
**Traceability of molluscan products —
Specifications on the information to
be recorded in captured molluscan
distribution chains**

*Traçabilité des mollusques — Spécifications relatives aux
informations à enregistrer dans les chaînes de distribution de
mollusques issus de la pêche*

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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Abbreviations	3
5 Principle	4
6 Requirements	4
6.1 Identification of the units traded.....	4
6.2 Recording of information.....	4
6.3 Controlled relaying and depuration.....	6
6.4 Capture.....	6
6.5 Vessel landing businesses and first sale.....	9
6.6 Processors.....	11
6.7 Transporters and store operators.....	15
6.7.1 Live molluscs.....	15
6.7.2 Molluscs other than live.....	17
6.8 Traders and wholesalers.....	19
6.9 Retailers and caterers.....	21
6.10 Bringing in materials from outside the domain.....	23
Bibliography	25

[ISO 18539:2015](https://standards.iteh.ai/catalog/standards/sist/f7c03a4d-e4e8-48d5-afed-2ea43c27b0f8/iso-18539-2015)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document ISO/TC 234, *Fisheries and aquaculture*.

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Introduction

There are increasing demands for detailed information on the nature and origin of food products. Traceability is becoming a legal and commercial necessity.

The ISO definition of traceability concerns the ability to trace the history, application, and location of that which is under consideration, and for products, this can include the origin of food materials and non-food parts thereof, the processing history and the distribution and location of the product after delivery. Traceability includes not only the principal requirement to be able to physically trace products through the distribution chain, from origin to destination and vice versa, but also to be able to provide information on what they are made of and what has happened to them. These further aspects of traceability are important in relation to food safety, quality, and labelling.

The scheme specified in this International Standard does not demand perfect traceability, i.e. that a particular retail product is to be traceable back to a capture operator and batch of origin. Pragmatically, it is recognized that mixing of animals or materials is often commercially necessary at a number of stages in the distribution chains, e.g. in grading at first sale prior to sale and in the processing of raw materials into products. As a result, there will be occasions where whole chain traceability of materials and products is neither possible nor commercially practical. These limitations are to be recognized and taken into consideration when auditing against this International Standard and are not to preclude compliance so as to disadvantage otherwise compliant operators. Where such mixing necessarily occurs, the food business shall generate a trade unit or units only from the point that identification of units is possible. The requirement for traceability is that the business records the IDs of created or received trade units that can be input into each subsequently created unit thereafter, and vice versa. The particular product or products are then traceable through the supply chain (as far as is practical) to generate information on the maximum number of stages of the chain as possible.

Given the variety of molluscan products and of their distribution chains that operate within and between different countries, and varying legal requirements, the information specifications cannot itemize all the information that can possibly be required in every situation. This International Standard provides a generic basis for traceability. Flexibility is allowed for businesses to record further information, in their own non-standardised files, but keyed to the same unit IDs.

The information remains in the ownership of the food business that generated it but is available when required by law for the purposes of traceability (in the event of a food safety problem) or by commercial agreement between businesses. The structure, names, and content of the information is standardised so that it can be readily communicated from business to business through the distribution chains, ensuring common understanding of terms and meanings.

Commercial arrangements for businesses to communicate information through the distribution chains are to be encouraged, particularly for the information desired by the trade to be visible at the various transaction points in the chains, but that is not the subject of this International Standard.

Although this International Standard is designed with electronic representation and communication of data in mind, the specifications can be met by paper systems.

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Traceability of molluscan products — Specifications on the information to be recorded in captured molluscan distribution chains

1 Scope

This International Standard specifies the information to be recorded in wild-caught molluscs supply chains in order to establish the traceability of products originating from wild-caught molluscs. It specifies how molluscan products traded are to be identified and the information to be generated and held on those products by each of the food businesses that physically trade them through the distribution chains. It is specific to the distribution for human consumption of molluscs and their products, from wild caught through to retailers or caterers.

