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and fishery products

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Safety control of frozen edible fish
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Status of inspection

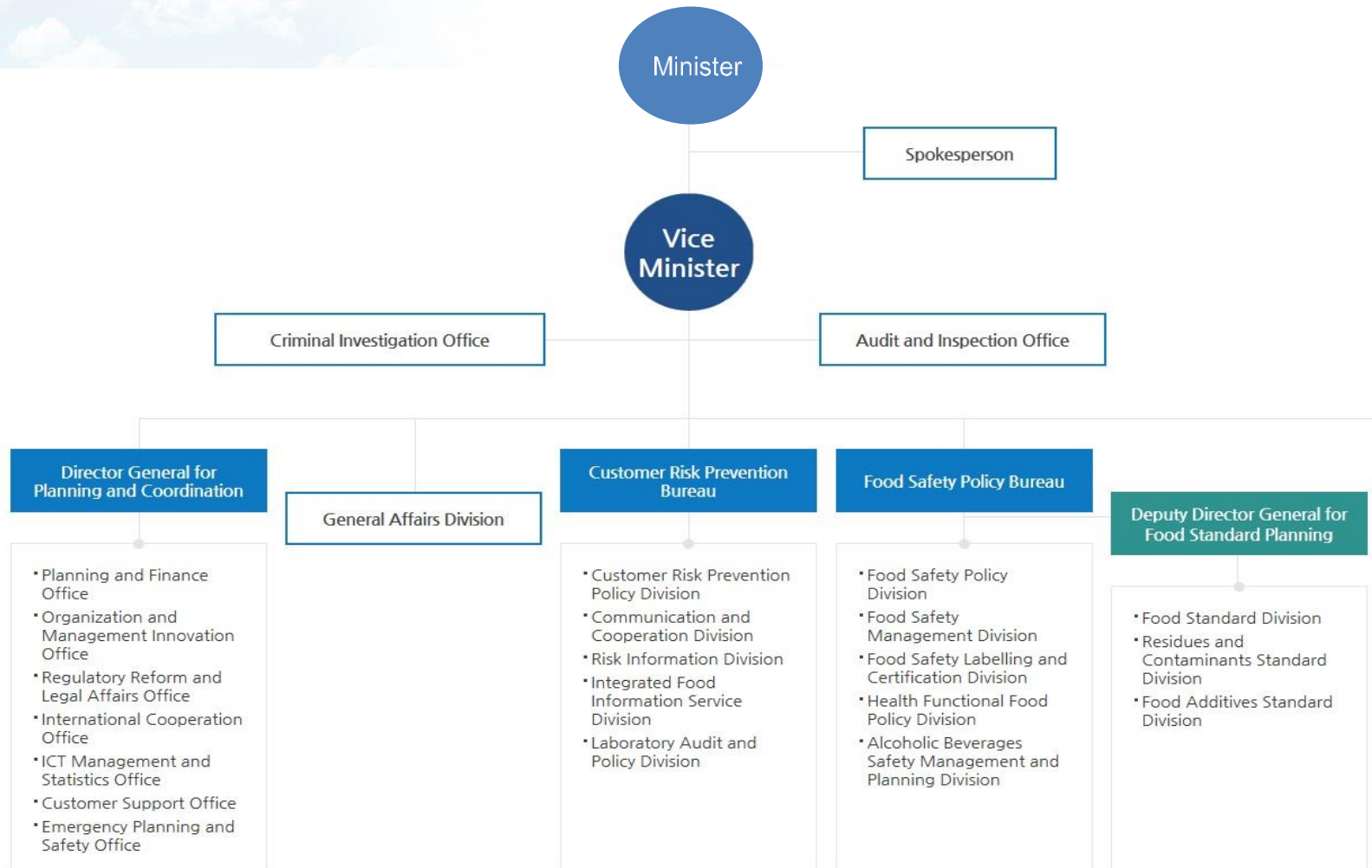


1

The introduction of the MFDS

1. The organizational chart of the MFDS

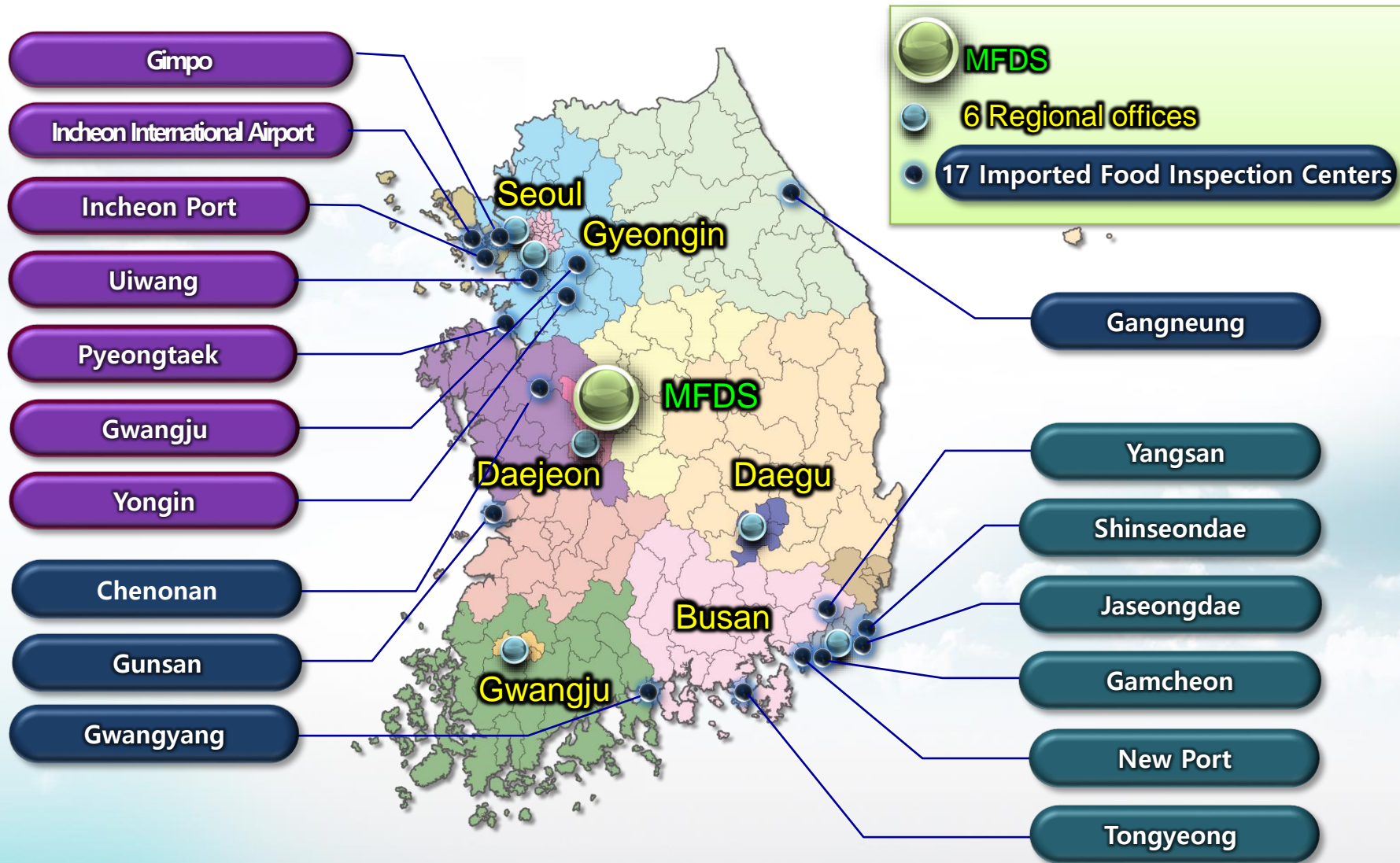
- ✓ **Main office**
 - The Director General for Planning and Coordination, the Deputy Director General for Food Standard Planning, 7 bureaus (consist of 48 divisions)
- ✓ **Affiliated organizations**
 - The National Institute of Food and Drug Safety Evaluation, 6 Regional Offices



