

No. 20354

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**SPAIN  
and  
ITALY**

**Agreement on standards of wholesomeness for edible molluscs for export (with annexes). Signed at Rome on 11 May 1979**

*Authentic texts: Spanish and Italian.*

*Registered by Spain on 19 August 1981.*

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**ESPAGNE  
et  
ITALIE**

**Accord relatif aux normes sanitaires auxquelles doivent répondre les mollusques destinés à l'exportation (avec annexes). Signé à Rome le 11 mai 1979**

*Textes authentiques : espagnol et italien.*

*Enregistré par l'Espagne le 19 août 1981.*

## [TRANSLATION — TRADUCTION]

AGREEMENT<sup>1</sup> BETWEEN THE SPANISH STATE AND THE ITALIAN REPUBLIC ON STANDARDS OF WHOLESOMENESS FOR EDIBLE MOLLUSCS FOR EXPORT

## AGREEMENT

The two Contracting Governments, with a view to initiating and expanding their collaboration in the surveillance of imported food products for hygiene and wholesomeness in such a way as not to disrupt their reciprocal trade in such products, and with a view to facilitating the import of live molluscs produced or harvested in the other Contracting State, have agreed as follows:

*Article 1.* It shall be permitted, in both countries, to import edible live molluscs which satisfy the requirements of article 7 and meet the following conditions:

- (a) The live molluscs shall come from maritime areas whose waters do not impart abnormal organoleptic properties to them or render them hazardous to human health and whose waters, on the basis of appropriate microbiological, chemical radioactivity and biological tests, meet the established hygiene and health standards in the two countries;
- (b) The competent authorities of the country of origin shall periodically, at least once a month, test the said waters of cultivation or harvest as appropriate to ascertain that they continue to meet the standards indicated in subparagraph (a) above;
- (c) The above-mentioned authorities shall also conduct tests on the molluscs cultivated or harvested in the said waters, the results of which shall serve, on the one hand, to assess the condition of the waters themselves and, on the other hand, to ascertain the effectiveness of the purification process.

*Article 2.* If the results of the above-mentioned tests indicate that the waters in all or in some of the areas of cultivation or harvest do not meet the requirements established in the preceding article or if they reveal ecological changes that might become a public health risk, the authorities of the country of origin must immediately inform the competent authorities of the country of destination, at the same time suspending the export of molluscs produced or harvested in the waters of the affected area until the situation returns to normal.

In particular, the exporting State undertakes, as soon as the first manifestations of a bloom of toxic algae are observed in any area of cultivation or harvest, to so inform the importing State immediately, indicating the type of algae which are producing water-soluble and/or fat-soluble biotoxins.

*Article 3.* Where in one of the Contracting States a given species is subject to compulsory purification if it is intended for consumption, that process may be carried out in the purification plants of either the exporting or the importing State,

<sup>1</sup> Came into force on 19 July 1981, i.e., 30 days after the exchange of the instruments of ratification, which took place at Madrid on 19 June 1981, in accordance with article 14.

provided that such plants have been licensed and declared acceptable to both States by the members of the Joint Commission referred to in article 10 below.

To that end, the competent authorities of both States shall indicate which mollusc purification plants they wish to have licensed. The plants must be inspected for licensing purposes within a period of no more than six months from the date of any given request.

Where the said inspection is not conducted within the specified period, for reasons imputable to the non-requesting State, it shall be understood that the latter recognizes the uninspected purification plant or plants in question as acceptable, and they shall therefore be considered automatically licensed.

Where the authorities responsible for inspecting the purification plants find that any of them do not meet the established standards, or are not operating properly, they shall so inform the authorities of the other State. Moreover, they shall not issue the required certificates and shall simultaneously take steps to suspend the export of molluscs purified in such plants to the other Contracting State. Once the causes which prompted such suspension are no longer present, and after communication with and approval by the authorities of the importing State in accordance with the second and third paragraphs above, exports may resume as stipulated.

The competent authorities of the two Contracting States shall also notify each other as soon as the licence of any plant is revoked.

*Article 4.* Molluscs for export, whether or not they come from installations licensed by either of the two States, shall be subjected to washing, selection, classification\* and packaging operations, lot by lot, with a view to satisfying the requirements of the regulations in force in the importing State.

To that end, the two States shall notify each other of any change that may take place in their respective laws currently in force, as listed in annexes 5(a) and 5(b) of this Agreement.

