

## Poisonous and Deleterious Substances Control Law

(Law No. 303 of December 28, 1950)

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### (Purpose)

Article 1 The purpose of this Law is to carry out the necessary controls on poisonous and deleterious substances from the point of view of health and hygiene.

### (Definitions)

Article 2 The term "poisonous substance" in this Law refers to the substances listed in Attached Table 1, and does not apply to either drugs or quasi-drugs.

2. The term "deleterious substance" in this Law refers to the substances listed in Attached Table 2, and does not apply to either drugs or quasi-drugs.

3. The term "special substance" in this Law refers to the poisonous substances listed in Attached Table 3.

### (Rules on Prohibition)

Article 3 Only persons who are registered as manufacturers of poisonous or deleterious substances shall manufacture poisonous or deleterious substances for the purpose of selling them or giving them away.

2. Only persons who are registered as importers of poisonous or deleterious substances shall import poisonous or deleterious substances for the purpose of selling them or giving them away.

3. Only persons who are registered as sellers of poisonous or deleterious substances shall sell them or give them away, or store, transfer or exhibit poisonous or deleterious substances for the purpose of selling them or giving them away. However, this does not apply to the case where manufacturers or importers of poisonous or deleterious substances sell or give away, or store, transport or exhibit poisonous or deleterious substances which themselves have manufactured or imported, to another manufacturer, importer or seller of poisonous or deleterious substances (hereinafter referred to as "business operators handling poisonous or deleterious substances") for such purposes.

Article 3-2 Only persons who are manufacturers of poisonous or deleterious substances or who have obtained a license for manufacturing or using special poisonous substances for academic research from a prefectural governor (hereinafter referred to as “researcher into special poisonous substances”) shall manufacture special poisonous substances.

2. Only persons who are importers of poisonous or deleterious substances or researchers into special poisonous substances shall import special poisonous substances.
3. Only persons who are researchers into special poisonous substances or who are permitted to use a specific special poisonous substances as designated specifically for that substance by a Cabinet Order (hereinafter referred to as a “user of special poisonous substances”) shall use special poisonous substances. However, this does not apply to the case where manufacturers of poisonous or deleterious substances use special poisonous substances for manufacturing poisonous or deleterious substances.
4. Researchers into special poisonous substances shall not use special poisonous substances for any purpose other than academic research.
5. User of special poisonous substances shall not use special poisonous substances for the purpose other than those designated specifically for that substance by a Cabinet Order.
6. Only persons who are business operators handling poisonous or deleterious substances, researchers into special poisonous substances, or users of special poisonous substances shall transfer or receive special poisonous substances.
7. The persons listed in the preceding paragraph shall not transfer special poisonous substances to persons other than those listed in the same paragraph or receive special poisonous substances from persons other than those listed in the same paragraph.
8. Business operators handling poisonous or deleterious substances and researchers into special poisonous substances shall only transfer the special poisonous substances to users of special poisonous substances if the user is permitted to use those substances.
9. If criteria for the quality, coloring, labeling or display of special poisonous substances have been set down by a Cabinet Order to prevent hazards to public

health and hygiene, business operators handling poisonous or deleterious substances and researchers into special poisonous substances shall not transfer said special poisonous substances to users of special poisonous substances unless they meet the criteria.

10. No person who is a business operator handling poisonous or deleterious substances, researcher into special poisonous substances, or user of special poisonous substances shall possess special poisonous substances.
11. A user of special poisonous substances shall not receive or possess special poisonous substances except for those which he or she is permitted to use.

Article 3-3 No poisonous or deleterious substance (including substances containing these) which has a stimulant, hallucinogenic or narcotic effect, as set down in a Cabinet Order, shall be taken without proper reason, or inhaled or possessed for such purposes.

Article 3-4 No poisonous or deleterious substance which is flammable, ignitable or explosive, as set down in a Cabinet Order, shall be possessed, except for business purposes or for a justifiable reason.

(Registration of Business)

Article 4 Registration for manufacture or import of poisonous or deleterious substances shall be granted to manufacturing plants or business offices individually by the Minister of Health, Labour and Welfare, and registration for selling shall be granted to stores individually by the governor of the prefecture where the store is located (the mayor of the municipality or ward, if the store is located in a municipality set down in Article 5, Paragraph 1 of Cabinet Order of the Community Health Law (Law No. 101 of 1947) (hereinafter referred to as "municipality with a health center") or in a region in a special ward; the same applies to Paragraph 3, Paragraph 3 of Article 7, Paragraph 1 of Article 10, and Paragraph 1 of Article 21).

2. Persons wishing to receive registration for the manufacture or import of poisonous or deleterious substances shall submit an application form to the Minister of Health, Labour and Welfare for each manufacturing plant, in the case of a manufacturer, and for each business office in the case of an importer, by way of the governor of the prefecture where that manufacturing plant or business office is located.

3. Persons wishing to receive registration for selling poisonous or deleterious substances shall submit an application form for each store separately to the governor of the prefecture where the store is located.
4. Registrations for manufacture or import shall become invalid after 5 years, unless renewed, and registrations for selling shall likewise become invalid after 6 years.

#### (Type of Registration for Selling)

Article 4-2 The types of registration for selling poisonous or deleterious substances are classified as follows:

- (1) Registration for selling general products
- (2) Registration for selling agricultural products
- (3) Registration for selling specified products

#### (Restriction on Selling Items)

Article 4-3 Persons who are registered as sellers of agricultural products shall only sell or give away, or store, transport or exhibit poisonous or deleterious substances, which are necessary for agriculture, as set down by the Ministry of Health, Labour and Welfare (MHLW) Ordinance, for the purpose of selling them or giving them away.