1. The organizational chart of the MFDS



1. Organizations in Charge of Imported Food Inspection



3. The total number of workers and related laws

- ✓ The total number of workers(our present staff) ▫ 1,858 people (1,753)
 - ✓ Main office: 598, The National Institute of Food and Drug Safety Evaluation: 423, Regional Offices: 837
- ✓ Acts : The application of the 16 laws relevant to food policy, policy of drug and medical device

Food

- ① FRAMEWORK ACT ON FOOD SAFETY
- ② **FOOD SANITATION ACT**
- ③ FUNCTIONAL HEALTH FOODS ACT
- ④ SPECIAL ACT ON SAFETY CONTROL OF CHILDREN'S DIETARY LIFE
- ⑤ LIVESTOCK PRODUCTS SANITARY CONTROL ACT
- ⑥ AGRICULTURAL AND FISHERY PRODUCTS QUALITY CONTROL ACT
- ⑦ **SPECIAL ACT ON IMPORTED FOOD SAFETY MANAGEMENT**
- ⑧ ACT ON ESTABLISHMENT AND OPERATION OF THE KOREA AGENCY OF HACCP ACCREDITATION & SERVICE

Drug

- ⑨ PHARMACEUTICAL AFFAIRS ACT
- ⑩ SAFETY, MANAGEMENT, ETC. OF HUMAN TISSUE ACT
- ⑪ ACT ON THE CONTROL OF NARCOTICS, ETC.
- ⑫ COSMETICS ACT
- ⑬ MEDICAL DEVICES ACT
- ⑭ LABORATORY ANIMAL ACT

➤ Commonness of Food and Drug

- ⑮ ACT ON TESTING AND INSPECTION IN THE FOOD AND DRUG INDUSTRY
- ⑯ ACT ON THE PROMOTION OF TECHNOLOGY FOR ENSURING THE SAFETY OF FOOD, DRUGS, ETC.



2

SAFETY CONTROLS OF IMPORTED FISH AND FISHERY PRODUCTS

1. Legal basis of inspection of imported fish and fishery products

◆ Article 20(import declaration) and 21(import inspection) of the Special Act on Imported Food Safety Control

The person who import food with the purpose of sale and business use should report import declarations and receive import inspections from the Ministry of Food and Drug Safety in accordance with the instruction of the Korean Prime Minister