*Article 5.* The lots of imported molluscs must bear, on each and every package or wrapping, an appropriate label, separate from any other commercial label, indicating that they have been inspected for wholesomeness in accordance with the requirements of this Agreement.

The said labels (annexes 1(a) and 1(b)), which shall be yellow, shall contain the following indications:

- Authority and State of origin;
- Species (as detailed in annexes 1(a) and 1(b));
- Identification number of the purification plant (perforated);
- Date of consignment (perforated, indicating the day, month and year of shipment from the purification plant);
- Weight in kilograms using fractions or multiples thereof (perforated).

Every lot of molluscs of the same species shall also be accompanied by an export certificate of wholesomeness, conforming to the models in annexes 2(a) and 2(b).

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\* Classification means classification by species, origin and size.

This certificate, which guarantees that the product meets the standards of this Agreement, shall be valid for seven days from the date of purification, the said product to be maintained constantly at a temperature of 6° C, within a tolerance of  $\pm 2^\circ$  C.

The molluscs shall be transported in such a way as to guarantee that, at the time they are imported, their wholesomeness, their original organoleptic properties and their full vitality will still be safeguarded. In all cases, the means of transport must meet the requirements of the existing laws of the importing State which provide for such safeguards, as listed in annexes 5(a) and 5(b).

*Article 6.* Where, pursuant to the provisions of the first paragraph of article 3 above, purification takes place in the importing State, the mollusc lots shall be accompanied by a red label bearing the indication “NON-PURIFIED PRODUCT” (annexes 3(a) and 3(b)).

All documents accompanying the shipment shall also bear the indication “NON-PURIFIED PRODUCT”.

*Article 7.* At the time they are imported into one of the Contracting States, live molluscs originating in the other State must satisfy the following conditions:

- (a) They shall—whether or not they have been subjected to purification—be free of any micro-organisms, toxins and parasites hazardous to human health, which cannot be totally eliminated by the purification treatment;
- (b) The colibacterial count of purified molluscs, to be determined by the method of analysis specified in annex 4, shall not exceed 500 *E. coli* per 1,000 ml of molluscs (soft tissue and intervalvular water);

However, it shall be permissible for 25 per cent of the samples taken during the importing season to show a higher colibacterial count, but it may in no case exceed, according to the above-mentioned method of analysis, 600 *E. coli* per 1,000 ml;

- (c) The content of biotoxins which are in any way hazardous to human health, especially paralytic molluscan toxin, shall in no case exceed levels that may be considered dangerous, according to the criteria applied by the health authorities of the importing State, until such time as an international standard is established on the basis of new scientific information;
- (d) The heavy metal concentration shall not exceed that recommended by the European Economic Community, and the mercury concentration shall not exceed 0.5 parts per million;
- (e) The maximum permissible concentration of radionuclides must conform to that established in the EURATOM tables for drinking water and food.

*Article 8.* Frontier, port and airport health authorities shall authorize the import of lots which conform to the provisions of the preceding articles, but may, at the time of inspection, take samples of molluscs for immediate laboratory analysis, at the same time retaining enough samples for possible additional testing, in order to ascertain, according to the methods indicated in annex 4, that they meet the conditions of article 7 above.

If the test results do not satisfy the requirements of article 7, the lots in question shall be withdrawn from the market and returned or destroyed at the

expense of the exporter. The said test results shall be communicated to the competent authorities of the State of origin, so that they may take appropriate steps in each case.

The health authorities of the importing Contracting State may, on the basis of the health risk disclosed by the test results, temporarily suspend the import of molluscs from the areas of cultivation or harvest or from the purification plants in which the sub-standard lots have been purified and packaged.

In addition to the above-mentioned testing and inspection, the respective official services of the two Contracting States may conduct any checks they deem necessary either of lots being exported to the other State or of imported lots, in accordance with the provisions of their respective laws in force.

*Article 9.* The competent authorities of each Contracting State may, where they deem it necessary, make inspection visits to the areas of cultivation or harvest, and shall be given access to the corresponding purification installations or plants referred to in this Agreement, after prior communication with the competent authorities of the other State, who may designate their own officials to be present during the said inspections.

In addition, technical co-operation shall be developed under the direction of the two Contracting States to investigate thoroughly all health problems relating to the quality control of edible molluscs.