2. Persons who are registered as sellers of specified products shall only sell or give away, or store, transport or exhibit the poisonous or deleterious substances which are set down in the MHLW Ordinance, for the purpose of selling them or giving them away.

#### (Criteria for Registration)

Article 5 If the Minister of Health, Labour and Welfare, prefectural governor, the mayor of the municipality or special ward with a health center finds that the facilities of a person wishing to receive registration for the manufacture, import or sale of poisonous deleterious substances do not conform to the criteria set down in the MHLW Ordinance, or if the registration of a person is canceled pursuant to the provisions of Paragraph 2 or Paragraph 4 of Article 19, and a period of 2 years has not passed since the date of cancellation, that person may not receive registration under Article 4.

(Items Registered)

Article 6 Registration in Article 4 shall be made for the following items:

- (1) The name and address of the applicant (in the case of a corporation, the name and address of its main business office)
- (2) In the case of registration for manufacture or import, the poisonous or deleterious substances that may be manufactured or imported
- (3) The address of the manufacturing plant, business office or store

(Licenses for Researchers into Special Poisonous Substances)

Article 6-2 Persons wishing to receive a license as a researcher into special poisonous substances shall submit an application form to the prefectural governors.

2. The prefectural governors shall grant a license for a researcher into special poisonous substances only to persons who have proper knowledge of poisonous substances and who need to manufacture or use special poisonous substances for academic research.
3. The prefectural governors must refuse to grant a license for a researcher into special poisonous substances to the following persons:
  - (1) Persons who are unable to carry out the work of a researcher into special poisonous substance properly, due to the mental or physical disabilities set down in the MHLW Ordinance
  - (2) Persons who are addicted to narcotics, marijuana, opiates or stimulants
  - (3) Persons who have committed crimes related to poisonous or deleterious substances or the Pharmaceutical Affairs Law and have been given a court sentence imposing a fine or a more severe sentence, where a period of 3 years has not passed since the date on which the sentence was completed or the date on which the sentence became ineffective
  - (4) Persons whose license was canceled pursuant to the provisions Paragraph 4 of Article 19, where a period of 2 years has not passed since the date of cancellation

(Person Responsible for Handling Poisonous or Deleterious Substances)

Article 7 Business operators handling poisonous or deleterious substances shall appoint a full time employee responsible for handling poisonous or deleterious substances

at each manufacturing plants, business offices or stores where poisonous or deleterious substances are directly handled, to prevent hazards to public health and hygiene due to poisonous or deleterious substances. However, this does not apply to manufacturing plants, business offices or stores where the business operator handling poisonous or deleterious substances takes charge of the prevention of hazards to public health and hygiene due to poisonous or deleterious substances, acting as the person responsible for handling poisonous or deleterious substances.

2. If a business operator handling poisonous or deleterious substances manages two or more operations, among the manufacturing, importing or selling of poisonous or deleterious substances, at the same time, and manufacturing plants, business offices or stores are adjacent to each other, or two or more operations involving the sale of poisonous or deleterious substances are conducted in the same store, it is sufficient to appoint one person responsible for handling poisonous or deleterious substances for all of these institutions, notwithstanding the provisions of the preceding paragraph.
3. If a business operator handling poisonous or deleterious substances has appointed a person responsible for handling poisonous or deleterious substances, the name of the appointee shall be reported to the Minister of Health, Labour and Welfare within 30 days, by way of the governor of the prefecture where the manufacturing plant or business office is located if the person has been registered as a manufacturer or importer, or through the governor of the prefecture where the store is located if the person has been registered as a seller. This also applies if a person responsible for handling poisonous or deleterious substances is replaced.

#### (Qualifications of Persons Responsible for Handling Poisonous or Deleterious Substances)

Article 8 Only the following persons may be responsible for handling poisonous or deleterious substances as in the preceding article:

- (1) Pharmacists
- (2) Persons who have completed a course of study in applied chemistry at a school set down in the MHLW Ordinance
- (3) Persons who have passed an examination for handling poisonous or deleterious substances organized by the prefectural governors

2. The following persons may not serve as persons responsible for handling poisonous or deleterious substances as in the preceding paragraph:
  - (1) Persons less than 18 years of age
  - (2) Persons unable to carry out the work of a person responsible for handling poisonous or deleterious substances properly due to mental or physical disabilities, as set down in the MHLW Ordinance
  - (3) Persons who are addicted to narcotics, marijuana, opiates or stimulants
  - (4) Persons who have committed crimes related to poisonous or deleterious substances or the Pharmaceutical Affairs Law and have been given a court sentence imposing a fine or a more severe sentence, where a period of 3 years has not passed since the date on which the sentence was completed or the date on which the sentence became ineffective
3. The examinations for handling poisonous or deleterious substances in Paragraph 1, Item (3) shall be divided into classes: one for handling general poisonous or deleterious substances, one for handling poisonous or deleterious substances for agricultural products, and one for handling poisonous or deleterious substances for specified products.
4. A person who has passed an examination for handling poisonous or deleterious substances for agricultural products or an examination for handling of poisonous or deleterious substances for specified products may serve as a person responsible for handling that type of poisonous or deleterious substances at the business office of an importer or the store of a seller of agricultural products, if that person handles only the poisonous or deleterious substances in Article 4-3, Paragraph 1 set down in the MHLW Ordinance, or at the business office of an importer or the store of a seller of specified products, if that person handles only the poisonous or deleterious substances in Article 4-3, Paragraph 2 set down in the MHLW Ordinance.
5. Matters concerning the examination for handling poisonous or deleterious substance in addition to those given by this Law, for example the subjects of the examination, shall be set down in the MHLW Ordinance.