▶ Fish and fishery products

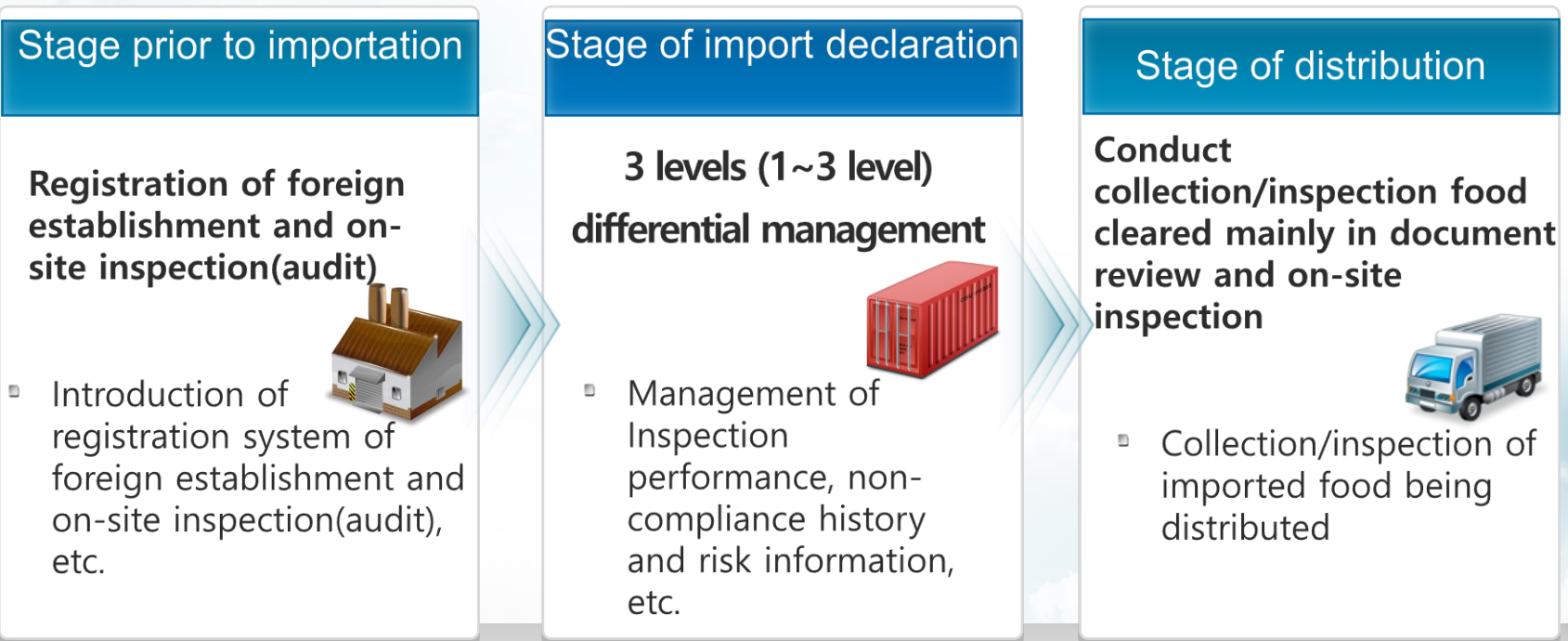
- Live fish and shellfish · fresh product · chilled product · frozen product ,dried product and seaweed.
- Fish, aquatic animals and seaweed that are simply processed such as cut, heated, fully- cooked (steamed or boiled), dried or salted, preserved in brine, smoked, chilled, or frozen without using food additives or other ingredients except for edible salt, to the extent the original shape can be identified. (including fish eggs and smoked fish)
- * Quarantines of fish and fishery products : Check for disease on imported fish and fishery products (Aquatic Life Disease Control Act)

▶ Processed products

- Fishery products that are manufactured, processed and packaged using food additives or
- other ingredients, to the extent the original shape can t be identified.

2. Safety control system of imported food

- ✓ Imported food safety control from the exporting country to domestic distribution



Three stages of safety system

Ensuring enhanced and robust imported food safety control system



『 The Special Act on Imported Food Safety Control 』 (enforcement date: Feb. 4, 2016)

2-1. Safety control system of imported fishery products

First Grade Imported Food

- ✓ Foods imported in accordance with each of the following subparagraphs-(including raw materials for manufacturing its own products in the case of livestock products)
 - 1) Foods imported for the first time
 - 2) Imported foods whose standards and specifications have been newly established or strengthened after being imported for the first time and undergoing detailed inspection
 - 3) Imported foods that do not meet the requirements of the same food imported from the same establishment with the period under each item of subparagraph 4 elapsed after being imported for the first time and undergoing detailed inspection.
- ✓ Imported foods returned from foreign countries (excluding cases falling under document inspection among the types of inspection under attached table 9)
- ✓ Imported foods that the heads of Regional Offices of Food and Drug Safety deems necessary to conduct a detailed inspection as a result of field inspection.