*Article 10.* Any technical or scientific updating which may become necessary in connection with the application of this Agreement shall be dealt with by a Joint Commission, which shall also review any questions that may arise in the course of the application of the Agreement.

The said Commission shall be composed of three or more members appointed by each Party, at least two of whom, one per Party, shall be experts in health microbiology.

Meetings of the Commission, officially requested by one of the Parties with a specified agenda, shall be held in the non-requesting State within a period of two months from the date of receipt of the request. That State may also include other items in the agenda.

The agenda items on which the Commission does not reach agreement and which therefore remain unresolved shall be dealt with through the diplomatic channel.

*Article 11.* The health authorities referred to in this Agreement are:

In the case of Spain:

Dirección General de Saluda Pública  
(Ministerio de Sanidad y Seguridad Social) — Dirección  
Plaza de España, 17  
Madrid 13

In the case of Italy:

Direzione Generale Igiene Alimenti e Nutrizione  
(Ministero della Sanità)  
00144 Roma — Piazzale Marconi — Palazzo Italia

*Article 12.* The competent authorities referred to in this Agreement are:

In the case of Italy:

Direzione Generale Igiene Alimenti e Nutrizione  
(Ministero della Sanità)  
00144 Roma — Piazzale Marconi — Palazzo Italia

In the case of Spain:

Junta Central Inspector para la Calidad  
y Salubridad de los Moluscos,  
con domicilio en la Subsecretaría  
de Pesca y Marina Mercante  
Calle Ruiz de Alarcón 1

*Article 13.* This Agreement shall in no way affect the rights and commitments which have previously been undertaken or might in future be undertaken by either Contracting Party on the basis of multilateral international agreements. However, products imported from third States may not be made subject to less rigorous standards of wholesomeness without prior technical assessment and approval by the Joint Commission.

*Article 14.* This Agreement shall enter into force on the thirtieth day following the date of exchange of the instruments of ratification. It is concluded for an indefinite period and may be denounced at any time with six months' advance notice.

DONE at Rome on 11 May 1979 in two copies, in the Italian and Spanish languages, both texts being equally authentic.

For the Italian Republic:  
[ARNALDO FORLANI]

For the Spanish State:  
[D. CARLOS ROBLES PIQUER]

A N N E X 1 (a)

			SERIES AND NUMBER LABEL
Purification plant	Kilogrammes	Date	

			SERIES AND NUMBER LABEL
Purification plant	Kilogrammes	Date	

			SERIES AND NUMBER LABEL
Purification plant	Kilogrammes	Date	

The background letters correspond to the following species:

M = Mussels      O = Oysters      V = Miscellaneous species

COLOUR: YELLOW

ANNEX 1 (b)

			SERIES AND NUMBER LABEL
Purification plant	Kilogrammes	Date	
Region	ITALIAN REPUBLIC MINISTRY OF HEALTH Department of Food Hygiene and Nutrition Health Official of the Municipality of		

			SERIES AND NUMBER LABEL
Purification plant	Kilogrammes	Date	
Region	ITALIAN REPUBLIC MINISTRY OF HEALTH Department of Food Hygiene and Nutrition Health Official of the Municipality of		

			SERIES AND NUMBER LABEL
Purification plant	Kilogrammes	Date	
Region	ITALIAN REPUBLIC MINISTRY OF HEALTH Department of Food Hygiene and Nutrition Health Official of the Municipality of		

COLOUR: YELLOW

The letters inscribed on the above-mentioned labels correspond to the following:

M = Mussels    O = Oysters    V = Other edible molluscs of various species



A N N E X 2 (a)

MINISTRY OF HEALTH  
AND SOCIAL SECURITY

MINISTRY OF COMMUNICATIONS  
AND TRANSPORT

Department of Public Health

Department of Maritime Fishing

CERTIFICATE OF WHOLESOMENESS

The undersigned, an official of the Department of Public Health or the Department of Maritime Fishing (Spanish Oceanographic Institute), pursuant to the Joint Ordinance of the Ministry of the Interior and the Ministry of Commerce dated 24 September 1956, and to the Decree of 20 August 1970,

CERTIFIES

that the shipment of ..... composed of ..... packages, bearing the indications ....., weighing ..... kilograms, intended for export and shipped by ..... at ..... addressed to ....., at ..... satisfies the requirements of the Agreement concluded between the Spanish and Italian authorities on ....., 197...