The types of businesses identified in this International Standard for wild-caught molluscan distribution chains are the following:

- capture;
- landing business and first sale;
- depuration and shucking, etc.;
- processors;
- transporters and store operators;
- traders and wholesalers;
- retailers and caterers;
- logistics including materials brought from other domains.

Any given molluscan distribution chain can be made up of some or all of the above components but not necessarily in the sequence listed.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

traceability

ability to trace the history, application, or location of that which is under consideration

Note 1 to entry: When considering product, traceability can relate to

- origin of materials and parts,

ISO 18539:2015(E)

- processing history, and
- distribution and location of the product after delivery.

[SOURCE: ISO 9000:2005, 3.5.4 — modified]

3.2

Unique Logistic Unit Identifier

ULUI

any composition established for transport and/or storage that needs to be identified and managed through the supply chain

3.3

Unique Trade Unit Identifier

UTUI

smallest unit, which is guaranteed to retain its integrity as it moves from one link of the chain to the next

Note 1 to entry: It is the smallest unit that is kept whole and undivided with no change in content or label/identification.

3.4

molluscan

invertebrate animal belonging to the phylum Mollusca

Note 1 to entry: A molluscan has a soft unsegmented body and is covered by a calcium carbonate shell, of one to eight parts or sections. In some species, the shell is lacking or reduced. Major cultured molluscs are mussels, oysters, scallops, cockles, clams (bivalves), and abalone (gastropod).

3.5

molluscan products

products prepared out of molluscs or parts thereof

3.6

capture fishing

commercial fishing activities with or without vessel which can be motorized or not, with mechanized or manual devices

3.7

capture operators

persons or entities engaged in capture fishing

3.8

relaying

removal of bivalve molluscs from a microbiologically contaminated growing area to an acceptable growing or holding area under the supervision of the agency having jurisdiction and holding them there for the time necessary for the reduction of contamination to an acceptable level for human consumption

3.9

depuration

reduction of micro-organisms to a level acceptable for direct consumption by the process of holding live bivalve molluscs for a period of time under approved, controlled conditions in natural or artificial seawater suitable for the process, which may be treated or untreated

3.10

heat shocking

process of subjecting bivalve molluscs in the shell to any form of heat treatment, such as steam, hot water or dry heat, for a short period to facilitate rapid removal of meat from the shell for the purpose of shucking

3.11

shucking

process of removing the meat from the shell

4 Abbreviations

CAC	Codex Alimentarius Commission
EPC	Electronic Product Code, a unique number provided by GS1 used to identify instances of trade items (individual trade units) particularly suited for representation in an RFID chip
FAO	Food and Agriculture Organization of the United Nations
FBO	Food Business Operator, generic term for someone in the supply chain who processes, sends or receives relevant trade units or logistic units
GLN	Global Location Number, a 13 digit globally unique number provided by GS1 used to identify parties and physical locations
GMP	Good Manufacturing Practice
GS1	Global non-profit organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors; previously EAN/UCC
GTIN	Global Trade Item Number, an 8-digit to 14-digit globally unique number provided by GS1 used to identify types of trade items (product types)
HACCP	Hazard Analysis Critical Control Points
HS	Harmonized Commodity Description and Coding System
IQF	Individually Quick Frozen
LAT	Latin Name
LU	Logistic Unit
RFID	Radio-Frequency Identification, the use of an object (typically referred to as an RFID tag) applied to or incorporated into a product for the purpose of identification and tracking using radio waves
RFMO	Regional Fisheries Management Organization
SGTIN	Serialized Global Trade Item Number, a unique number provided by GS1 used to identify instances of trade items (individual trade units) by extending the GTIN
SSCC	Serial Shipping Container Code, an 18-digit globally unique number provided by GS1 used to identify logistics units
TSN	Taxonomic Serial Number
TU	Trade Unit
UI	Unique Identifier
ULUI	Unique Logistic Unit Identifier
UTUI	Unique Trade Unit Identifier

5 Principle

The fundamental principle of chain traceability is that trade units (TU) shall be identified by unique codes (UI). This code may be globally unique in itself (for instance, the GS1 SGTIN or EPC numbers) or it could be unique in that particular scope only, which means that it should be no other TUs in that part of the chain that might have the same number. If the scope (product type, company, chain, sector, country, or similar) is assigned globally unique number, the combination of the globally unique scope number and the locally unique TU number shall constitute a globally unique identifier for the TU.