2-1. Safety control system of imported fishery products

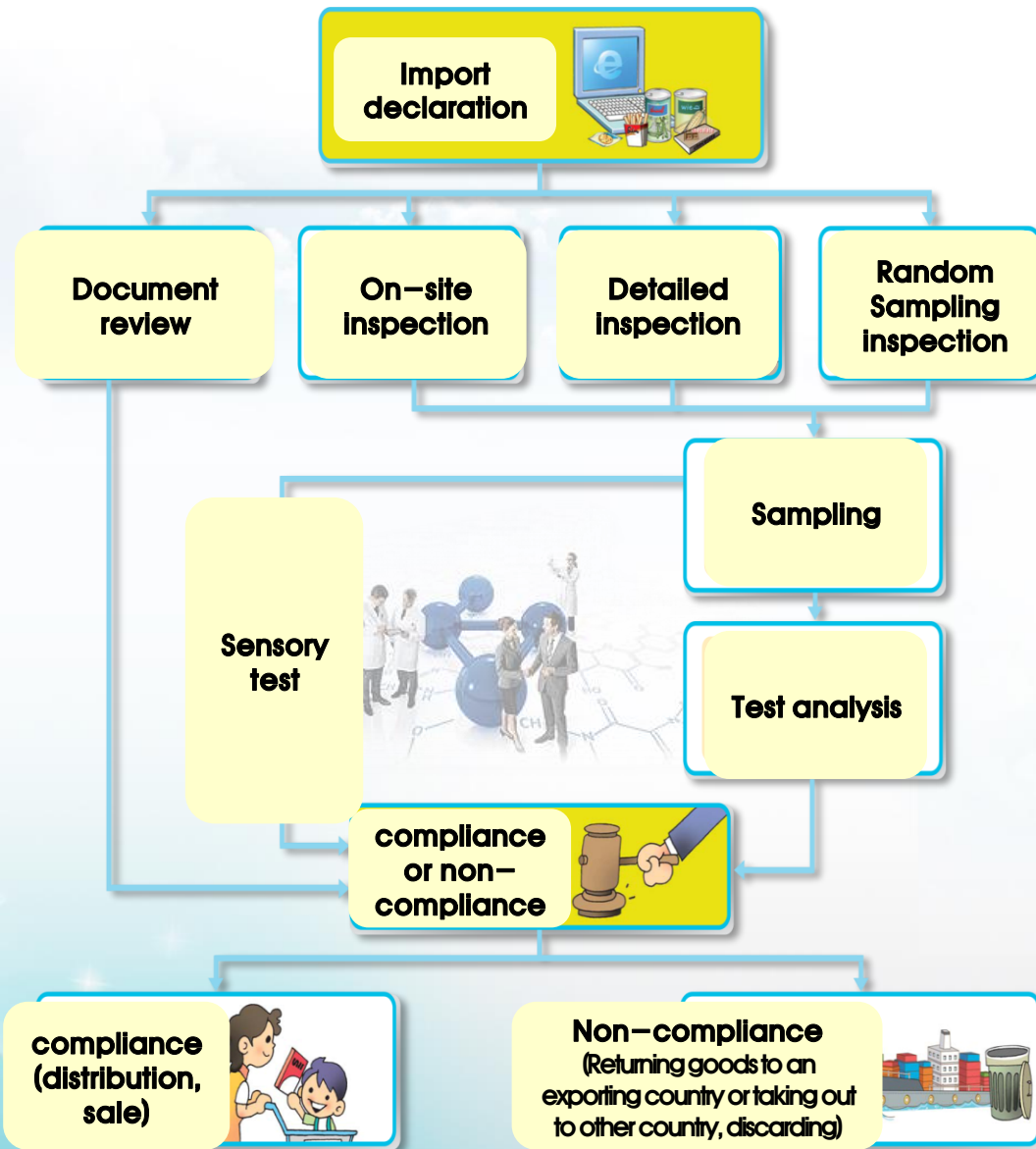
Second Grade Imported Food

- ✔ Imported foods that the Minister of Food and Drug Safety deems necessary to conduct a detailed inspection following issues raised based on domestic and foreign food safety information
- ✔ Imported foods that falls under any of subparagraph 4 in the case of re-import after receiving disposition of non-compliance as results of detailed inspection and random sampling inspection according to Article 21 of the Act, or collection inspection according to Article 25 of the Act

Third Grade Imported Food

- ✔ Foods imported by business entities under a special management (Article 26 (1) 3)
- ✔ Foods manufactured or exported by an overseas manufacturer in which hazardous substances determined and notified by the Minister of Food and Drug Safety have been detected, and imported within two years from the date of disposition of non-compliance

3. The flow diagram of inspections of imported food



- ## ✓ Inspection types and outline
- ✓ Document review (2/3 days)
 - The same product from the same establishment, raw materials for manufacturing the importer's products, products for acquiring foreign currency, etc.

 - ✓ On-site inspection (3/5 days)
 - Products are determined by a regional office of FDS among products subject to document review

 - ✓ Detailed inspection (10/18 days)
 - Products imported for the first time and reimported products with history of non-compliance, etc.

 - ✓ Random sampling inspection (5/18 days)
 - Random sampling among products subject to document review and on-site inspection, etc.

4. The inspection procedure of imported fish and fishery products

Office work



Registration



Delivery to inspectors



Document screening

On-site work



Customs clearance



Laboratory inspection



On-site inspection

5. The types of inspections of imported food

Document review

- Determine compliance/non-compliance by reviewing declared documents

On-site inspection

- Determine compliance/non-compliance by examining products' nature, condition, flavor, scent, color, labeling, packaging, history of detailed inspection, etc.

safe imported
food from import
to table

Random Sampling inspection

Detailed inspection

- Use physical, chemical and microbiological methods
- Conduct document review and on-site inspection

- Use physical, chemical and microbiological methods based on MFDS' sampling plans
- Conduct document review and on-site inspection

6. Detailed inspections and Random sampling inspections

✓ Content of detailed inspections

✔ The object of inspection

- Initial imported fish and fishery products
- Fish and fishery products posed problems of harmful substances both inside and outside the country
- Reimported fish and fishery products after non-compliance
- Manufacturing and importing companies detected harmful substances

✔ The list of inspection

- Inspection lists in accordance with the standards and specifications of foods(84 lists)
 - 4 types of heavy metals
 - 54 kinds of veterinary drugs
 - 6 kinds of microbiological organisms(Bacteria, Listeria etc.)
 - 11 types of the others (Tetrodotoxin etc.)
 - Add 10 types in the list of harmful information
- ※ Harmful information : Methylene Blue, Trimethoprim etc.

✓ Content of sampling inspections

✔ The object of inspection

- Fish and fishery products where inspections are necessary in accordance with sampling plan and with consideration of different type of health risks among the imported fish and fishery products

✔ Application of inspection

- Imported fish and fishery products where non-compliance occurs frequently(twice a half year)
- Fish and fishery products produced by overseas manufacturers where foreign materials and pigments such as artificial water and metals has been detected
- Imported fish and fishery products in facilities which are under the mutual recognition arrangement after non-compliance occurs (inspect 5 times)
- Imported fish and fishery products in facilities that are not under the mutual recognition arrangement after non-compliance causes (inspect 10 times)

7. Fish and fishery products inspection items

✓ Heavy metal

| Inspection Item | Mollusks | Shellfish | Crustacean | Fish | Note |
|-----------------|----------|-----------|------------|------|---------------|
| Lead | ○ | ○ | ○ | ○ | |
| Cadmium | ○ | ○ | ○ | ○ | |
| Mercury | ○ | ○ | | ○ | |
| Methylmercury | | | | ○ | Deep-sea fish |

✓ Drug residue(53)

| Inspection Item | Crustacean | Fish | Note |
|--|------------|------|----------|
| OTC/CTC/TC/Doxycycline | ○ | ○ | Abalones |
| Spiramycin/Erythromycin | ○ | ○ | |
| Amoxicillin/Ampicillin | ○ | ○ | |
| Neomycin | ○ | ○ | Abalones |
| Cefalexin | | ○ | |
| Lincomycin, Colistin , Florfenicol, Trimethoprim | ○ | ○ | |
| Ormethoprim, Tiamulin, Deltamethrin | | ○ | |

7. Fish and fishery products inspection items

✓ Drug residue(53)

| Inspection Item | Crustacean | Fish | Note |
|--|------------|------|------|
| Enro/Ciprofloxacin/Oxolinic acid/Flumequin/ Difloxacin | ○ | ○ | |
| Nalidixic acid | | ○ | |
| Kitasamycin/(Josamycin | | ○ | |
| Sulfacetamides 15 | | ○ | |
| Bithionol, Fenobucarb, Fumagillin, Cefadroxil, Dehydrocholic acid, Trichlorfon, Isoeugenol, Ceftiofur, Praziquantel, Clindamycin, Gentamicin, Thiamphenicol | | ○ | |
| Ethoxyquin | ○ | ○ | |

