Self-declaration for country freedom from *Gyrodactylus salaris* by Republic of Korea.

Declaration sent to the OIE on 29 September 2020 by Dr. Daegyun Kim, OIE Delegate for the Republic of Korea and Chief Veterinary Officer, Animal Health Policy Bureau, Ministry of Agriculture, Food and Rural Affairs.

1. Introduction

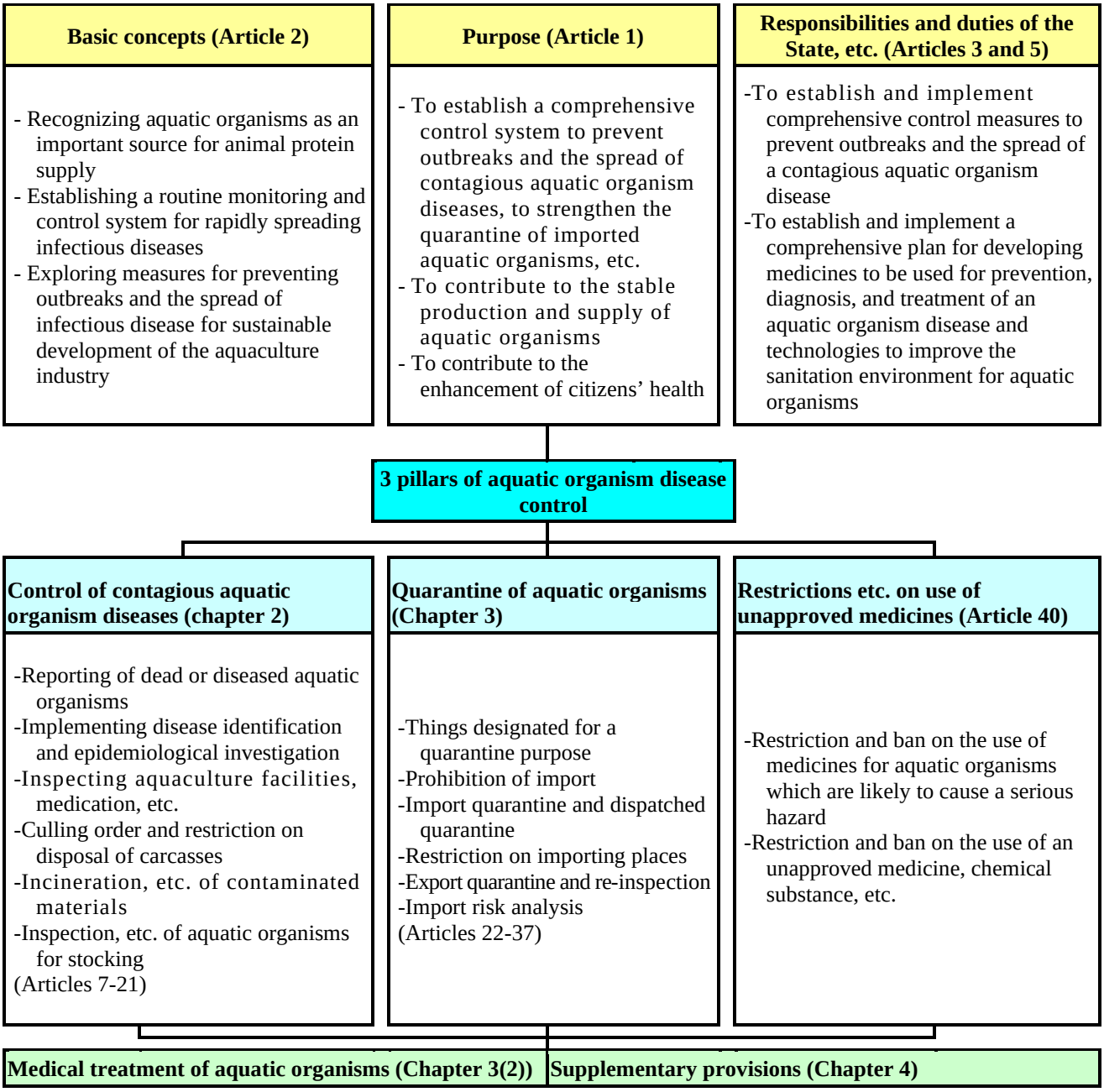
The National Institute of Fisheries Science, the Ministry of Oceans and Fisheries, the Republic of Korea officially requests the publication by the World Organisation for Animal Health (OIE) of a self-declaration of freedom from *Gyrodactylus salaris* of the entire country of the Republic of Korea as of August 1, 2020. This is the first self-declaration of freedom from the disease of the country.

1. As a country where the infection status of *G. salaris* before targeted surveillance was unknown, the Republic of Korea has met the requirements for obtaining the status of freedom from *G. salaris* of the country described in Article 1.4.6 and 10.3.4 point 3 of the OIE *Aquatic Animal Health Code (Aquatic Code)* as (a) basic biosecurity conditions have been continuously met for at least the last 5 years and (b) targeted surveillance activities as described in Chapter 1.4 of the *Aquatic Code* has been in place for at least the last 5 years without any detection of the disease
2. The Republic of Korea declares that the entire country is free from *G. salaris* as it has fulfilled the requirements for obtaining the disease-free status described in Chapter 10.3.4 point 3 of the *Aquatic Code* and Chapter 2.3.3 of the OIE *Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual).*
3. The national aquatic life disease control organization of the Republic of Korea has carried out for 9 years targeted surveillance as described in Chapter 1.4 of the Aquatic Code for susceptible species listed in Article 10.3.2 of the same chapter following the recommendations provided in Chapter 2.3 of the *Aquatic Manual*, without any detection of *G. salaris*.
4. Therefore, the Delegate of the Republic of Korea to the OIE declares to the OIE that the country is free from *G. salaris*.