NOTE 1 The UTUI term is introduced to indicate a TU identifier which is or can be made globally unique.

Trade Units (TUs) may be grouped together to make Logistic Units (LUs) or LUs may be grouped together to make higher level LUs. A fundamental principle of chain traceability is that logistic units shall be identified by a unique code. This code shall be a national code which may be globally unique in itself (similar to the GS1 SSCC code) or it could be unique in that particular scope only, which means that there should be no other LUs in that part of the chain that might have the same number. If the scope (product type, company, chain, sector, country) is assigned a globally unique number, the combination of the globally unique scope number and the locally unique LU number shall constitute a globally unique identifier for the LU.

NOTE 2 The ULUI term is introduced to indicate a LU identifier which is or can be made globally unique.

The key to the operation of this traceability scheme is the labelling of each unit of goods traded, whether of raw materials or finished products, with a unique ID. This shall be done by the food business that creates each unit. Businesses that transform units, such as processors who convert the units of raw materials received into the products dispatched, shall create new units and shall give them new IDs.

As indicated above, the simplest way of implementing UTUIs and ULUIs is to use the GS1 SGTIN/EPC and SSCC codes. This practice is recommended but is not mandatory. The central principle behind this International Standard is that businesses which create TUs or LUs should assign unique numbers to them.

Each of the food businesses that create or physically trade in those units, throughout the distribution chains from catcher through to retailer or caterer, shall generate and hold the information necessary for traceability. The information is to be held on paper or electronically keyed to the unit IDs.

6 Requirements

6.1 Identification of the units traded

Businesses that bring in supplies of captured molluscan products from outside of the domain of the specifications and trade them onwards shall identify each unit traded and record associated information elements as indicated in [Table 3](#) to [Table 10](#).

6.2 Recording of information

To distinguish between the different categories of information, all information elements are classified as either “shall”, “should”, or “may”, with definition (see [Table 1](#)).

Table 1 — Classification of informative elements

	Definition	Explanation
“shall”	This category contains recordings related to identifiers and transformations that are necessary in order to trace the history, application, or location of an entity. This means the unique identity of trade and logistic units, as well as the dependencies between the identifiers of inputs and outputs in a process.	“shall” elements are data elements that are deemed necessary to record to ensure that traceability is possible. Data elements relating to product properties are not in this category, even if these properties are essential for other purposes like product documentation or food safety.
“should”	This category contains parameters that describe and provide supporting information on the units being traced. Common parameters required by law, commercial requirements or good manufacturing practises are recorded, but only where an established international format or data list for the value exists.	This includes parameters like “species”, “production date”, etc. If certification according to this International Standard is to happen in the future, the “should” parameters are to be considered.
“may”	This category contains parameters that describe and provide supporting information on the units being traced. It contains parameters that are not part of the “should” category, but that might still be useful or relevant to record. It also contains parameters that might be deemed important, but where no established international format or data list exists.	The “may” category is informative only, and it is included to enable use and uptake of the International Standard. If certification according to this International Standard is to happen in the future, the recording of “may” parameters are not to be considered when evaluating adherence. The list of “may” elements is not definitive or exclusive, it is by design extendible, and the threshold for including new elements in this category is low.

Businesses that physically trade in molluscan products shall generate and hold the required information, appropriate to the type of business, for each of the units traded. The detailed information requirements are tabulated in [Table 2](#).