7. Fish and fishery products inspection items

✓ Natural toxin

| Inspection Item | Mollusks | Shellfish | Crustacean | Fish | Note |
|-----------------|----------|-----------|------------|------|-----------|
| PSP | | ○ | | | |
| DSP | | ○ | | | |
| Domoic acid | | ○ | ○ | | |
| Tetrodotoxin | | | | ○ | Fugues |
| Histamine | | | | ○ | Tunas etc |

✓ Proximate

| Inspection Item | Mollusks | Shellfish | Crustacean | Fish | Note |
|----------------------------------|----------|-----------|------------|------|------|
| Sulfur dioxide(SO ₂) | | | ○ | | |
| PCBs | | | | ○ | |
| Benzopyrene | ○ | ○ | ○ | ○ | |
| Radioactivity | ○ | ○ | ○ | ○ | |
| Carbon monoxide(CO) | | | | ○ | |
| Melamine | | | | ○ | |

7. Fish and fishery products inspection items



Microbial

| Inspection Item | Mollusks | Shellfish | Crustacean | Fish | Note |
|--------------------------------|----------|-----------|------------|------|----------|
| <i>Listeria monocytogenes</i> | ○ | ○ | ○ | ○ | Raw Food |
| <i>Salmonella</i> spp. | ○ | ○ | ○ | ○ | |
| <i>Staphylococcus aureus</i> | ○ | ○ | ○ | ○ | |
| <i>Vibrio parahaemolyticus</i> | ○ | ○ | ○ | ○ | |
| <i>Vibrio cholerae</i> | ○ | ○ | ○ | ○ | |
| <i>Vibrio vulnificus</i> | ○ | ○ | ○ | ○ | |
| Bacterial count | ○ | ○ | ○ | ○ | |
| E.coli | ○ | ○ | ○ | ○ | |

7. Fish and fishery products inspection items

✓ Inhibitory material

| Inspection Item | Crustacean | Fish | Note |
|---------------------------------|------------|------|-------------------------------|
| Norfloxacin | ○ | ○ | |
| Ofloxacin | ○ | ○ | |
| Pefloxacin | ○ | ○ | |
| Chloramphenicol | ○ | ○ | |
| Methylene Blue | ○ | ○ | |
| Malachite green and metabolites | ○ | ○ | Leuco-malachite green |
| Nitrofurans and metabolites | ○ | ○ | AMOZ, AOZ,AHD, SEM, Nitrobin) |
| GentianViolet and metabolites | ○ | ○ | Leuco -gentian violet |

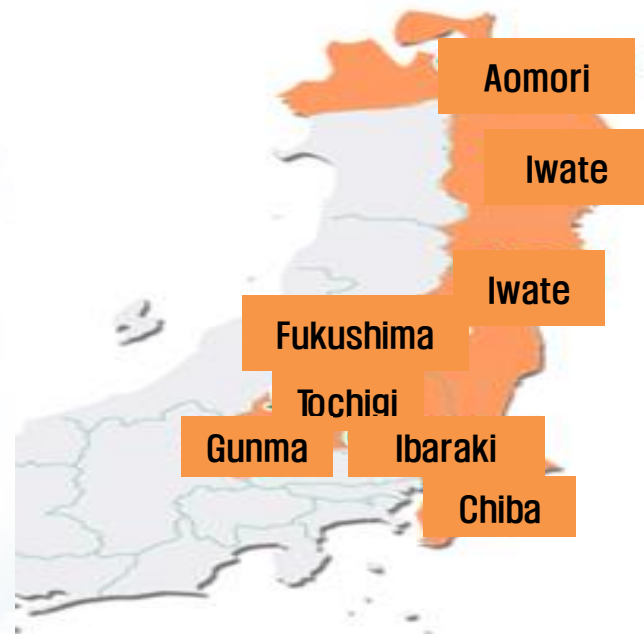
8. Safety control of radioactivity in Japan

Import ban

- All fishery products on eight prefectures

Fukushima, Ibaraki, Gunma,

Miyagi, Iwate, Tochigi, Chiba, Aomori



Mandatory submission of a certificate

- Certificates of origin : 47 prefectures
- Inspection certificates of radioactivity : 8 prefectures
- **Range of import ban : All fishery products of 8 prefectures**

Radioactivity inspection

- Conduction of radioactivity inspections every time
- Detection of radioactivity : Additional requirements of inspection certificates of radioactivity on other nuclides



3

Mutual Recognition Arrangement of
imported fish and fishery products

1. Mutual Recognition Arrangement with other countries

Legal Basis (Article 37 of the Act)

- ▶ The regulations regarding entering into arrangement and management with foreign institutes (Article 566 by the instruction of the Korean Prime Minister)
 - Making a mutual recognition arrangement on imports and exports of fish and fishery products with major trading partners such as China, Vietnam and so on.
 - Requiring notification management on **registered facilities** and obligation to **attach health certificates**



Operation of the arrangement and control of import inspections

(Operation of arrangement)

- Participation of working-level meetings between countries under arrangement (representatives of government agencies) for smooth implementation of the arrangement and for resolving the problems
 - * China holds a meeting twice a year, Vietnam has a meeting once a year, and the others hold a conference if necessary
- Having a conference with relative agencies in advance on current issues such as consultation of arrangement (the Ministry of Oceans and Fisheries, the National Fishery Products Quality Management Service)
 - * Discussion on countermeasures via conference between countries under arrangement, inspection plans for harmful information, follow-up management after non-compliance occurrences, modification of a health certificate form and so on.
- Review of its revisions and presentation of our MFDS's opinion when changing the arrangement

3. Process of notifications of suspension such as import interruption

Actions on registered facilities arising issues of hygiene safety

First category (general factors)

- Paralytic Shellfish Poison, Tetrodotoxin, OTC, Enrofloxacin/Ciprofloxacin, Viable cell count, Coliform group, Sulfur dioxide, heavy metal and metallic foreign substance (its unintentional injection) and so on.
- Target of interruption : Import suspension on non-compliance **items**
- Investigating the causes of non-compliance and notifying the result of measures and requirement on lifting of the suspension after improvement management for over one month
- * Import countries are able to retract them after looking through the withdrawal request of export countries.