2. Conditions for Aquatic Biosecurity in the Republic of Korea

2.1 Aquatic Biosecurity System in the Republic of Korea

The Republic of Korea has established a systematic national disease control and quarantine infrastructure based on its Aquatic Life Disease Control Act[1] along with financial resources to support for the system. The Aquatic Life Disease Control Act is aimed to contribute to the stable production and supply of aquatic organisms and the enhancement of citizens' health by establishing a comprehensive disease control system to prevent outbreaks or the spread of contagious aquatic organism disease (Figure 1).



[1] Aquatic Life Disease Control Act

- License of aquatic organism disease inspector - Prohibition against unlicensed medical treatment - Medical treatment register and carcass examination register - Public aquatic organism disease inspector - Reporting on suspension and closure of business	- Education on control of contagious aquatic organism disease -Compensation and subsidization to owners of aquatic organisms that have become subject to culling, etc. - Appointment of an honorary observer for control of aquatic organism disease - Subsidization, etc. for expenses

Figure 1. Summaries of the Aquatic Life Disease Control Act

The Act, which is administered by the Ministry of Oceans and Fisheries, designates the National Institute of Fisheries Science(NIFS)[2] as the national aquatic life disease control organization and the National Fishery Products Quality Management Service (NFQS)[3] as the national aquatic life quarantine organization. The national disease control system of the Republic of Korea has established the early warning system for aquatic life diseases in order to prevent the spread of contagious aquatic organism diseases through control measures specified in the provisions from the article 9 (Reporting of dead or diseased aquatic organisms) through the article 19 (Prohibition of excavation) of the Aquatic Life Disease Control Act (Figure 2). The Republic of Korea has put in place and has been operating an effective surveillance system for systematic data collection and analysis which is needed for establishing the early detection, reporting system, epidemiological investigations, etc. The national aquatic life disease control organization (NIFS) of the Republic of Korea, in accordance with the "Notification on Designation and Operation of Disease Identification Institutes for Aquatic Organisms", designates local governments, universities or private institutes as disease identification institutes, manage and supervise the institutes, provides them with standardized diagnostic techniques, provides training to the staff of these institutes every year, and organizes national proficiency tests. In the case that an infectious disease has occurred or is concerned to occur, the Korean government implements epidemiological investigations as part of activities (for understanding the scale of disease outbreak, tracking the source of infection, etc.) to prevent the outbreaks and the spread of the disease. Purposes of an epidemiological investigation are to understand the health status of a population and disease characteristics by identifying the cause and the mechanism of transmission of the disease and to decide on reasonable disease control measures to prevent the reoccurrence of the disease.

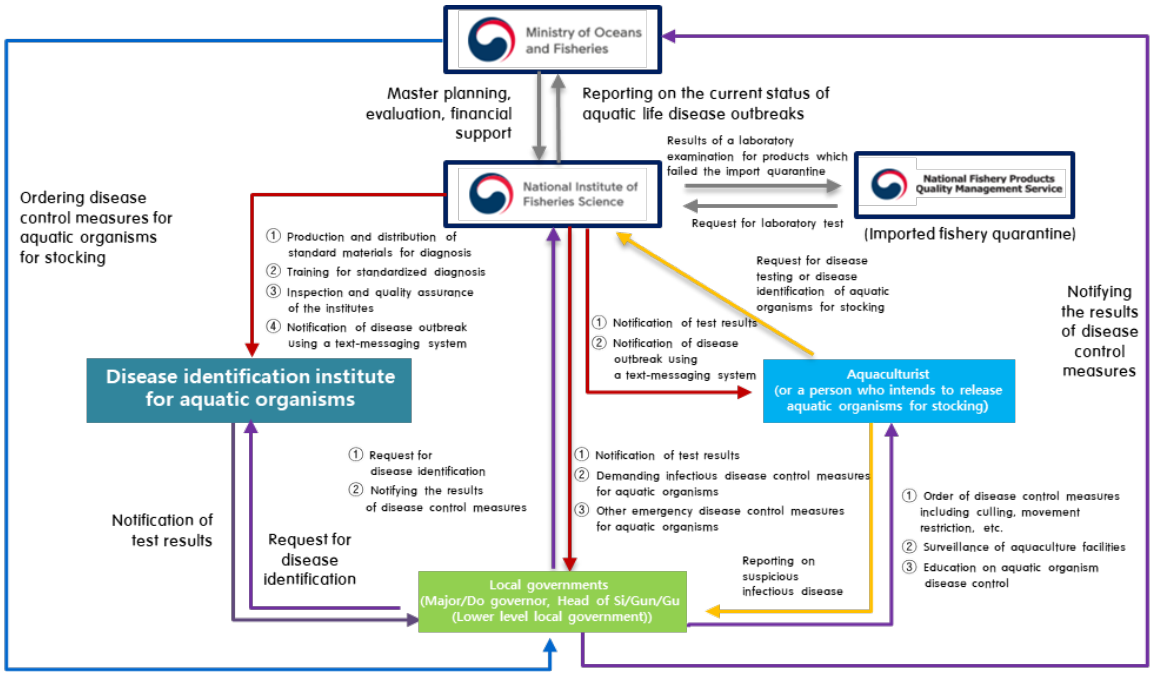


Figure 2. Diagram of the national aquatic life disease control system in the Republic of Korea

[2] http://www.nifs.go.kr/page?id=en_index

[3] http://www.nfqs.go.kr/foreign/en/main.asp

In addition, the “Aquatic Life Disease Control Act” prescribes that disease control measures shall be taken if an outbreak of infectious disease is confirmed through surveillance, confirmatory diagnosis, or epidemiological investigation. Equipment, tools, etc. at a facility where the infectious disease has occurred shall be disinfected, incinerated, or buried and aquatic organisms at the affected facility shall be subjected to measures like culling, and isolation/movement restriction, etc.