(Changes in Registration)

Article 9     Manufacturers or importers of poisonous or deleterious substances who wish to manufacture or import poisonous or deleterious substances for which

registration has not been granted must first receive a registration for change related to the item in Article 6, Item (2).

2. The provisions in Article 4, Paragraph 2 and Article 5 shall apply likewise to changes in the registration.

#### (Giving Notice)

**Article 10** If any of the events listed below occurs to a business operator handling poisonous or deleterious substances, said operator shall give notice of this event within 30 days to the Minister of Health, Labour and Welfare, via the governor of the prefecture where the manufacturing plant or business office is located, in the case of a person registered as a manufacturer or importer, or through to the governor of the prefecture where the store is located, for a person registered for selling.

- (1) A change of name or address (in the case of a corporation, a change in the name and address of its main business office).
  - (2) A change in an important aspect of the facilities used for manufacturing, storing, or transporting poisonous or deleterious substances.
  - (3) Changes to any other items set down in the MHLW Ordinance.
  - (4) The closure of operations at the said manufacturing plant, business office or store.
2. If any of the following events occurs to a researcher into special poisonous substances, notice of this event shall be given to the prefectural governor within 30 days.
    - (1) A change of name or address.
    - (2) A change in another item set down in the MHLW Ordinance.
    - (3) The end of the relevant research.
  3. In the case of Paragraph 1, Item (4) or Item (3) of the preceding paragraph, the said registration or license will become invalid when such notice is given.

#### (Handling of Poisonous or Deleterious Substances)

**Article 11** Business operators handling poisonous or deleterious substances and researchers into special poisonous substances shall take the necessary measures to prevent the theft or loss of poisonous or deleterious substances.

2. Business operators handling poisonous or deleterious substances and researchers into special poisonous substances shall take the necessary measures to preventing poisonous or deleterious substances or substances containing them, as set down in a Cabinet Order, from splashing, leaking, flowing, or permeating out of the manufacturing plant, business office, store or research center, or from soaking into the ground of the institutions concerned.
3. If a business operator handling poisonous or deleterious substances or a researcher into special poisonous substances transports poisonous or deleterious substances or substances in the preceding paragraph set down by the Cabinet Order, in places other than the manufacturing plant, business office, store or research center, the necessary measures shall be taken to prevent the substances concerned from splashing, leaking, flowing, or permeating out.
4. A business operator handling poisonous or deleterious substances and researcher into special poisonous substances shall not use containers which are usually used for food or drinks to store poisonous substances or deleterious substances set down in the MHLW Ordinance.

#### (Labeling and Display of Poisonous or Deleterious Substances)

Article 12 On the containers and wrappers of poisonous or deleterious substances, business operators handling poisonous or deleterious substances and researchers into special poisonous substances shall mark the words "FOR NON MEDICAL USE," and the words "POISONOUS SUBSTANCE" in white letters on a red background on poisonous substances and the words "DELETERIOUS SUBSTANCE" in red letters on a white background on deleterious substances.

2. Business operators handling poisonous or deleterious substances shall not sell or give away poisonous or deleterious substances unless the following items are marked on the container and wrapper.
  - (1) The name of poisonous or deleterious substances
  - (2) The composition and quantity of the poisonous or deleterious substances
  - (3) The names of antidotes for each poisonous or deleterious substance, where set down by the MHLW Ordinance
  - (4) The handling of poisonous or deleterious substances, and any other information deemed to be necessary for use as set down by the MHLW Ordinance

3. In places where a poisonous or deleterious substance are stored or arranged, business operators handling poisonous or deleterious substances and researchers into special poisonous substances shall display the words "FOR NON MEDICAL USE," the words "POISONOUS SUBSTANCE" for poisonous substances, and the words "DELETERIOUS SUBSTANCE" for deleterious substances.

(Selling or Giving Away Poisonous or Deleterious Substances Used for Specific Purposes)

Article 13 Business operators handling poisonous or deleterious substances shall not sell or give away poisonous or deleterious substances listed in the Cabinet Order as agricultural products unless they have been colored in accordance with the procedures specified by MHLW Ordinance.

Article 13-2 Business operators handling poisonous or deleterious substances shall not sell or give away those poisonous or deleterious substances deemed to be used mainly in the households of general consumers as set down in the Cabinet Order, unless the composition, quantities, container and wrapper meet the criteria set down in the Cabinet Order.

(Procedures for Transferring Poisonous or Deleterious Substances)

Article 14 Every time a business operator handling poisonous or deleterious substances sells or gives a poisonous or deleterious substance to another relevant business operator, the following information shall be recorded in a document.

- (1) The name and quantity of the poisonous or deleterious substance
  - (2) The date the substance was sold or given
  - (3) The name, occupation and address of the receiver (in the case of a corporation, its name and main business office)
2. Business operators handling poisonous or deleterious substances shall not sell or give poisonous or deleterious substances to persons other than business operators handling poisonous or deleterious substances, unless they are given a document prepared as set down in the MHLW Ordinance containing the information in the preceding paragraph by the receiver.
  3. In the case in the preceding paragraph, business operators handling poisonous or deleterious substance shall be allowed to receive the material required in the

document concerned by methods involving electronic data processing or other information communication technology, in place of providing the document pursuant to the provisions of the preceding paragraph, with the approval of the said receiver, as set down in the Cabinet Order. In this case, the said business operator handling poisonous or deleterious substances shall be considered to have received the said document.