Second category (important factors)

- Banned substances such as Chloramphenicol, Malachitegreen, Ofloxacin · Norfloxacin · Pefloxacin, Salmonella, CO and metallic foreign substance (its intentional injection), compulsory water injection and so on.
- Target of interruption : Temporary import suspension on **corresponding registered establishments**
- Investigating the reasons of non-compliance and notifying the result of measures and requirement on lifting of the suspension after improvement management for over three months
- * Import countries can retract them after reviewing the withdrawal request of export countries.

4. Operating plans of this Arrangement

Establishing of continuous consultation system by assignment of a point of contact between government agencies after concluding an arrangement

(Regular meeting) Improving matters identified in the process of implementation of this arrangement and writing minutes on contents for concurrence of opinion (once or twice a year)

(Technical negotiation) Mutual consultation and support on information between two agencies such as standards of the inspection, training of inspectors of manufacturing establishments, standards of the hygienic control

(On-site inspections) Managing and supervising overseas manufacturing facilities by exporting country's government but fulfilling a monitoring for on-site facilities by importing country's government once or twice a year

(Operation of point of contact) Operating of practical point of contact such as notification on overseas manufacturing establishments, computerized management and release of approved facilities, modification, registration, consultation with relevant organizations etc.

(Follow-up managements) Implementation of follow-up managements such as import ban, investigation of cause and a review of the measures of recurrence protections on corresponding facilities when non-compliance occurs

5. Treatments for export countries after making an arrangement

Registration and renewal of overseas manufacturers

Other countries that are not under this arrangement should register individually for importers and renew again biennially. However, countries under this arrangement entrust exporting country with all tasks regarding it.

* Only managing information such as new regulation, modification, cancellation noticed by exporting country's government without renewal.

On-site inspections of overseas manufacturers

Other countries that are not under this arrangement take on-site inspections and take action to discontinue import but countries under this arrangement inspect monitoring for it.

* Consultation of on-site inspections between two countries concentrating upon manufacturers which non-compliance causes

Detailed inspections

When harmful element is found, then countries that are under this arrangement take detailed inspections mitigatedly by level of one-half in comparison with other countries that are not under this arrangement.

* Other countries that are not under this arrangement undergo inspection 10 times and countries that are under this arrangement undergo inspection 5 times when importing again from non-compliance facilities.



4

Safety control of frozen edible fish
heads and intestines

1. Safety control of frozen edible fish heads and intestines

General provision and common standard of Korea Food Standards Codex

What is the frozen edible fish heads?

It means that the parts of pectoral fins and ventral fins of fish head such as *Gadus morhua*, *Merluccius australis*, Tunas, *Dissostichus eleginoides* are cut in condition connected, and it is suitably processed products for edibility by quick freezing in order that its central temperature maintains below -18°C to separate edible portions among edible fish (excepting puffer fish) heads of all types.

Its requirements of raw materials, etc.

- (A) Raw materials are classified by edibility (HS 0303) in the International Convention on the Harmonized Commodity Description and Coding System of World Customs Organization and are verified by relevant institutes that manage them in a sanitary way
- (B) Handling them hygienically after eliminating internal organs and fills of fish when they cut
- (C) No use of other materials such as food additives

1. Safety control of frozen edible fish heads and intestines

General provision and common standard of Korea Food Standards Codex

Frozen edible fish intestines

It means that it is suitably processed products for edibility by quick freezing in order that its central temperature maintains below -18°C to separate edible fish eggs (excepting eggs of puffer fish), intestines of pollack, hard roe, nidamental gland of the squid and so on.

Its requirements of raw materials, etc.

- (A) Raw materials are classified by edibility(HS 0303, 0306, 0307) in the International Convention on the Harmonized Commodity Description and Coding System of World Customs Organization and are verified by relevant institutes that manage them in a sanitary way
- (B) Eliminating other intestines of fish when they cut
- (C) No use of other materials such as food additives

2. Process of on-site inspections

On-site inspections of registered establishments under arrangement



On-site inspections of registered facilities of frozen edible fish heads and intestines



3. Control methods by countries of frozen edible fish heads and intestines

| Classification | Contents |
|--|--|
| <p>New import countries</p> | <ul style="list-style-type: none"> ○ Government agencies of corresponding export countries <ul style="list-style-type: none"> - Recognition of edibility (HS 0303, 0306, 0307) - Submission of lists of export processing companies - Attaching health certificates (each time) ○ Confirmation of import countries <ul style="list-style-type: none"> - <u>Import approvals after on-site inspections on processing establishments of export countries (by countries, by products)</u> |
| <p>Existed import countries (that is not under the arrangement)</p> | <ul style="list-style-type: none"> ○ Government agencies of corresponding export countries <ul style="list-style-type: none"> - Recognition of edibility (HS 0303, 0306, 0307) - Submission of lists of export processing companies - Attaching health certificates (each time) ○ Confirmation of import countries <ul style="list-style-type: none"> - <u>Hygiene monitoring on processing facilities of export countries</u> |
| <p>Countries under the arrangement (China, Indonesia, Vietnam Thailand, Russia, Ecuador)</p> | <ul style="list-style-type: none"> ○ Government agencies of corresponding export countries <ul style="list-style-type: none"> - Recognition of edibility (HS 0303, 0306, 0307) - Attaching health certificates (each time) ○ Confirmation of import countries <ul style="list-style-type: none"> - <u>Hygiene monitoring on processing facilities of export countries</u> |