The Republic of Korea has been carrying out quarantine of imported aquatic organisms since December 2008, under the Aquatic Life Disease Control Act, with the aims of preventing the introduction of exotic diseases into the country and protecting its ecosystem. As specified in Articles 22 (Quarantine of exported and imported organisms), 23 (Things designated for quarantine purpose), 27 (Quarantine inspection on imports), and 31 (Quarantine inspection on exports) of the Aquatic Life Disease Control Act, quarantine inspections of 21 kinds of notifiable diseases in fish, shellfish, crustacean species among aquatic organisms for transplant, eating, ornament, testing, research and survey, frozen and chilled abalone, oysters, and shrimps, and diagnostic reagents including pathogens are carried out (Figure 3).

In addition to live aquatic animals, some kinds of frozen and chilled products and live aquatic organisms with high risk of introducing infectious diseases are also subject to import quarantine. The country drew up a standard form of health certificate (April 2018), which improved quarantine efficiency by encouraging exporting countries to issue health certificates using the standard form. The Republic of Korea is enhancing import quarantine by mandating a health certificate for all imported fishery products and adding on the lists of aquatic organism diseases subject to quarantine and notifiable diseases emerging overseas diseases identified through import risk analysis.

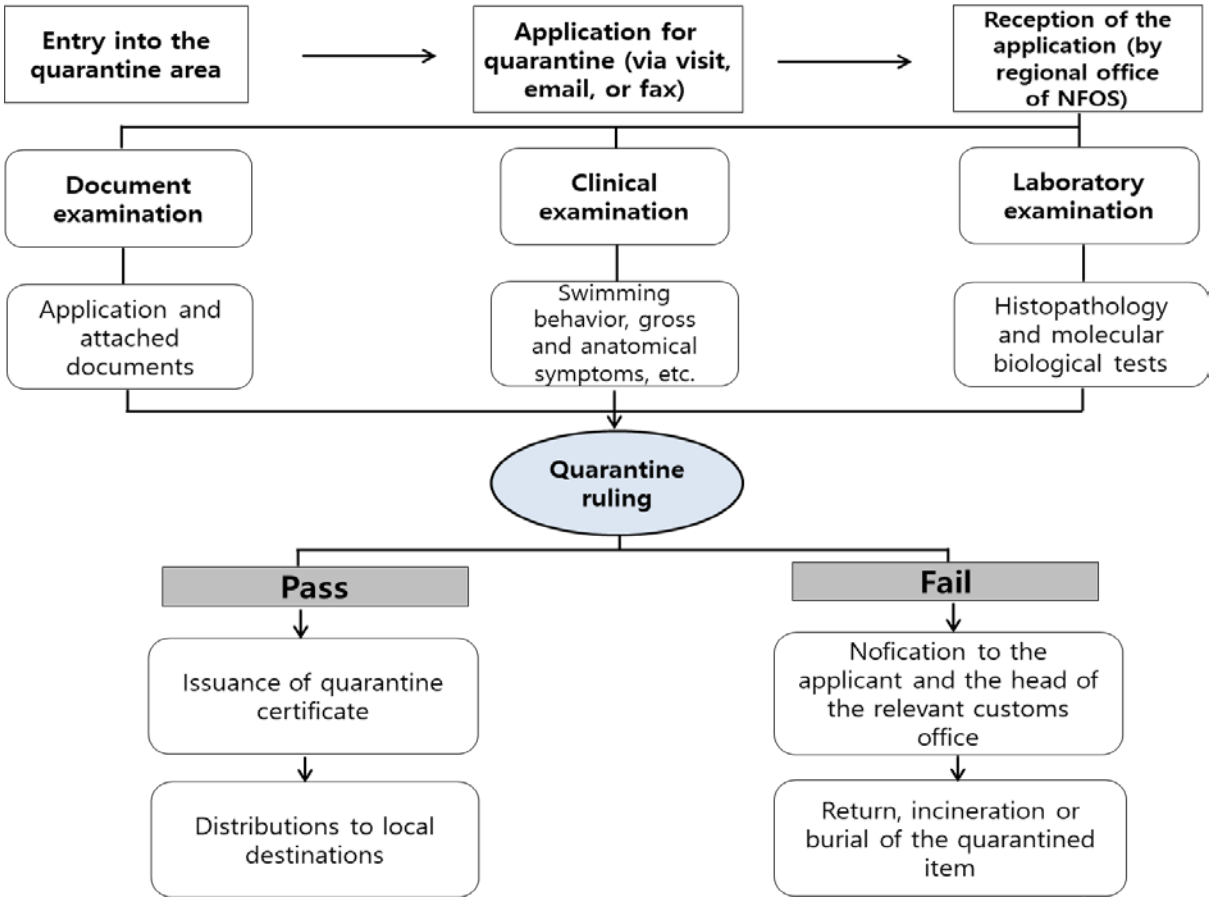


Figure 3. Import quarantine procedure for aquatic organisms in the Republic of Korea