4. When the documents in Paragraphs 1 and 2 are used, and the method specified in the first part of the preceding paragraph is taken, the business operator handling poisonous or deleterious substances shall preserve electromagnetic records created by a relevant method (records created by electronic methods, electromagnetic methods or other methods that cannot be recognized by the human sensory system, used in information processing by electronic computers as set down in the MHLW Ordinance) for a period of 5 years from the date of when the poisonous or deleterious substance concerned was sold or given.

#### (Restrictions on the Delivery of Poisonous or Deleterious Substances)

Article 15 Business operators handling poisonous or deleterious substances shall not deliver poisonous or deleterious substances to the following persons:

- (1) Persons who are less than 18 years of age
  - (2) Persons who are unable to take proper measures to prevent hazards of poisonous or deleterious substances to public health and hygiene due to mental or physical disabilities, as set down in the MHLW Ordinance
  - (3) Persons who are addicted to narcotics, marijuana, opiates or stimulants
2. Business operators handling poisonous or deleterious substances shall not deliver the items in Article 3-4 set down in the Cabinet Order unless they have verified the name and address of the receiver concerned, pursuant to the provisions of the MHLW Ordinance.
  3. Business operators handling poisonous or deleterious substances shall keep books, and when they perform the verification process required by the preceding paragraph, they shall enter information concerning the verification in the books as set down in the MHLW Ordinance.
  4. A business operator handling poisonous or deleterious substances shall keep the books required in the preceding paragraph for a period of 5 years from the date of the last entry.

(Disposal)

Article 15-2 Poisonous or deleterious substances and substances in Article 11, Paragraph 2 set down in the Cabinet Order shall only be discarded by disposal in accordance with the technical criteria set down in the Cabinet Order.

(Recall Orders, etc.)

Article 15-3 If a prefectural governor (or, for a seller of poisonous or deleterious substances, the mayor of the municipality or special ward with a health center where the store is located; as in Article 17, Paragraph 2, Article 23, Item (3)) find that the methods of disposal of poisonous or deleterious substances or those in Article 11, Paragraph 2 designated by Cabinet Order, used by a business operator handling poisonous or deleterious substances or a researcher into special poisonous substances, does not meet the criteria in the preceding article set down in the Cabinet Order, and there is a risk to the health and hygiene of the general public if this is neglected, the governor may order the person concerned to recall the said waste, eliminate its toxicity or take other measures necessary to prevent hazards to public health and hygiene.

(Technical Criteria for Transport, etc.)

Article 16 Technical criteria related to the transport, storage or other handling of poisonous or deleterious substances may be set down by a Cabinet Order to prevent hazards to public health and hygiene, as deemed necessary.

2. The following items may be set down by a Cabinet Order to prevent hazards to public health and hygiene, if deemed particularly necessary.
  - (1) Technical criteria for handling materials which have come into contact with special poisonous substances or materials containing special poisonous substances.
  - (2) Forbidding the sale or giving away of materials containing special poisonous substances unless the manufacturer or importer of the materials containing special poisonous substances concerned complies with certain criteria on quality or coloring.
  - (3) Forcing manufacturers, importers or sellers of substances containing special poisonous substances who sell these or give them away to display certain notices.

(Procedures in an Accident)

Article 16-2 If a poisonous or deleterious substances or a substance in Article 11, Paragraph 2 set down in the Cabinet Order, being handled by a business operator handling poisonous or deleterious substances or a researcher into special poisonous substances, have splashed, leaked, flowed or permeated out or soaked into the ground, the business operator handling poisonous or deleterious substances or the researcher into special poisonous substances concerned shall immediately notify the public health department, police or fire service of this event if there is a risk to the health and hygiene of the general public, and shall take the necessary emergency measures to prevent hazards to public health and hygiene.

2. If a poisonous or deleterious substance handled by a business operator handling poisonous or deleterious substances or a researcher into special poisonous substances, is stolen or lost, the business operator handling poisonous or deleterious substances or the researcher into special poisonous substances concerned shall immediately notify the police of this.

(On the Spot Inspections, etc.)

Article 17 If deemed necessary for public health and hygiene, the Minister of Health, Labour and Welfare may request that a manufacturer or importer of poisonous or deleterious substances make a report or have a person who has been appointed as a pharmaceutical inspector enter the manufacturing plant, business office, or other site where poisonous or deleterious substances are being handled by the manufacturer or importer concerned, and inspect accounting documents or other materials, question related persons, or collect samples of poisonous or deleterious substances or substances in Article 11, Paragraph 2 set down in the Cabinet Order or substances which are suspected to be such substances, using only the minimum quantity necessary for examination.

2. If deemed necessary for public health and hygiene, a prefectural governor may request that seller of poisonous or deleterious substances or a researcher into special poisonous substances make a report or have a person who has been appointed as a pharmaceutical inspectors enter the store, research center, or other sites where poisonous or deleterious substances are being handled by the seller or researcher concerned in the course of business, and to inspect accounting documents or other materials, question related persons, or collect samples of poisonous or deleterious substances or substances in Article 11, Paragraph 2 designated by Cabinet Order or substances which are suspected to

be such substances, using only the minimum quantity necessary for examination.

3. The person designated pursuant to the provisions of preceding two paragraphs above shall be called an inspector of poisonous and deleterious substances.
4. Inspectors of poisonous and deleterious substances shall carry certificates identifying themselves and present it to the persons concerned on demand.
5. The provisions in Paragraphs 1 and 2 shall not be construed as giving inspectors the authority to detect crimes.

Article 18 Deleted

(Cancellation of Registration, etc.)