4. Management status of frozen edible fish heads and intestines



Nations and items allowed imports of frozen edible fish heads and intestines

| No. | Nation | Exportable items | No. | Nation | Exportable items |
|-----|-------------|---|-----|--------------------|---|
| 1 | France | Edible portion of fish heads | 15 | Norway | Fish heads, edible portion of fish heads, fish intestines |
| 2 | Japan | Edible portion of fish heads, fish intestines | 16 | Thailand | Edible portion of fish heads, fish intestines |
| 3 | Peru | Edible portion of fish heads, fish intestines | 17 | Indonesia | Fish heads, edible portion of fish heads, fish intestines |
| 4 | Philippine | Edible portion of fish heads, fish intestines | 18 | Vietnam | Fish heads, edible portion of fish heads |
| 5 | Chile | Fish heads, edible portion of fish heads, fish intestines | 19 | China | Edible portion of fish heads, fish intestines |
| 6 | Uruguay | Edible portion of fish heads | 20 | South Africa | Edible portion of fish heads, fish intestines |
| 7 | Iceland | Edible portion of fish heads, fish intestines | 21 | The United Kingdom | Edible portion of fish heads, fish intestines |
| 8 | Ecuador | Fish heads, edible portion of fish heads, fish intestines | 22 | Ukraine | Edible portion of fish heads |
| 9 | Singapore | Edible portion of fish heads | 23 | Panama | Edible portion of fish heads, fish intestines |
| 10 | Russia | Fish heads, edible portion of fish heads, fish intestines | 24 | Argentina | Edible portion of fish heads, fish intestines |
| 11 | Micronesia | Edible portion of fish heads | 25 | Fiji | Edible portion of fish heads |
| 12 | USA | Fish heads, edible portion of fish heads, fish intestines | 26 | Falkland Islands | Edible portion of fish heads, fish intestines |
| 13 | Mauritius | Edible portion of fish heads, fish intestines | 27 | Spain | Edible portion of fish heads, fish intestines |
| 14 | New Zealand | Edible portion of fish heads, fish intestines | 28 | Sri Lanka | Fish heads, edible portion of fish heads, fish intestines |



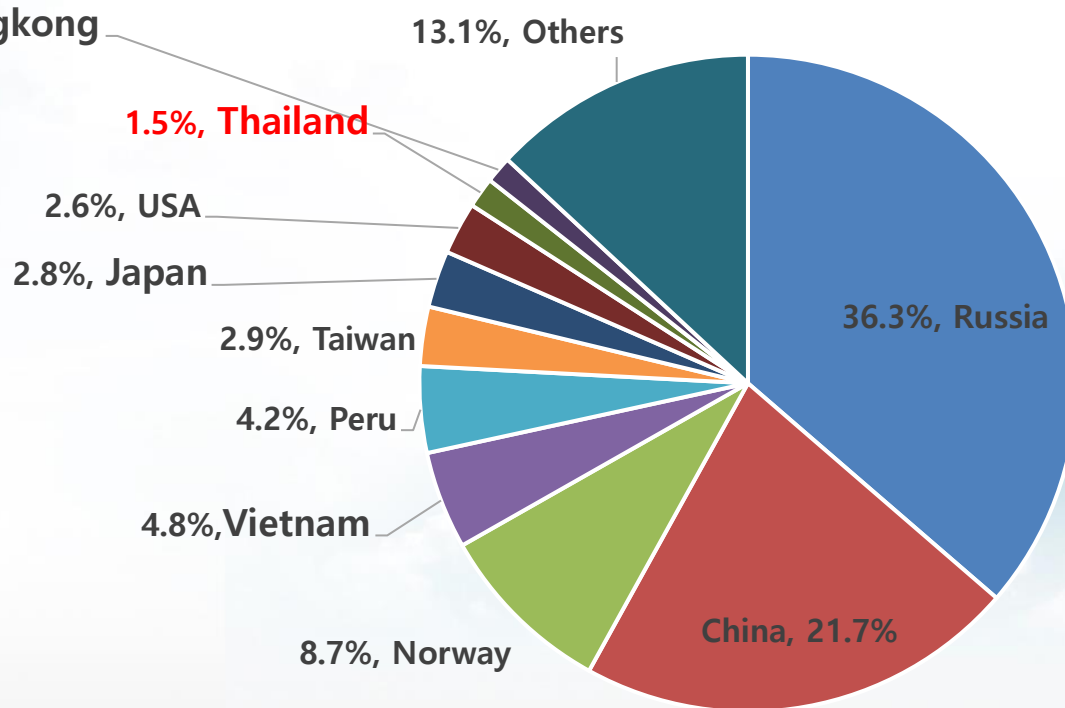
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Status of inspection

1. Status of inspection by countries on imported fish and fishery products(2021)

(Unit : ton)

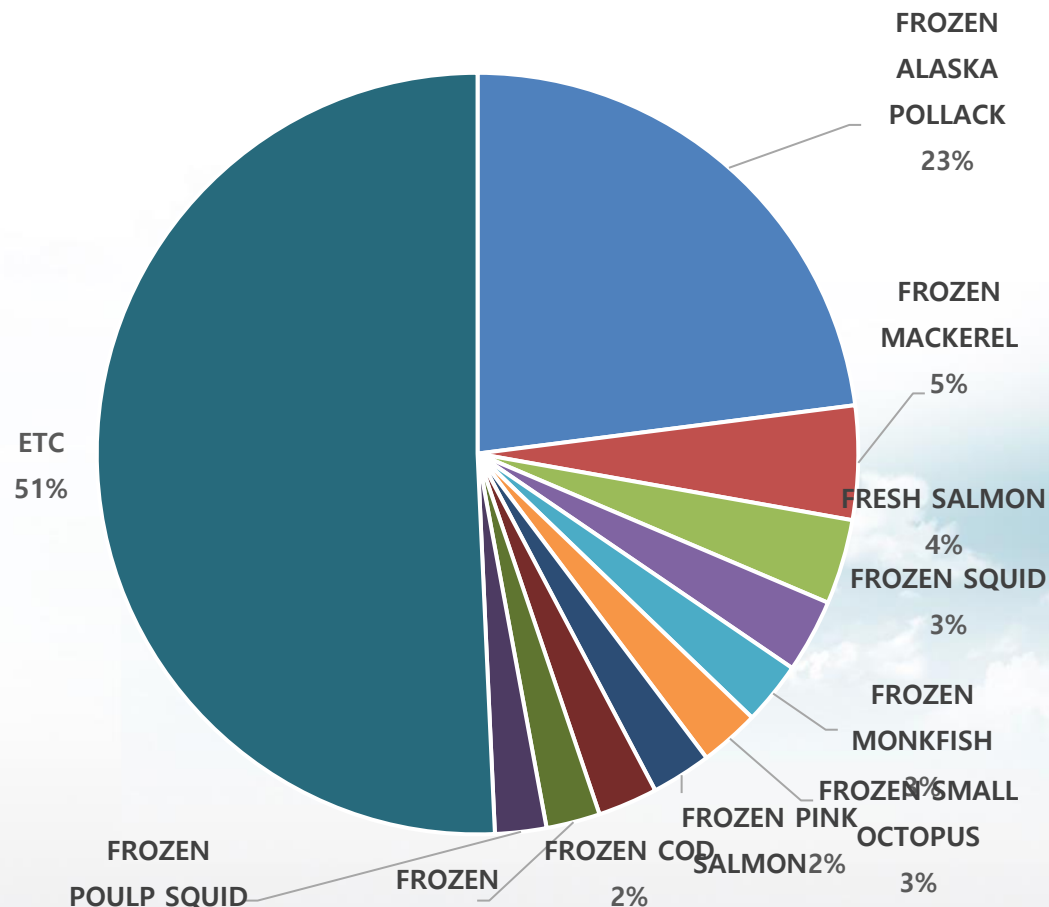
| | |
|--------------|------------------|
| Total | 1,143,405 |
| Russia | 415,510 |
| China | 248,078 |
| Norway | 100,018 |
| Vietnam | 54,948 |
| Peru | 48,580 |
| Taiwan | 33,317 |
| Japan | 31,970 |
| USA | 29,346 |
| Thailand | 17,046 |
| Hongkong | 15,070 |
| Others | 149,522 |