2.2 Biosecurity conditions for *G. salaris*

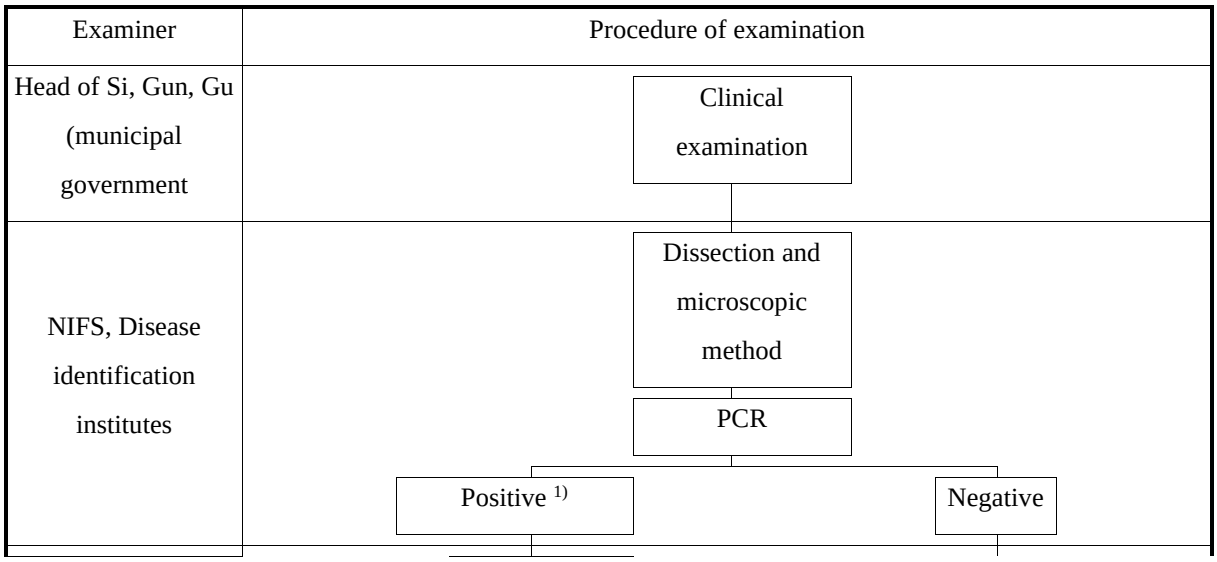
G. salaris is listed as a nationally notifiable disease in the Republic of Korea under the article 2 of the "Enforcement Rule of the Aquatic Life Disease Control Act[4]". Therefore, all measures related to surveillance and disease control are specified in the current law to ensure that an appropriate level of biosecurity should be achieved for this disease. These measures include:

- Any detection of the presence or suspicion of *G. salaris* must be reported to the competent authority by law
- The early warning system of the disease has been in place since 2008. In the case of a disease outbreak, a trained aquatic organism disease inspector or a veterinarian shall conduct a clinical test and technical follow-up measures at the affected farms.
- Targeted surveillance has been adopted (twice a year) to detect the presence of *G. salaris*, which is accompanied with general surveillance by staff of the competent authority. The surveillance results are all uploaded and maintained in an integrated network for aquatic infectious diseases[5] .
- If *G. salaris* is confirmed by a confirmatory diagnosis, epidemiological investigations and control measures shall be implemented to prevent the transmission and spread of the disease.
    - To prevent the introduction of G. salaris into the national territory, conditions specified in the Aquatic Code apply to imported Salmonidae (Salmo salar, Oncorhynchus mykiss, Salvelinus alpinus, Salvelinus fontinalis, Thymallus thymallus, Salvelinus namaycush,and Salmo trutta).

2.3 Methods for Laboratory Examination of *G. salaris*

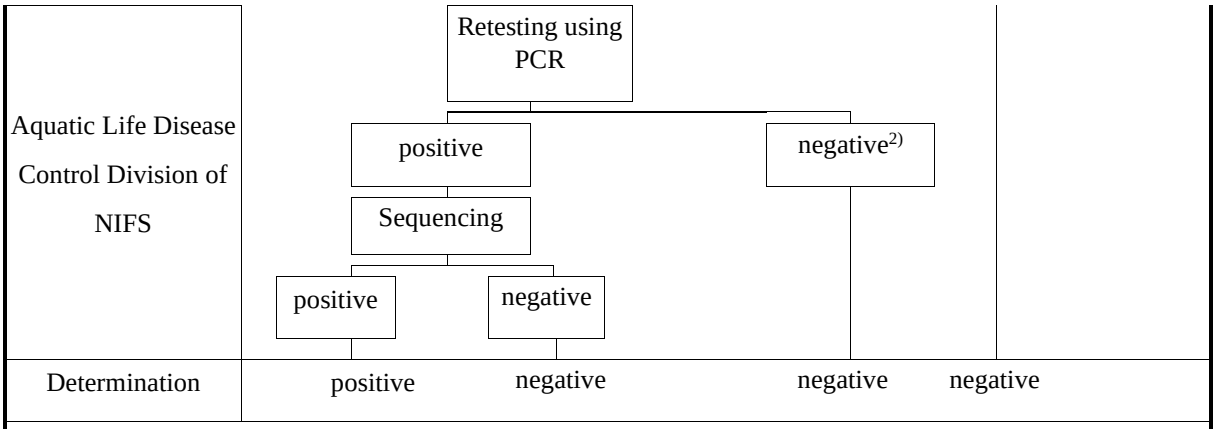
Confirmatory diagnosis of *G. salaris* is conducted at Aquatic Life Disease Control Division of NIFS, which is the national reference laboratory for aquatic organisms in the Republic of Korea. The Laboratory carries out the diagnosis as prescribed in the *Aquatic Manual*, and is equipped with necessary facilities for diagnostic work on *G. salaris*.

Figure 4. Procedure of laboratory examination of *G. salaris*



[4] Enforcement Rule of the Aquatic Life Disease Control Act

[5] http://www.nifs.go.kr/fishguard/monitor/user/login.do



1) In the case of a positive PCR result, the specimens are sent to Aquatic Life Disease Control Division of NIFS for a confirmatory diagnosis

2) A negative PCR result means a negative confirmation

※ Final positive confirmation is only made when PCR test (including sequencing) shows positive

For sampling, an adequate number of individuals including those showing clinical signs are collected following the provisions described in Chapter 2.3.3.3 of the Aquatic Manual.