Article 19 If the facilities owned by the person concerned are thought not to comply with the criteria in the provisions of Article 5 set down in the MHLW Ordinance, the Minister of Health, Labour and Welfare may order registered manufacturers or importers of poisonous or deleterious substances, or the prefectural governors (the mayors of the municipalities or special wards in the case of sellers with store located in municipalities or special wards with health centers, as in Paragraphs 3 and 4) may order registered sellers, to take the necessary measures so that their facilities meet the criteria in the provisions of the same article in the MHLW Ordinance, within an appropriate designated period.

2. If a person who has received the order in the preceding paragraph does not take the necessary measures within the designated period, the Minister of Health, Labour and Welfare, or a prefectural governor, or the mayor of a municipalities or special ward with a health center, shall cancel the registration of the person concerned.
3. The Minister of Health, Labour and Welfare may order manufacturers or importers to replace persons responsible for handling poisonous or deleterious substances for manufacture or import of poisonous or deleterious substances, and prefectural governors may order sellers to replace persons responsible for handling poisonous or deleterious substances for selling of poisonous or deleterious substances, if they have violated this Law or are considered unfit for their post.

4. The Minister of Health, Labour and Welfare may cancel the registration of registered manufacturers or importers of poisonous or deleterious substances, and the prefectural governors may cancel the registration of registered sellers or researchers into special poisonous substances, or cancel their license as a researcher into special poisonous substances, or these bodies may order the suspension of the whole or a part of a business for a specified period, if the persons concerned have violated this Law or any of the measures taken based on this Law (including violations of Article 6-2, Paragraph 3, Items (1) to (3) for researchers into special poisonous substances).
5. If a prefectural governor deems it necessary to apply the legislation in the preceding paragraphs to manufacturers or importers of poisonous or deleterious substances, he or she shall report this to the Minister of Health, Labour, and Welfare.
6. The Minister of Health, Labour and Welfare may, if he or she deems it necessary in an emergency, instruct the prefectural governors or the mayors of the municipalities or special wards with health centers to take measures based on the provisions of Paragraphs 1 through 4.

(Special Cases Concerning Methods of Hearings, etc.)

Article 20 The notice required in Article 15, Paragraph 1 and Article 30 of the Administrative Procedures Law (Law No. 88, 1993) for measures pursuant to the provisions of Paragraphs 2 to 4 of the preceding article shall be given one week prior to the date of a hearing or the submission deadline of a document giving justification (if the person concerned is given an opportunity to provide justification orally, the date and time of this justification).

2. The Minister of Health, Labour and Welfare or the prefectural governors or the mayors of the municipalities or special wards with health centers shall publicly announce the date and place of the hearing at the time of giving the notice required in Article 15, Paragraph 1 of the Administrative Procedures Law for the cancellation of a registration pursuant to the provisions of Paragraph 2 of the preceding article, an order to replace the persons responsible for handling poisonous or deleterious substances pursuant to the provisions of Paragraph 3 of the same article, or the cancellation of a license pursuant to the provisions of Paragraph 4 of the same article (referred to as “measures for canceling registration” in the next paragraph).

3. The session conducted on the day of hearing for the measures for canceling registration shall be open to the public.

(Measures to be Taken in the Case of Invalid Registration, etc.)

**Article 21** If the registration for a business or a license as a researcher into special poisonous substances becomes invalid, or a user of special poisonous substances stops using these substances, the applicable business operators handling poisonous or deleterious substances, researchers into special poisonous substances or users of special poisonous substances shall report the name of the products and the quantity which he or she currently possesses within 15 days, to the Minister of Health, Labour and Welfare, in the case of manufacturers or importers of poisonous or deleterious substances, via the governor of the prefecture where the manufacturing plant or business office is located, or, in the case of sellers of poisonous or deleterious substances, to the governor of the prefecture where the store is located.

2. If a person obliged to give notice pursuant to the provisions of the preceding paragraph transfers his or her poisonous or deleterious substances to a business operator handling poisonous or deleterious substances, a researcher into special poisonous substances or a user of special poisonous substances in the same paragraph within 50 days from the date of having an obligation to give the relevant notice, the provisions of Article 3-2, Paragraphs 6 and 7 shall not apply to said transfer and receipt, nor shall the provisions of Article 3-2, Paragraph 10 apply to the possession of the special poisonous substances by the person concerned in the preceding paragraph during this period.
3. If a person who was a business operator handling poisonous or deleterious substances or a researcher into special poisonous substances transfers special poisonous substances listed in Paragraph 1 within the period in the preceding paragraph, the provisions of Article 3-2, Paragraphs 8 and 9 shall apply to the person concerned, with that person regarded as a business operator handling poisonous or deleterious substances or a researcher into special poisonous substances.
4. If a business operator handling poisonous or deleterious substances, a researcher into special poisonous substances, or a user of special poisonous substances dies, or the corporation concerned ceases to exist after a merger, the provisions of the preceding three paragraphs shall apply mutatis mutandis to the

heir or the person managing the inheritance on behalf of the heir, or the representative continuing to exist or the appointer after the merger.

(Notice Given by Operation Handlers)

Article 22 Persons who carry out the operations set down in the Cabinet Order and handle sodium cyanide or other poisonous or deleterious substances set down in the Cabinet Order in the course of business shall report the following items, set down in the MHLW Ordinance, for each of the operation sites within 30 days from the date of handling the poisonous or deleterious substances concerned in the course of business to the governor of the prefecture where their site of operation is located.