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Table 2 — Information requirements to be recorded by the different businesses

Food Business Operator (FBO) type	Table	Data prefix ^a	Receive	Transform	Create/Produce	Dispatch
Capture	3	MFV	—	Yes	TU/LU	TU/LU
Landing businesses and first sale centre	4	MLA	TU	—	TU/LU	TU/LU
Processors	5	MPR	TU/LU	Yes	TU/LU	TU/LU
Live molluscan transporters	6	MTR	TU/LU	Yes	TU/LU	TU/LU
Transporters and cold store operators for molluscs other than live	7	MTS	TU/LU	No	LU	TU/LU
Traders and wholesalers	8	MTW	TU/LU	No	TU/LU	TU/LU
Retailers and caterers	9	MRC	TU/LU	Yes	TU/LU	—
Bringing in materials from outside the domain	10	MOT	TU/LU	—	TU/LU	TU/LU

^a For the purpose of unique identification to establish an extendable framework for data element identification, each table has been identified with a three letter alphanumeric code. This code plus three digits is used to give a unique number to each data element.

The information specifications separately tabulate the information to be recorded by each of these types of business. Some businesses may carry out the functions of more than one of the types listed,

for example, distribution businesses may act as wholesalers and as transporters in which case, those businesses shall record the relevant information requirements for each of the functions carried out.

NOTE 1 This International Standard is limited in scope to the distribution for human consumption of molluscs and their products. The captured molluscs information specifications are substantially the same from processing onward.

Pragmatically, it is recognized that some supplies of molluscan products and supplies of ingredients, etc., will come from outside of the domain and may lack the required IDs and information records. To accommodate this, a business that brings in molluscs and materials from outside of the domain is required to generate and hold the key information necessary for the traceability of the units brought in, and if they are to be traded on, to label those units with the required IDs.

NOTE 2 These specifications are designed with electronic representation and communication of data in mind, but this is not a requirement when using the International Standard. The specifications can also be met by paper systems.

Note that the specification is for data to be generated, recorded, and stored at the respective link. For all links, relevant data shall be generated in a previous link in the supply chain and passed along with the trade unit/logistic unit.

NOTE 3 In these tabulations, there is no repetition of the information originally recorded to describe the units created and their history, although businesses receiving those units later in the distribution chain will often need some of that information. The information is keyed to the unit IDs and can be supplied by commercial agreement between the businesses without having to re-input the data.

6.3 Controlled relaying and depuration

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Bivalve molluscs concentrate contaminants from the water column in which they grow. These contaminants might then cause illness to humans when the bivalves are eaten. Depuration is effective in removing many contaminants from shell fish. Relay systems (natural or in containers) and land-based depuration establishments are efficient methods of achieving microbiologically safe bivalve molluscs that are harvested from approved areas. Each registered facility that depurates or relays molluscs should follow their Quality Management Program and appropriate documentation should be maintained for the process. The details of traceability of depuration process are shown in [Table 3](#).

6.4 Capture

For the purposes of this International Standard, *capture* means commercial fishing activities with or without vessel which can be motorized or not with mechanized or manual devices that catch molluscs and transport it to the point of discharge. Molluscs may also be frozen on fishing vessels. Fishing vessels may carry out their own discharging operations that may include grading, weighing, and boxing, prior to dispatch to the next food business. Alternatively, the food business operator may discharge from the fishing vessel.

The trade units created by capture operators can range from single mollusc or boxes of graded molluscs including live molluscs that have been individually/collectively harvested by the operators, for passing on to the next food business.

In practice, some of the information elements specified below may be recorded linked to the trips and fishing grounds/location. The information so recorded shall be linked to the trade unit (UTUI) from the capture operators.

Fishing vessels such as factory vessels or freezer vessels that carry out further processing operations such as pre-processing or freezing shall be considered both as capture operators and processors.