2. Status of inspection by item on imported fish and fishery products(2021)

(Unit : ton)

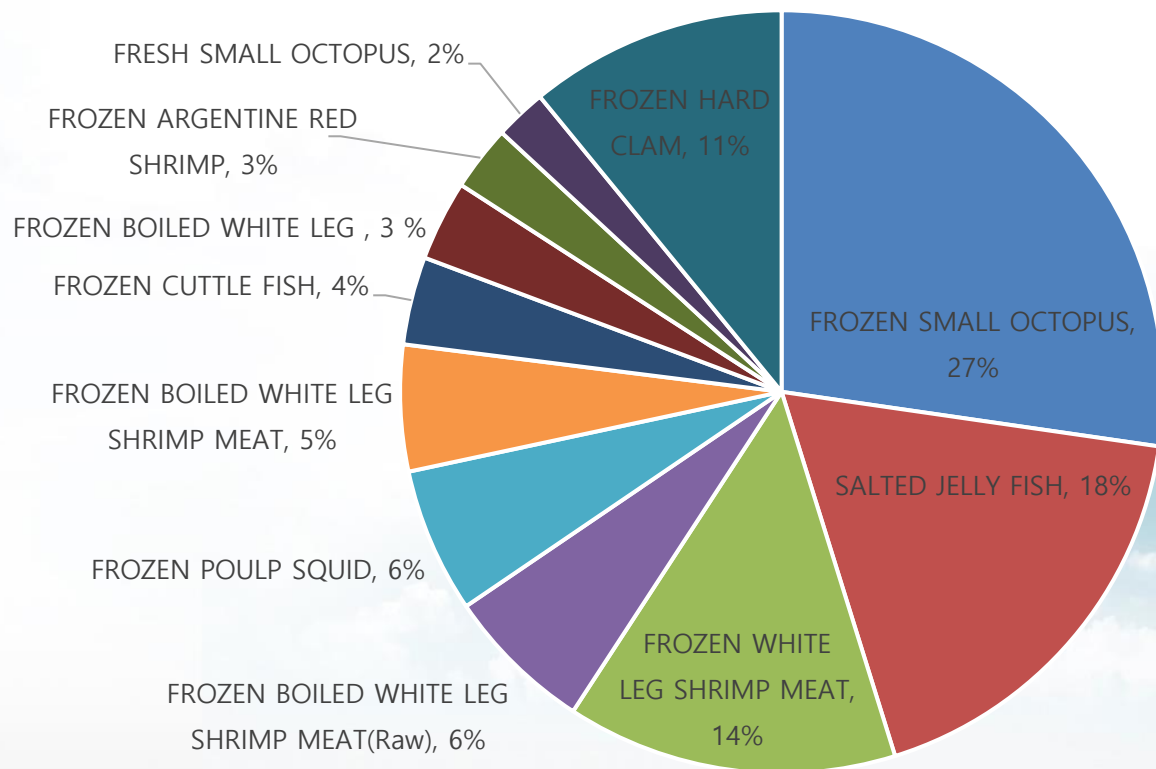
| | |
|-----------------------|-----------|
| Total | 1,143,405 |
| FROZEN ALASKA POLLACK | 262,639 |
| FROZEN MACKEREL | 55,224 |
| FRESH SALMON | 41,198 |
| FROZEN SQUID | 35,668 |
| FROZEN MONKFISH | 30,498 |
| FROZEN SMALL OCTOPUS | 29,065 |
| FROZEN PINK SALMON | 29,063 |
| FROZEN COD | 29,003 |
| FROZEN MACKEREL PIKE | 26,137 |
| FROZEN POULP SQUID | 24,886 |
| ETC | 580,025 |



3. Status of inspection by Thailand on imported fish and fishery products(2021)

(Unit : ton)

| | |
|---|---------------|
| Total | 17,046 |
| FROZEN SMALL OCTOPUS | 4,651 |
| SALTED JELLY FISH | 3,052 |
| FROZEN WHITE LEG SHRIMP MEAT | 2,389 |
| FROZEN BOILED WHITE LEG SHRIMP MEAT(RAW) | 1,073 |
| FROZEN POULP SQUID | 1,047 |
| FROZEN BOILED WHITE LEG SHRIMP MEAT | 912 |
| FROZEN CUTTLE FISH | 636 |
| FROZEN BOILED WHITE LEG SHRIMP | 580 |
| FROZEN ARGENTINE RED SHRIMP | 472 |
| FRESH SMALL OCTOPUS | 373 |
| ETC | 1,862 |



Thank you.