....., 197..  
Health Inspector of Molluscs

A N N E X 2 (b)

CERTIFICATE OF WHOLESOMENESS

ITALIAN REPUBLIC

MINISTRY OF HEALTH

Department of Food and Nutrition

Series ..... No. ....

Region .....

Province .....

Municipality .....

*Consignor*

First name .....

Surname .....

Address .....

*Means of transport* .....

*Consignee*

First name .....

Surname .....

Address .....

*Nature of product—species* .....

Number of packages .....

Bearing the indications .....

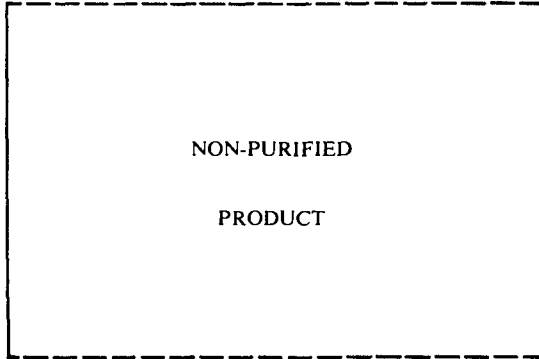
Total weight of packages .....

## IT IS CERTIFIED

that the above-mentioned products come from the purification plant of .....  
 operated by ..... licensed by the Provincial Medical Officer through Decree  
 No. .... dated ..... and recognized as acceptable in conformity with  
 the provisions of the Spanish-Italian Agreement of .....

The Health Official of the Municipality of .....

A N N E X 3 (a)



COLOUR: RED

## ANNEX 3 (b)



NON-PURIFIED

PRODUCT

COLOUR: RED

## A N N E X 4

## METHODS OF ANALYSIS

—In the case of Spain, those indicated in the Ordinance of 11 April 1973 (*Official Gazette* of 16 April 1973).

—In the case of Italy, those indicated in the Ministerial Decree of 27 April 1978.

## A N N E X 5 (a)

SPANISH LEGISLATION IN FORCE REGARDING WHOLESOMENESS  
AND QUALITY OF MOLLUSCS

Decree No. 2284/1964 of 23 July, establishing the regulations for ascertaining the quality and wholesomeness of molluscs (*Official Gazette* No. 198, 18 August 1964);

Department of Health resolution of 28 July 1967 on the compulsory purification of molluscs (*Official Gazette* No. 190, 10 August 1967);

Department of Health resolution of 19 January 1970 on compulsory purification (*Official Gazette* of 29 March 1970);

Decree No. 2699/170 of 10 August, amending Decree No. 2284/1984 (*Official Gazette* No. 232, 28 September 1970);

Department of Health resolution No. 32440 of 16 October 1974, on purification of molluscs (*Official Gazette* No. 275, 29 November 1974);

Department of Health resolution No. 16242 of 11 July 1975, on purification of molluscs (*Official Gazette* No. 182, 31 July 1975);

Department of Tariff and Import Policies resolution of 18 July 1975, establishing Barcelona as the sole inspection point for edible molluscs (*Official Gazette* No. 171, 18 July 1975);

Decree No. 1835/1975 of 24 July, amending Decree No. 2284/1974 (*Official Gazette* No. 187, 8 August 1975);

Royal Decree No. 1521/1977 of 3 May, adopting the technical health regulations for fish products intended for human consumption (*Official Gazette* No. 157, 2 July 1977);

Department of Health resolution of 28 July 1977 on the use of yellow containers.

## A N N E X 5 (b)

ITALIAN LEGISLATION IN FORCE REGARDING  
WHOLESOMENESS OF MOLLUSCS

Act No. 192 of 2 May 1977 (*Official Gazette* No. 132 of 17 May 1977);

Ministerial Decree of 27 April 1978 (Regular Supplement to *Official Gazette* No. 125 of 8 May 1978);

Ministry of Health notice of amendment to Ministerial Decree of 27 April 1978 (*Official Gazette* No. 209 of 27 July 1978);

Ministerial Decree of 4 October 1978 (*Official Gazette* No. 286 of 12 October 1978);

Ministerial Decree of 5 October 1978 (*Official Gazette* No. 286 of 12 October 1978);

Presidential Decree No. 185 of 13 February 1964;

Ministerial Decree of 6 June 1968;

Ministerial Decree of 2 February 1971.