticides in Japan

| Pesticide year                             | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|--|------|------|------|------|------|------|------|------|
| Insecticide                                | 1702 | 1631 | 1542 | 1424 | 1288 | 1248 | 1205 | 1217 |
| Fungicide                                  | 1170 | 1123 | 1122 | 1093 | 1022 | 980  | 950  | 967  |
| Pesticide-fungicide                        | 560  | 561  | 566  | 555  | 539  | 498  | 481  | 507  |
| Herbicide                                  | 1363 | 1360 | 1345 | 1379 | 1374 | 1331 | 1302 | 1316 |
| Chemical fertilizer                        | 47   | 48   | 41   | 29   | 35   | 41   | 43   | 50   |
| Rodenticide                                | 39   | 37   | 34   | 34   | 34   | 34   | 34   | 33   |
| Plant growth regulator                     | 118  | 111  | 101  | 108  | 100  | 95   | 87   | 82   |
| Pesticide-fungicide plant growth regulator | 11   | 11   | 9    | 6    | 6    | 6    | 2    | 2    |
| Others                                     | 185  | 177  | 162  | 153  | 143  | 136  | 137  | 137  |
| Total                                      | 5205 | 5059 | 4922 | 4781 | 4541 | 4369 | 4241 | 4341 |

Note: The pesticide year starts in October and ends in September. This is unique to the pesticide industry of Japan.

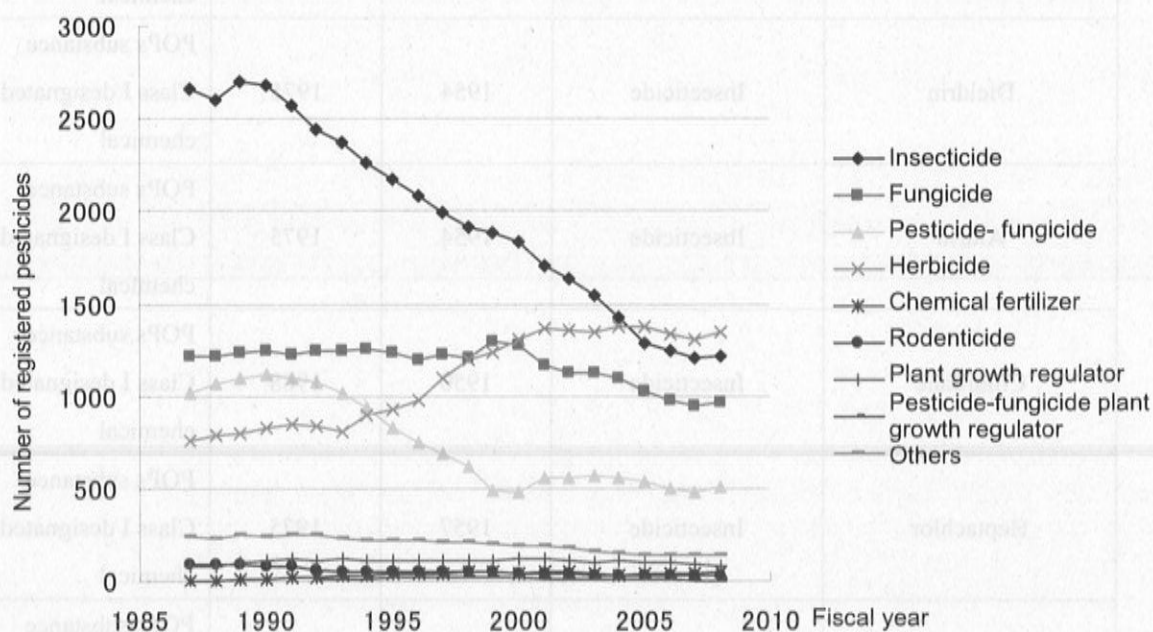


Figure 17 Movements in the Number of Registered Pesticides in Japan

### Banned Pesticides

Following revision of the pesticides control law in 2012, the following pesticides were newly added to the list of pesticides banned from use (Article 11 of the revised law). Prior to this, there was no system of prohibited use but only a prohibited sale system.