Clinical and laboratory diagnosis is carried out as described in Chapter 2.3.3 point 4 (Diagnostic methods) of the *Aquatic Manual*. In the Republic of Korea, the microscopic method and molecular technique are used for disease identification. DNA is extracted from live or ethanol-preserved (80-100%) specimens. PCR amplifications of a 1300 base pair product of analysis of the ribosomal RNA gene internal transcribed spacer(ITS) region(5'-TTT-CCG-TAG-GTG-AAC-CT-3' and 5'-TCC-TCC-GCT-TAG-TGA-TA-3') and a 820 base pair product of analysis of the mithochondrial cytochrome oxidase 1(CO1) gene(5'-TAATCGGCGGGTTCGGTAA-3') are used. All of the amplified products are sequenced to identify *G. salaris*. Primer sets recommended in the *Aquatic Manual* are additionally sequenced to differentiate between *G. salaris* and *G. thymalli*. Finally, if the obtained PCR product has a 100% match with the *G. salaris* sequence (phylogenetic analysis), the final determination of a positive result is made.

3. Declaration of Freedom from *G. salaris* of the Republic of Korea

3.1 Control and Management of *G. salaris*

3.1.1 Susceptible Fish Species to *G. salaris*

Article 10.3.2 of the *Aquatic Code* (2019) lists Arctic char *(Salvelinus alpinus)*, Atlantic salmon *(Salmo salar)*, brown trout *(Salmo trutta)*, grayling *(Thymallus thymallus)*, North American brook trout *(Salvelinus fontinalis),* and rainbow trout *(Oncorhynchus mykiss)* as susceptible to *G. salaris*. Among the above-mentioned species, rainbow trout and Atlantic salmon are farmed and thus subject to surveillance of *G. salaris* in the Republic of Korea.

Chum salmon (*Oncorhynchus keta*), which is not susceptible to *G. salaris*, is the only wild Salmonidae species found in the Republic of Korea.

Atlantic salmon has been listed as a potential risk species (by Notification by the Ministry of Environment 2016-1235) and an introduction of this species into the country should be approved by the Ministry of Environment. Eyed Atlantic salmon eggs had been imported for research once every year from 2015 until 2017; from 2018, eyed eggs were no longer imported either for aquaculture or for research (Table 5). The eggs imported until 2017 had been stocked at a freshwater aquaculture

facility (the same facility where rainbow trouts are grown) where they were grown until juvenile (1 year old, 100g) and all of them were then bought by a research institute under a local government (Cold Water Resources Center in Gangwon province) where they underwent seawater acclimation before being used for aquaculture research in land-based seawater aquaculture facilities. Currently working on the development of land-based aquaculture techniques for Atlantic salmon, the research institute is rearing a total of 779 Atlantic salmons in separate tanks and carrying out regular disease control activities with fish carcasses being treated and disposed of by the Ministry of Environment.

In Korea, the aquaculture of rainbow trout was started in 1965 when 10,000 eyed eggs were imported from the U.S. for exploratory aquaculture. Currently, 161 freshwater farms produce about 3,100 tons of the fish (Table 1). The rainbow trout aquaculture farms across the country are under similar aquaculture environment and conditions. Rainbow trouts are farmed in land-based farm facilities of which rearing water is supplied from the groundwater, so fish escaping from farms during flooding are not supposed to survive.

Table 1. Aquaculture production of the Salmonidae (unit: M/T)

(Source: Fishery Information Portal, Ministry of Oceans and Fisheries)

Year	2011	2012	2013	2014	2015	2016	2017	2018	2019
Rainbow trout	3,015	3,067	3,390	3,304	3,064	3,066	3,358	3,179	3,285

3.1.2 General Surveillance Activities of *G. salaris* and the Results

G. salaris has been listed as a notifiable disease since 2008 in the Republic of Korea and the year-round routine surveillance system has been established to carry out surveillance inspection of the disease. General surveillance is implemented for people which own, manage and operate aquaculture facilities subject to surveillance through activities to promote the disease prevention and by the means of field visits or telephone using Q&A surveys like interviews and questionnaire surveys on the history and the current status of disease occurrences, mortalities, etc. The process of early detection of disease has been established as diseases are detected by producers. The 180 Salmonidae farms should undergo general surveillance. An annual average of 3.2 visits has been made since 2014 for each aquaculture farm to perform inspections on disease occurrence (Table 2).

Table 2. Number of general surveillance activities for Salmonidae (2011-1st half of 2020) (Source: NIFS, Ministry of Oceans and Fisheries)

Year	2011	2012	2013	2014	2015	2016	2017	2018	2019	1st half 2020	Total
No. of general surveillance activities	19	19	203	648	743	714	602	424	316	171	3,861

3.1.3 Targeted Surveillance Activities of *G. salaris* and the Results

To demonstrate a freedom from *G. salaris*, a targeted surveillance program was designed and implemented in accordance with the OIE recommendations (Chapter 1.4. Aquatic Animal Health Surveillance in the *Aquatic Animal Health Code* 2019). From 2011 to 2018, a one-stage random sampling method was applied for the targeted surveillance of *G. salaris*. Parameters of the one-stage random sampling were set as follows: 35% of design prevalence, 95% of sensitivity, 95% of specificity, 5% of desired precision, and 95% of confidence. The required sample size was estimated as 440 fish. In practice, the country monitored annual numbers of fish ranging from 445 to 1,263, which are up to 3 times higher than the required sample size, from 2011 to 2018. The target surveillance had been carried out for 8 years, from 2011 to 2018, and all tested individuals were not confirmed with *G. salaris* infection (Table 3).