- (1) The name and address (or in the case of a corporation, the name and address of its main business office)
  - (2) The poisonous or deleterious substances handled, from among sodium cyanide and the other poisonous or deleterious substances set down in the Cabinet Order
  - (3) The address of the site of operations
  - (4) The other items set down in the MHLW Ordinance
2. If a Cabinet Order is enacted based on the provisions of the preceding paragraph, and a person is subject to the provisions of the same paragraph due to the execution of the Cabinet Order, he or she shall give notice of the items specified in the same paragraph, within 30 days of the date of execution of the Order.
  3. If the operation concerned at the said site of operation is no longer being conducted, or if the poisonous or deleterious substance applicable to Paragraph 1 is no longer used in the course of business at the said site of operations, or any of the details listed in the same paragraph changes, the person who gave notice pursuant to Paragraph 2 above shall give notice of this to the governor of the prefecture where the said site of operation is located.
  4. The provisions of Paragraphs 1 and 3 of Articles 7, 8, 11, and 12, Article 15-3, Article 16-2, and Paragraphs 2 to 5 of Article 17, and Paragraphs 3 and 6 of Article 19 shall apply mutatis mutandis to the persons specified in Paragraph 1 (including the persons specified in Paragraph 2; this applies hereafter within this article).

5. The provisions of Article 11 and Paragraphs 1 and 3 of Article 12, Article 16, Item (2) and Paragraphs 2 to 5 of Article 17 shall apply likewise to persons who handle poisonous or deleterious substances set down in the MHLW Ordinance in the course of business and who are not business operators handling poisonous or deleterious substances, researchers into special poisonous or persons specified in Paragraph 1.
6. If persons to which Paragraph 1 applies are considered to have made a violation of the procedure given in Article 7 applied mutatis mutandis to Paragraph 4, or the provisions of Article 11, or Paragraph 3 of Article 19 applied mutatis mutandis to the same paragraph, or that persons to which the preceding paragraph applies are thought to have made a violation of the provision given in Article 11 applied mutatis mutandis to the same paragraph, the Minister of Health, Labour and Welfare and the prefectural governors may order the persons concerned to take the necessary measures within an appropriate designated period of time.
7. The provisions of Article 20 shall apply mutatis mutandis if the Minister of Health, Labour and Welfare or a prefectural governor takes the measures in Article 19 of Paragraph 3, applied mutatis mutandis to Paragraph 4 or the measures in the preceding paragraph.

(Fees)

Article 23 The persons specified in the following items (limited to applicants to the Minister of Health, Labour and Welfare) shall pay fees to the national treasury in the amount set down in the Cabinet Order, taking into account the expenses required for the national review of applications for the item concerned.

- (1) Persons applying for registration for manufacture or import of poisonous or deleterious substances
- (2) Persons applying for a renewal of registration under Item (1)
- (3) Persons applying for a change in registration under Item (1)

(Inquiries to the Central Pharmaceutical Affairs Council)

Article 23-2 The Minister of Health, Labour and Welfare shall ask the opinion of the Central Pharmaceutical Affairs Council before proposing that the Cabinet Orders given in Paragraph 1 of Article 16, Attached Table 1, Item (28), Attached Table 2, Item (94), and Attached Table 3, Item (10) are established, changed or

removed. This does not apply if the Pharmaceutical Affairs Council finds that the matter concerned is of minor importance.

(Work Processed by the Prefectural Authorities)

Article 23-3 Part of the work performed under the authority of Minister of Health, Labour and Welfare pursuant to the provisions of this Law may be undertaken by the prefectural governors, as set down in the Cabinet Order.

(Work Conducted by the Ministry of Health and Labour in an Emergency)

Article 23-4 Work performed under the authority of the prefectural governors pursuant to the provision of Article 17, Paragraph 2 shall be performed by the Minister of Health, Labour and Welfare or the prefectural governors if it is found by the Minister of Health, Labour and Welfare to be an urgent necessity. In such cases, the provisions in this Law related to the prefectural governor (but only those related to said work) shall apply to the Minister of Health, Labour and Welfare, and shall be taken as provisions concerning the Minister of Health, Labour and Welfare.

2. If the Minister of Health, Labour and Welfare or the prefectural governor undertakes work as specified in the previous paragraph, the work concerned shall be performed under close mutual cooperation.

(Classification of Work)

Article 23-5 Work processed by the prefectural authorities pursuant to the provisions of Article 4, Paragraph 2 (including application mutatis mutandis of these provisions in Article 9, Paragraph 2), Article 7, Paragraph 3 (limited to part in relation to manufacturers or importers), Article 10, Paragraph 1 (limited to part in relation to manufacturers or importers), and Article 21, Paragraph 1 (limited to part in relation to manufacturers or importers and including application mutatis mutandis of these provisions in Article 21, Paragraph 4) shall be contract work under Item (1) as specified in Article 2, Paragraph 9, Item (1) of the Local Government Law (Law No. 67, 1947).

(Delegation of Authority)

Article 23-6 The authority of the Minister of Health, Labour and Welfare under the provisions of this Law may be delegated to the directors of local health authorities set down in the MHLW Ordinance.

2. The authority delegated to the directors of the local health authority pursuant to the provisions of the previous paragraph may be delegated by the directors to branches of the local health authority set down in the MHLW Ordinance.

(Delegation to Cabinet Order)

Article 23-7 In addition to the provisions of this Law, the details of the necessary procedures for the registration or renewal of registration for the manufacture, import, or sale of poisonous or deleterious substances, or for receiving a license given notice as required by a researcher into special poisonous substances, or the procedures in Article 19, Paragraph 4 for researchers into special poisonous substances shall be set down by Cabinet Order.

(Interim Measures)

Article 23-8 When a Cabinet Order or MHLW Ordinance is enacted, revised or removed based on the provisions of this Law, the required interim provisions for that Order or MHLW Ordinance may, within reasonable limits, be given by Cabinet Order or MHLW Ordinance as a result of the said establishment, or revision or removal.

(Penal Provisions)

Article 24 Any of the following acts is punishable by a maximum prison term of 3 years or a maximum fine of 2,000,000 yen, or both.

- (1) Violating the provisions of Articles, 3, 3-2, 4-3 or 9
- (2) Failing to provide the labeling or display in Article 12 (including its application mutatis mutandis to Paragraphs 4 and 5 of Article 22) or providing false labeling
- (3) Violating the provisions of Articles 13, 13-2 or 15, Paragraph 1
- (4) Violating the provisions of Article 14, Paragraph 1 or 2
- (5) Violating the provisions of Article 15, Paragraph 2
- (6) Violating an order to suspend business issued pursuant to the provisions of Article 19, Paragraph 4

Article 24-2 Any of the following acts is punishable by a maximum prison term of 2 years or a maximum fine of 1,000,000 yen, or both.

- (1) Selling or giving away any of the substances specified in Article 3-3 set down in the Cabinet Order, knowing that they may be taken or inhaled without proper reason or possessed for such purposes
- (2) Selling or giving away any of the substances specified in Article 3-4 set down in the Cabinet Order, knowing that they will not be possessed for the purpose of business or any other justifiable reason
- (3) Violating an order under the provisions of Article 22, Paragraph 6

Article 24-3 Any violation of the provisions of Article 3-3 is punishable by a maximum prison term of 1 year or a maximum fine of 500,000 yen, or both.

Article 24-4 Any violation of the provisions of Article 3-4 is punishable by a maximum prison term of 6 months or a maximum fine of 500,000 yen, or both.

Article 25 Any of the following acts is punishable by a maximum fine of 300,000 yen.

- (1) Neglecting to give notice or giving false notice of the details set down in Article 10, Paragraph 1, Item (4) or Paragraph 2, Item (3)
- (2) Violating the provisions of Article 14, Paragraph 4
- (2-2) Violating the provisions of Article 15, Paragraphs 2 to 4
- (3) Violating the provisions of Article 16, Paragraph 2 (including its application mutatis mutandis to Article 22, Paragraphs 4 and 5)
- (4) Neglecting to report or giving a false report when subject to a request from the Minister of Health, Labour and Welfare, a prefectural governor or the mayor of a municipalities or special ward with a health center pursuant to the provisions of Article 17, Paragraph 1 or 2 (including application mutatis mutandis in Article 22, Paragraphs 4 and 5)
- (5) Refusing, obstructing or evading entry, inspections, questions or the acquisition of samples pursuant to the provisions of Article 17, Paragraph 1 or 2 (including its application mutatis mutandis to Article 22, Paragraphs 4 and 5)
- (6) Violating the provisions of Article 21, Paragraph 1 (including its application mutatis mutandis to Paragraphs 4 of the same article)
- (7) Neglecting to give notice or giving false notice as specified in Article 22, Paragraphs 1 to 3

**Article 26** If any representative of a corporation, or any agent, employee or other worker of a corporation or an individual has violated the provisions of Articles 24, 24-2, 24-4 or the preceding article, in a manner connected to the business of the corporation or the individual, the person who committed such act and the corporation or person responsible shall both be fined under this article. However, this shall not apply to the corporation or individual if it is proved that appropriate precautions had been taken and monitoring had been conducted to prevent agents, employees or other workers of a corporation or individuals from committing said violations relation to the business.

**Article 27** A Cabinet Order based on the provisions of Article 16 may provide for a person who has violated the Cabinet Order to be liable to a maximum prison term of 2 years or a maximum fine of 1,000,000 yen, or both, and that any representative of a corporation, or any agent, employee or other worker of a corporation or individual has violated the Cabinet Order, in a way connected to the business of the corporation or the individual, the person who committed this act and the corporation or the person responsible shall both be fined under this article.

**Attached Table 1**

- (1) O-Ethyl O-4-nitrophenyl phenyl phosphonothioate (EPN)
- (2) Phosphorus (Yellow)
- (3) Octachlorotetrahydro methanophthalan
- (4) Octamethyl-pyrophosphoramidate (Schradan)
- (5) Curare
- (6) Tetraalkyl lead
- (7) Hydrogen cyanide
- (8) Sodium cyanide
- (9) Diethyl-paranitrophenyl-thiophosphate (Parathion)
- (10) Dinitrocresol
- (11) 2,4-Dinitro-6-(1-methylpropyl)-phenol
- (12) Dimethylethylmercapto ethylthiophosphate (Demeton-methyl)
- (13) Dimethyl-(diethylamido-1-chlorocrotonyl)-phosphate
- (14) Dimethylparanitrophenyl thiophosphate (Parthion-methyl)
- (15) Mercury
- (16) Selenium
- (17) Thiosemicarbazide
- (18) Tetraethylpyrophosphate (TEPP)

- (19) Nicotine
- (20) Nickel carbonyl
- (21) Arsenic
- (22) Hydrogen fluoride
- (23) Hexachloro-epoxy-octahydro-endo, endo-dimethanonaphthalene (Endrin)
- (24) Hexachloro-hexahydro-methano-benzo-dioxathiepine oxide
- (25) Monofluoroacetate
- (26) Monofluoroacetamide
- (27) Phosphorus sulfide
- (28) In addition to the substances in the previous items, preparations containing those in the previous items, and other toxic substances which are designated by Cabinet Order.

#### Attached Table 2

- (1) Acrylonitrile
- (2) Acrolein
- (3) Aniline
- (4) Ammonia
- (5) 2-Isopropyl-4-methylpyrimidyl-6-diethylthiophosphate (Diazinon)
- (6) Ethyl-N-(diethyldithiophosphoryl acetyl)-N-methylcarbamate
- (7) Ethylene chlorohydrin
- (8) Hydrogen chloride
- (9) Mercurous chloride
- (10) Hydrogen peroxide
- (11) Sodium peroxide
- (12) Urea peroxide
- (13) Potassium
- (14) Alloy of potassium and sodium
- (15) Cresol
- (16) Ethyl chloride
- (17) Chlorosulfonic acid
- (18) Chloropicrin
- (19) Methyl chloride
- (20) Chloroform
- (21) Fluorosilicic acid
- (22) Sodium cyanate
- (23) Diethyl-4-chlorophenylmercaptomethyl dithiophosphate
- (24) Diethyl-(2,4-dichlorophenyl)-thiophosphate

- (25) Diethyl-2,5-dichlorophenyl mercapto methylthiophosphate
- (26) Carbon tetrachloride
- (27) Cycloheximide
- (28) Dichloroacetic acid
- (29) Dichlorobutylene
- (30) 2,3-di-(Diethylthiophosphoro)-paradoxan
- (31) 2,4-Dinitro-6-cyclohexylphenol
- (32) 2,4-Dinitro-6-(1-methylpropyl)-phenylacetate
- (33) 2,4-Dinitro-6-methylpropylphenoldimethylacrylate
- (34) 2,2'-Dipyridinium-1,1'- ethylene-dibromide
- (35) 1,2-Dibromoethane (EDB)
- (36) Dibromochloropropane (DBCP)
- (37) 3,5-Dibromo-4-hydroxy-4'-nitroazobenzene
- (38) Dimethyl ethylsulfinyl isopropyl thiophosphate
- (39) O,O-dimethyl-S-ethylthioethyl-dithiophosphate (Thiometon)
- (40) Dimethyl-2,2-dichlorovinyl-phosphate (DDVP)
- (41) Dimethylthiophosphorylphenyl acetic acid ethylester
- (42) O,O-Dimethyl-1,2-dibromo-2,2-dichloroethylphosphate
- (43) Dimethyl-phthalylimide methylthiophosphate
- (44) Dimethyl- methylcarbamylethyl thioethyl thiophosphate
- (45) O,O-Dimethyl-N-methylcarbamylymethyl-dithiophosphate (Dimethoate)
- (46) O,O-Dimethyl-O-4- (methylmercapto)-3-methylphenylthiophosphate
- (47) Dimethyl sulfate
- (48) Dichromic acid
- (49) Oxalic acid
- (50) Bromine
- (51) Nitric acid
- (52) Thallium nitrate
- (53) Potassium hydroxide
- (54) Sodium hydroxide
- (55) Sulfonal
- (56) Tetraethylmethylene bisdithiophosphate
- (57) Triethanolammonium-2,4-dinitro-6-(1 -methylpropyl)-phenolate
- (58) Trichloroacetic acid
- (59) Trichlorohydroxyethyl dimethylphosphonate
- (60) Trithiocycloheptadiene-3,4,6,7-tetracarbonitrile
- (61) Toluidine
- (62) Sodium

- (63) Nitrobenzene
- (64) Carbon disulfide
- (65) Oleum
- (66) p-Toluylyene-diamine
- (67) p-Phenylenediamine
- (68) Picric acid (Except for explosive agents)
- (69) Hydroxylamine
- (70) Phenol
- (71) Blasticidin S
- (72) Bromoethane
- (73) Hydrogen bromide
- (74) Methyl bromide
- (75) Hexachloro-epoxy-octahydro-endo,exo-dimethanonaphtalene (Dieldrin)
- (76) 1,2,3,4,5,6-Hexachlorocyclohexane (Lindane)
- (77) Hexachloro hexahydro dimethanonaphatalene (Aldrin)
- (78) Beta-naphthol
- (79) 1,4,5,6,7-Pentachloro-3a,4,7,7a-tetrahydro-4,7-(8,8-dichloromethano)-indene  
(Heptachlor)
- (80) Pentachlorophenol (PCP)
- (81) Formaldehyde
- (82) Chromium trioxide
- (83) Methanol
- (84) Methyl sulfonal
- (85) N-Methyl-1-naphthylcarbamate
- (86) Monochloroacetic acid
- (87) Hydrogen iodide
- (88) Iodine
- (89) Sulphuric acid
- (90) Thallium sulfate
- (91) Zinc phosphide
- (92) Ethyl rhodanacetate
- (93) Rotenone
- (94) In addition to the substances in the previous items, preparations containing those in the previous items, and other deleterious substances which are designated by Cabinet Order.

Attached Table 3

- (1) Octamethyl-pyrophosphoramide

- (2) Tetraalkyl lead
- (3) Diethyl-paranitrophenyl-thiophosphate
- (4) Dimethylethylmercapto ethylthiophosphate
- (5) Dimethyl-(diethylamido-1-chlorocrotonyl)-phosphate
- (6) Dimethylparanitrophenyl thiophosphate
- (7) Tetraethylpyrophosphate
- (8) Monofluoroacetate
- (9) Fluoroacetamide
- (10) In addition to the poisonous substances in the previous items, preparations containing those in the previous items, and other substances with significant toxicity which are designated by Cabinet Order.