Table 12 Pesticides Prohibited from Use in Japan

| Name of pesticide | Use         | Registered year           | Year of expiration | Remarks  |
|-------------------|-------------|---------------------------|--------------------|--|
| Lindane           | Insecticide | 1949                      | 1971               | POPs substance<br>(Note 1)<br>Class I designated chemical (Note 2) |
| DDT               | Insecticide | 1948                      | 1971               | POPs substance<br>Class I designated chemical                      |
| Endrin            | Insecticide | 1954                      | 1975               | POPs substance<br>Class I designated chemical                      |
| Dieldrin          | Insecticide | 1954                      | 1975               | POPs substance<br>Class I designated chemical                      |
| Aldrin            | Insecticide | 1954                      | 1975               | POPs substance<br>Class I designated chemical                      |
| Chlordane         | Insecticide | 1950                      | 1968               | POPs substance<br>Class I designated chemical                      |
| Heptachlor        | Insecticide | 1957                      | 1975               | POPs substance<br>Class I designated chemical                      |
| Hexachlorobenzene | Fungicide   | No record of registration | -                  | POPs substance<br>Class I designated chemical                      |
| Mirex             | Insecticide | No record of registration | -                  | POPs substance<br>Class I designated chemical                      |

|                                       |   |                           |      |   |
|---------------------------------------|---|---------------------------|------|---|
| Toxaphene                             | Insecticide   | No record of registration | -    | POPs substance<br>Class I designated chemical                                     |
| Parathion                             | Insecticide   | 1952                      | 1972 | Strong acute toxicity caused numerous accidents among users                       |
| Methyl parathion                      | Insecticide   | 1952                      | 1971 | Strong acute toxicity caused numerous accidents among users                       |
| TEPP                                  | Insecticide   | 1950                      | 1969 | Strong acute toxicity caused numerous accidents among users                       |
| Mercurial                             | Fungicide   | 1948                      | 1973 | Toxic in the human body   |
| Lead arsenate                         | Insecticide   | 1948                      | 1978 | Crop persistence  |
| 2, 4, 5-T                             | Herbicide   | 1964                      | 1975 | Suspicion of teratogenicity, etc.   |
| CNP                                   | Herbicide   | 1965                      | 1996 | Contains dioxins  |
| PCP                                   | Herbicide•Fungicide                                 | 1955                      | 1990 | Contains dioxins  |
| PCNB                                  | Fungicide   | 1958                      | 2000 | Contains dioxins  |
| Difoltan                              | Fungicide   | 1964                      | 1988 | In the food standards, ADI (Note 3) cannot be set. (Suspicion of carcinogenicity) |
| Tricyclohexyltin hydroxide (Plictran) | Insecticide   | 1972                      | 1987 | In the food standards, ADI (Note 3) cannot be set. (Suspicion of teratogenicity)  |
| Kelthane                              | Insecticide   | 1956                      | 2004 | Class I designated chemical   |
| Pentachlorobenzene                    | Pesticides and byproduct from pesticide manufacture | No record of registration | -    | POPs substance<br>Class I designated chemical                                     |

|                                    |                      |                           |   |   |
|------------------------------------|----------------------|---------------------------|---|---|
| Alpha hexachlorocyclohexane        | Byproduct of lindane | No record of registration | - | POPs substance<br>Class I designated chemical |
| Beta benzene hexachlorocyclohexane | Byproduct of lindane | No record of registration | - | POPs substance<br>Class I designated chemical |
| Chlordecone                        | Insecticide          | No record of registration | - | POPs substance<br>Class I designated chemical |

(Note 1) POPs substances refer to chemical substances that are basically prohibited from manufacture and use according to the Stockholm Convention on Persistent Organic Pollutants (commonly referred to as the POPs Convention, adopted in 2000), and such substances possess human and environmental toxicity, non-degradability, bio-accumulative properties and long-distance mobility.