Table 3. The 2011 - 2018 targeted surveillance of *G. salaris* results

Year		One-stage surveillance								
		2011	2012	2013	2014	2015	2016	2017	2018	Total
Rainbow trout	No. of farms inspected	39	43	29	39	42	45	99	51	387
	No. of tested fish per farm	15	16	15	15	25	28	13	24	151
	Total No. of tested fish	596	712	445	607	1,054	1,266	1,325	1,263	7,268
Atlantic salmon	No. of farms inspected	0	0	0	0	1	0	22	0	23
	No. of tested fish per farm	0	0	0	0	10	0	10	0	20
	Total No. of tested fish	0	0	0	0	10	0	234	0	244
Salmoni -dae	No. of farms inspected	39	43	29	39	43	45	121	51	410
	No. of tested fish per farm	15	16	14	15	24	27	13	23	166
	Total No. of tested fish	596	712	445	607	1,064	1,266	1,559	1,263	7,512

From 2019 to 2020, a two-stage random sampling was used for the targeted surveillance of *G. salaris*. For the 2019 surveillance, 3% of farm level design prevalence, 35% of individual level design prevalence, 95% of test sensitivity, 98% of farm level sensitivity, 95% of targeted system sensitivity, and 180 of population size were used as parameters to estimate the needed number of farms (stage one). In addition, 95% of test sensitivity, 97% of test specificity, 35% of individual level design prevalence, 5% of type I error, 5% of type II error, and 60,000 of population size were used as parameters to calculate the required number of individuals (stage two). As results, the sample size were 73 farms and 12 individuals for each farm (in total, 876 fish) with the number of cut-point one. The 73 rainbow trout farms were randomly selected with a consideration of the proportion of the number of farms in each province (Table 4). The number of sampled farms for each province may differ

from the planned one since some of the selected farms were not operated at the time of survey (Table 4). In 2019, 3,619 fish from 74 farms, which are about twice as many as the planned number of 1,752, were tested and all individuals were not confirmed with *G. salaris* infection.

Table 4. The 2019 targeted surveillance of *G. salaris* results (Source: NIFS, Ministry of Oceans and Fisheries)

		Administrative unit										
		Gangwon	Gyeonggi	South Gyeongsang	North Gyeongsang	City of Daejeon	South Jeolla	North Jeolla	Jeju	South Chungcheong	North Chungcheong	Total
No. of farms (2019)		111	2	2	36	3	1	5	1	8	11	180
Planned sample size	Farm	45	1	1	15	1	0	2	0	3	5	73
	Animal (2 tests per fish)	1,080	24	24	360	24	0	48	0	72	120	1,752
Performed sample size	Farm	46	3	-	14	-	-	2	-	2	7	74
	animal	2,205	193	-	701	-	-	100	-	60	360	3,619

For the 2020 surveillance, 2% of farm level design prevalence, 35% of individual level design prevalence, 95% of test sensitivity, 90% of farm level sensitivity, 95% of targeted system sensitivity, and 161 of population size were used as parameters to estimate the needed number of farms (stage one). In addition, 95% of test sensitivity, 97% of test specificity, 35% of individual level design prevalence, 5% of type I error, 5% of type II error, and 60,000 of population size were used as parameters to calculate the required number of individuals (stage two). As results, the sample size were 95 farms and 12 individuals for each farm (in total 1,140 fishes) with the number of cut-point one. The 95 rainbow trout farms were randomly selected with a consideration of the proportion of the number of farms in each province (Table 5). The number of sampled farms for each province may differ from the planned one since some of selected farms were not operated at that time of survey (Table 5). In 2020, 1,140 fish from 95 farms were tested and all individuals were not confirmed with *G. salaris* infection

Table 5. The 2020 targeted surveillance of *G. salaris* results (Source: NIFS, Ministry of Oceans and Fisheries)

		Administrative unit										
		Gangwon	Gyeonggi	South Gyeongsang	North Gyeongsang	City of Daejeon	South Jeolla	North Jeolla	Jeju	South Chungcheong	North Chungcheong	Total
No. of farms (2020)		94	7	2	32	0	0	3	0	5	18	161
Planned sample size	Farm	55	4	1	19	-	-	2	-	3	11	95
	Animal (2 tests per fish)	660	48	12	228	-	-	24	-	36	132	1,140
Performed sample size	Farm	59	3	-	19	-	-	1	-	-	13	95
	Animal	708	36	-	228	-	-	12	-	-	156	1,140

