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

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

Traçabilité des mollusques — Spécifications des informations à enregistrer dans les chaines de distribution de mollusques en ferme

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Foreword

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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 document 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 and IEC 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).

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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 is 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 should be traceable back to a hatchery and or farm 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 itemise all the information that may 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.

Though 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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INTERNATIONAL STANDARD ISO 18538:2015(E)

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

1 Scope

This International Standard specifies the information to be recorded in farmed molluscs supply chains (excluding cephalopods) in order to establish the traceability of products originating from farm-raised 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 farm through to retailers or caterers.

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

— farming;

  a) broodstock suppliers/natural seed collectors;

  b) hatcheries and nurseries;

  c) molluscan farm;

  d) harvesting;

— depuration and shucking etc.;

— processors;

— transporters and store operators;

— traders and wholesalers;

— retailers and caterers;

— logistics including materials brought from other domains;

— feed production.

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.

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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:

— the origin of materials and parts,

— the processing history, and

— the 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
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

3.7
depuration
reduction of microorganisms 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

3.8
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* (3.9)

3.9
shucking
process of removing the meat from the shell

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4 Abbreviations

In this International Standard, the following abbreviations apply:

ACC	Aquaculture Certification Council
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	The 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
GAqP	Good Aquaculture Practices
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- 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
LU	Logistic Unit
OIE	World Organization for Animal Health
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
TU	Trade Unit
UI	Unique Identifier
ULUI	Unique Logistic Unit Identifier
UTUI	Unique Trade Unit Identifier

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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 can have the same number. If the scope (the product type, the company, the chain, the sector, the country, or similar) is assigned a 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) can be grouped together to make logistic units (LUs) or LUs can 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 can 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 may have the same number. If the scope (the product type, the company, the chain, the sector, the 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 farmed 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 12.

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).

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Table 1 — Classification of informative elements

	Definition	Explanation
"shall"	This category contains recordings related to identifiers and transformations that is 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 may still be useful or relevant to record. It also contains parameters that may 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 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.

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
Brood stock suppliers/natural seed collectors	3	MBR	-	-	TU/LU	TU/LU
Hatcheries/nurseries	4	MHA	TU/LU	Yes	TU/LU	TU/LU
Molluscan farms	5	MFF	TU/LU	Yes	TU/LU	TU/LU
Processors	6	MPR	TU/LU	Yes	TU/LU	TU/LU
Live molluscan transporters	7.1	MTR	TU/LU	Yes	TU/LU	TU/LU
Transporters and cold store operators for molluscs other than live	7.2	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
Feed production	11	MFE	TU/LU	Yes	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,

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for example, distribution businesses can 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 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, except "Breeders", 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

Bivalve molluscs concentrate contaminants from the water column in which they grow. These contaminants may then cause illness to humans when the bivalves are eaten. Depuration is effective in removing many faecal contaminants from shellfish. Depuration means the reduction of microorganisms sand and other contaminants 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 sea water suitable for the process which may be treated or untreated. 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 5.

6.4 Broodstock supplier and natural seed collectors/suppliers

For the purposes of this International Standard, broodstock suppliers are considered to be establishments/self help groups/farmer groups/fisherman that produce/collect broodstocks that are supplied to hatcheries for further maturation and production of spat. They may carry out basic operations like collection and maintenance of broodstock under good management practices in a sustainable way.

Prior to dispatch, broodstock suppliers can carry out their own operations or get it done through approved agencies/laboratories for absence of OIE-listed diseases, quality, grading, etc.

The trade units created by broodstock suppliers can range from a few hundred to several thousand passed into the hands of the next food business, i.e. hatcheries.

For the purposes of this International Standard, natural seed collectors/suppliers are considered to be establishments that produce/collect seeds from natural sources that are supplied to farms for further maturation. They may carry out basic operations like collection and maintenance of natural seed in a responsible way to ensure sustainability.

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Table 3 — Detailed information for broodstock suppliers and natural seed collectors/suppliers

Data element		Description	Examples	Categorization		
				Shall	Should	May
BROODSTOCK SUPPLIERS AND NATURAL SEED COLLECTORS/SUPPLIERS						
MBR101	Food business ID	Unique national identification number for the unit plus country prefix or name and address of the group/business that operates maintenance of broodstock (either indegenous or exploited)	Name, reg. no., and country prefix	x		
MBR102	Broodstock supplier establish ment ID	Unique national identification number for the group/unit/organization plus country prefix or name and address of the broodstock supplier	Women self-help group, Padanna, Kasargod, Kerala (bivalve spat suppliers)	x		
MBR103	Broodstock supplier GAqP certificate ion	Any quality certification available	Norms suggested by National Competent Authority and aligned to codex GAqP			x
MBR104	Natural seed collector	Unique national identification number for the group/unit	Mahesh, Moothakunnam. N.paravur	x		
MBR105	Location	Specific location	Njarakkal, Vypin, Kerala, India	x		
MBR106	Area of relaying	RFMO or more specific location	Vypin	x		
MBR150-	(unassigned)	Further information elements that describe the breeder, linked to broodstock supplier ID	Certified wild broodstock bank			x
FOR EACH TRADE UNIT CREATED						
Identity						
MBR201	Unit ID	UTUI	ID can be created for a batch with national prefix depending up on the area and time of collection	x		
Description						
MBR202	Species	LAT- followed by Latin name or FAO- followed by FAO 3alpha code or TSN- followed by taxonomic serial number (may be repeated if several species)	LAT-*Perna virdis* FAO:MSV TSN:3161003202		x	
MBR203	Area/ country of origin	FAO area/RFMO area of the broodstock if captured from wild or country of origin for broodstock from farmed stock or more specific location	51	x		
In case of broodstock collectors from wild, this requirement will be scored in the may column.						

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