(Note 2) Class I designated chemicals possess non-degradability, high accumulative properties and long-term toxicity for humans, etc., and they are prohibited from manufacture, use and import, etc. in the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (1973, Law No. 117).

(Note 3) ADI, which stands for acceptable daily intake, refers to the amount of chemical substances that can be ingested every day over a lifetime without causing harm to health.

### Severely Restricted Pesticides

In Japan, there is a designation system for water polluting pesticides, soil persistent pesticides and crop persistent pesticides, and use of the designated pesticides is controlled. Water polluting pesticides are designated by the Minister of Environment as “pesticides that are used in large quantities over wide areas with risk of such use causing extreme damage to aquatic animals and plants” or “pesticides that carry risk of contaminating water quality and imparting damage to humans and livestock”. Water polluting pesticides can only be used in limited areas upon obtaining permission from the prefectural governor. As of August 2012, there are six designated water polluting pesticides, i.e. telodrin, endrin, benzoepin, PCP herbicide, rotenone and simazine (others have already been suspended from sale following expiration of their registration). As for pesticides that have strong persistence in soil, because of risk that they will pollute crops and cause damage to humans and livestock, they have been designated as soil persistent pesticides and also have controls imposed on use. Currently, two pesticides, dieldrin and aldrin, are designated, and both of these have already been suspended from sale following expiration of their registration. In addition, pesticides that persist in crops and risk causing harm to humans and livestock are controlled as persistent

pesticides. Currently, acidic lead arsenate and endrin are designated as crop persistent pesticides (both are no longer sold following expiration of their registration).

#### **System for Training and Licensing of Pesticides Managers and Users, etc. in Japan**

In Japan, there are several Good Agricultural Practices (GAP). Accordingly, an issue is the preparation of a common foundation for initiatives. As the common foundation for Good Agricultural Practices (GAP) including sophisticated initiatives targeting a wide scope such as food safety, environmental protection and labor safety, etc., the Ministry of Agriculture, Forestry and Fisheries compiled the Good Agricultural Practices (GAP) Common Foundation Guidelines for vegetables, rice and barley in April 2010. The guidelines underwent revision in March 2011 in order to add other crops and forestry products to the targets. The Ministry of Agriculture, Forestry and Fisheries has raised the policy goals of achieving 3,000 GAP-introducing production areas and 1,600 GAP-introducing production areas pursuant to the guidelines by 2015.

In Japan, there is a qualification system for pesticide management instructors and pesticide proper use advisors. The objective of this is to enable persons in instructing positions such as agricultural workers, pesticide retailers, pest control enterprises and golf course operators to acquire the knowledge to offer advice and guidance on the proper use of pesticides. Persons who pass qualification tests after sitting the pesticide management instructor training staged by prefectural governments are certified as pesticide management instructors by the prefectural governors. The valid period for this is three years in numerous prefectures. In some prefectures, it is necessary to sit refresher training. In the training, trainees learn about the characteristics of pesticides, the use criteria prescribed in Article 12 of the Agricultural Chemicals Control Act, guidelines on instruction of safe pesticide use in the prefecture concerned, safe use and handling of pesticides that have been designated as poisonous and deleterious substances in the Poisonous and Deleterious Substances Control Law, safe use of pesticides that require particular care, appropriate methods for controlling and preventing disease, pests and weeds, prevention of harmful effects on humans and livestock and environmental contamination in line with use of pesticides, and so on. The pesticide management instructor system in Japan differs from the license systems in the EU and America in that it basically does not target agricultural workers. A notification system is adopted for retailing of pesticides. Moreover, the Pesticides Regulation Act stipulates the following regarding pesticides: "Users of agricultural chemicals shall, when receiving instructions from the agricultural improvement promotion staff, as those specified in Paragraph 1 of Article 8 of the Law on Agricultural Improvement Promotion (Law No. 165 of 1948) or insect pest control staff specified in Paragraph 1 of Article 33 of the Plant Epidemics Prevention Law (Law No.151 of 1950), or any corresponding staff appointed by Prefectural Governors."

(The end of the Handout)