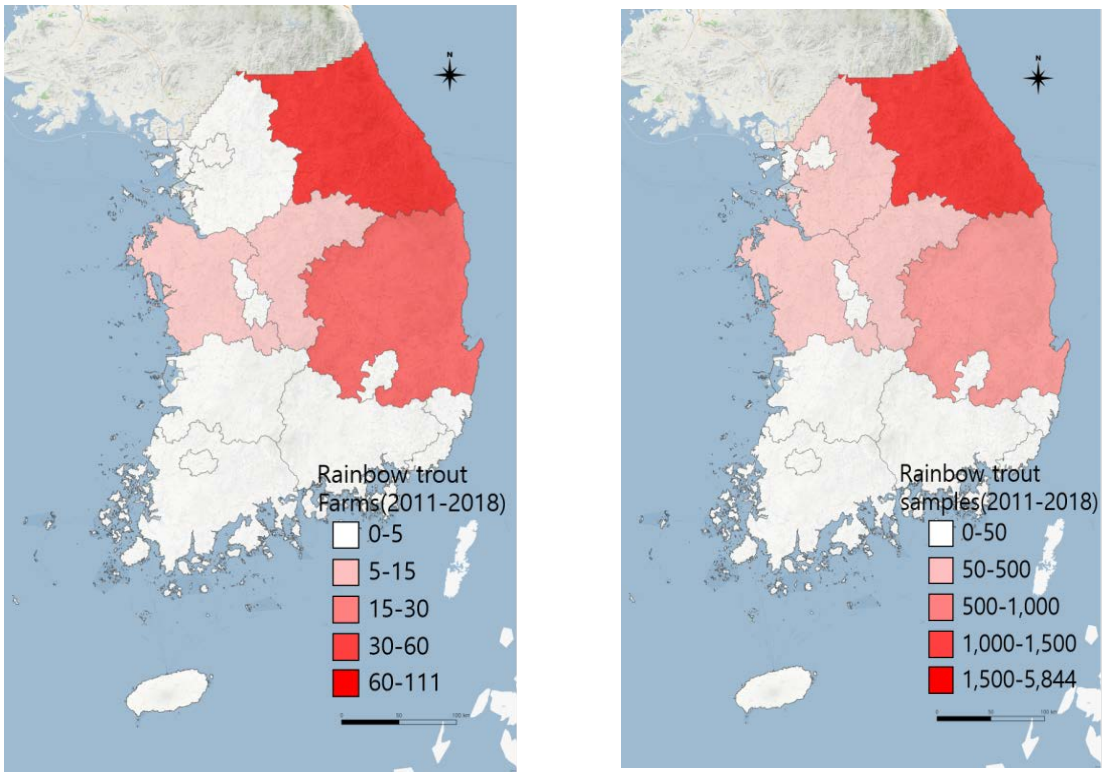


Figure 5. Distribution of the rainbow trout farms across the country from 2011 to 2018 (180 farms) and No. of inspections at rainbow trout farms by administrative unit (2011-2018; one-stage surveillance)

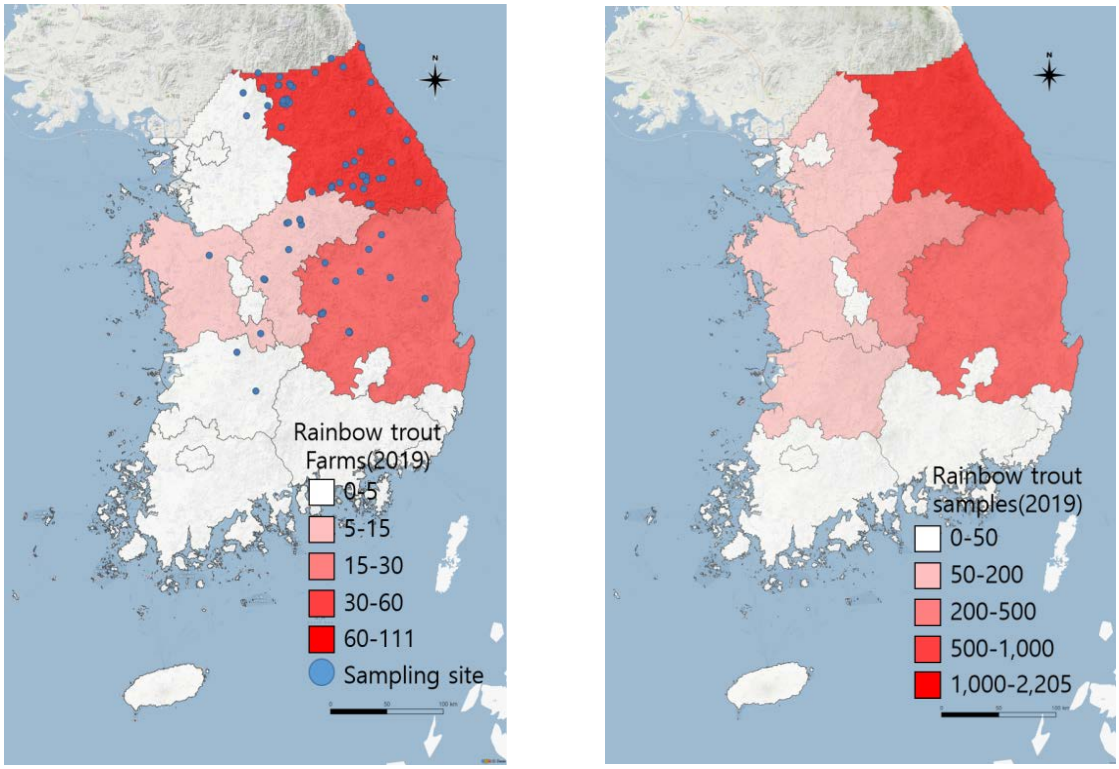


Figure 6. Distribution of rainbow trout farms across the country in 2019 (180 farms) and No. of inspections at rainbow trout farms by administrative unit (2019; two-stage surveillance)

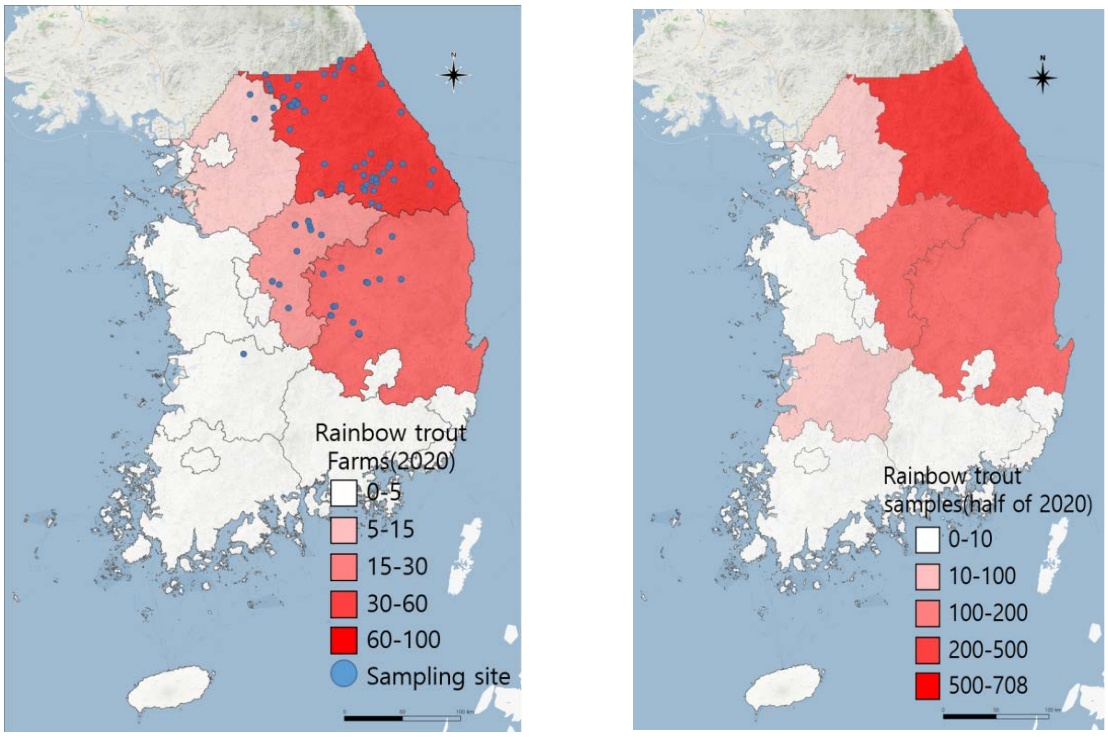


Figure 7. Distribution of rainbow trout farms across the country in 2020 (161 farms) and No. of inspections at rainbow trout farms by administrative unit (2020; two-stage surveillance)

3.2 Import Quarantine of *G. salaris*

If rainbow trouts (*Oncorhynchus mykiss*) and Atlantic salmons (*Salmo salar*) for transplant are imported into the country, the whole amount of the imported fish should undergo a lab examination of *G. salaris* to be permitted for being imported. The number of Salmonidae fish permitted for import is shown in Table 5. The country has been importing since 2018 eyed eggs of rainbow trout for aquaculture from Denmark and the U.S. These eggs are all imported from zones and aquaculture farms declared free from *G. salaris*. The exporting countries issue international aquatic animal health certificates based on the results of laboratory examinations of *G. salaris* prior to exportation. The competent authority of exporting countries of species susceptible to *G. salaris* to the Republic of Korea should attest to the freedom of *G. salaris* of the exports through inspections prior to export as requested by the competent authority of the Republic of Korea(NFQS). At arrival in the country, the imported eggs should undergo laboratory examinations of *G. salaris* as described in the *Aquatic Manual*, and those that pass the examinations are only allowed for customs clearance. The quarantine procedures for importing susceptible species to *G. salaris* will be maintained.

Table 5. Imports of Salmonidae for transplant (No. of importing event; kg) (Source: National Fishery Products Quality Management Service, Ministry of Oceans and Fisheries)

Species	2014		2015		2016		2017		2018		2019		1st half 2020	
	No.	kg	No.	kg	No.	kg	No.	kg	No.	kg	No.	kg	No.	kg
Atlantic salmon (*Salmo salar*, eyed eggs)	-	-	1	34	1	65	1	30	1	30	0	0	0	0
Rainbow trout (*Oncorhynchus mykiss*, eyed eggs)	10	289	12	386	12	457	9	415	9	401	8	318	2	40

4. Conclusion

Considering that the Republic of Korea does not share its inland water bodies with any other countries and

- Basic biosecurity conditions have been continuously met for at least 5 years,
- Targeted surveillance, as described in Chapter 1.4 of the Aquatic Code, has been in place for the last 9 years (at least five years) without any detection of *G. salaris* in the Republic of Korea, and
- To maintain its status of freedom from *G. salaris*, the Republic of Korea will maintain its targeted surveillance activities and basic biosecurity conditions following the provisions of Article 10.3.6. of the Aquatic Code and maintain quarantine following the provisions of Article 10.3.6. of the OIE Aquatic Code.

The OIE Delegate of the Republic of Korea declares that the country complies with the requirements of "a country free from infection with *Gyrodactylus salaris*" starting from 1 August 2020 in accordance with the provisions of Chapters 1.4 and 10.3 of the OIE *Aquatic Code,* and Chapter 2.3.3 of the Aquatic Manual (2019), and is consistent with the information provided in WAHIS.

Annex I

Statement to be included in the self-declaration document.

I, the undersigned, Dr. Daegyun Kim, Delegate of for the Republic of Korea to the World Organisation for Animal Health (OIE), takes responsibility for the self-declaration of freedom from *Gyrodactylus salaris* in accordance with the provisions of Chapter 10.3.4 of the OIE *Aquatic Code*.

DISCLAIMER

The OIE, after performing an administrative and technical screening of a self-declaration concerning the disease-free status of a country, a zone or compartment ("self-declaration"), as described in the standard operating procedures for self-declarations, reserves the right to publish or not the self-declaration on its website. There shall be no right of appeal from this decision or any recourse of any kind.
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(ii) The use which may be made of the information contained in a self-declaration;
(iii) Any direct or indirect consequences of any nature arising from or relating to the use of the information contained in a self-declaration.

Drawn up on 29 September 2020

Signature of the Delegate: