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Implementation of a pilot checklist for control standardization on fishery goods consignments at the Livorno border control post

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Abstract

To standardize control activities, it is necessary to introduce checklists to support the control of consignments entering the European Union through border control posts (BCPs). This study aimed to develop a pilot checklist for the control of fishery consignments, preliminarily identified as the predominant group of goods entering the Livorno (Italy) BCP. The design of the pilot checklist was preceded by i) a revision of the current European and national legislation on the general and specific objectives of border control activities on fishery products and ii) a comparative analysis of two checklists (one of the Ministry of Health and one of the former Livorno border inspection post) developed on the basis of the repealed legislation. This comparison aimed to define the pilot checklist structure, verification objectives, and selection of assessment scores to be included in defining consignment compliance and acceptability. Once developed, the clarity and ease of use of the first draft of the pilot checklist were verified through its use in a field test during the control of 64 fishery product consignments. 22 regulatory sources (18 European and 4 national) were selected as reference legislation. The pilot checklist was structured as a dynamic “read-do” document based on the workflow of control activities described in the current legislation. The field test was useful in improving the clarity of the verification objectives within the documentary, identity, and physical control sections and in facilitating the use of the checklist and the collection of evidence during the control activity. This study, which focused on fishery products, can provide a practical approach for the development of checklists for all the other goods categories under the responsibility of BCPs.

Introduction

Official border controls were first harmonized in Europe in 1984 with the adoption of Commission Dec.. 84/390/CEE and the creation of the EU system of border inspection and veterinary services (Commission of the European Communities, 1984). From 1993, these veterinary services acquired the status of border inspection posts (BIPs) (Council Dir. 90/675/EEC and Dir. 91/496/EEC, transposed in Italy by L. Decree No. 93 of 3 March 1993) (Council of the European Communities, 1990; Council of the European Union, 1991; Italian Republic, 1993).

Then, specific measures for harmonized checks at BIPs on products from third countries were implemented following the adoption of Council Dir. 97/78/EC and Council Dir. 97/79/EC, transposed in Italy by L. Decree No. 80 of February 25, 2000) (Council of the European Union, 1997a, 1997b; Italian Republic, 2000). Recently, the issuing of Reg. EU 2017/625 and relative implementing acts (European Commission, 2019a, 2019b, 2019c; respectively, Impl. Reg EU 2019/1014, Impl. Reg EU 2019/2129 and Impl. Reg EU 2019/2130) led to the redesignation of BIPs as border control posts (BCPs), together with an expansion of their competencies. Specifically, official controls are currently carried out on each consignment of the following categories entering the Union: live animals (LA), products of animal origin (POA), plants and plant products (P and PP), and products of non-animal origin (PNAO) (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Article 47; European Commission, 2019a - Impl. Reg. EU 2019/1014, Annex II). Each member state is responsible for the designation and approval of BCPs on its territory under the supervision of the European Commission. Then, after the verification of compliance with the general and specific infrastructure, equipment, and documentation requirements for the categories of animals and goods specified in the current regulations (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625; European Commission, 2019a - Impl. Reg. EU 2019/1014) each BCP is designated to control one or more of the categories described above.

In Italy, 28 BCPs, including 8 airports and 20 ports, have been designated by the Ministry of Health (DGSA-Ministry of Health, 2022) following the enactment of the L. Decree n. 24/2021 (Italian Republic, 2021). Among them, Livorno BCP (IT LIV 1) is designated to control POA (for human consumption, animal by products, feeds) and PNAO (for human consumption, feed and food contact materials).

BCP control activities consist of risk-based verification, which includes documentary, identity, and physical checks supplemented as needed with official analysis, applied to ensure the compliance and safety of animals and goods entering the Union (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Articles 43, 47, 49). At present, documentary checks are carried out on 100% of consignments regardless of the product categories; conversely, minimum frequency rates for identity and physical checks are defined based on risk analysis for the different categories (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Article 43, 54; European Commission, 2019b - Reg. EU 2019/2129).

Particularly, documentary check is aimed at verifying the conformity of the common health entry document (CHED), the authenticity and completeness of the official certificates, official attestations and other documents accompanying the consignments according to their nature (European Parliament and Council of the European Union, 2017 - Reg. 2017/625, Articles 49, 50, 56; European Commission, 2019c - Impl. Reg. EU 2019/2130, Article 2). The identity check is a visual control to verify that the identification marks or codes affixed to the consignment, of the means of transport, the seals, and the consignment content correspond to the information verified during the documentary check (European Commission, 2019c - Reg. EU 2019/2130, Article 3). It can be performed in a reduced form by checking only the means of transportation and the seals on the shipment (European Commission, 2019c - Reg. EU 2019/2130, Article 3). Finally, a physical check aims at verifying the consignments' compliance with the rules referred to in Article 1(2) of Reg. EU 2017/625 as defined in the official certificates and attestations previously checked (European Commission, 2019c - Reg. EU 2019/2130, Article 4). In the Impl. Reg EU 2019/2129, the baseline physical check frequency of the categories and specific risk factors that may lead to an increase in the established frequency are indicated (European Commission, 2019b).

At the conclusion of the control activity, the official veterinarian ratifies the final decision on the consignment by finalizing the CHED and proceeds to transfer the information to the Information Management System for Official Controls (IMSOC) (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Articles 55, 56, 57).

According to Reg. EU 2017/625, competent authorities (CAs) shall ensure the effectiveness adequacy and homogeneity of official controls (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Articles 5, 12) to guarantee transparency and a common assessment of the compliance of consignments with EU rules. In this respect, the application of documented procedures that provide for the implementation of standard operating criteria is essential (Milana *et al.*, 2022). CAs are therefore required to implement such documentation during official controls, using operational tools to be designed for this purpose. A typical operational tool used in this context is the checklist. The checklist is a list of parameters and criteria arranged systematically, allowing the user to record the presence/absence of each item listed, to ensure a complete and exhaustive evaluation of all the objectives for which the checklist was created (Motarjemi and Mortimore, 2023).

In 2016, the Italian Ministry of Health published operational guidelines for official control activities carried out at BIPs, to be used voluntarily for the control of LA, POA and PNAO consignments, (Ministry of Health, 2016). The guidelines were supplemented by a checklist based on the legislation in force at the time (European Parliament and Council of the European Union, 2004a - Reg. EC 854/2004). It is interesting to note that at around the same time an internal checklist was also drawn up at the former Livorno BIP.

Both the aforesaid checklists have never been updated and are therefore no longer applicable, as they were based on the legislation in force at the time (Italian Republic, 2000 - L. Decree 80/2000; European Parliament and Council of the European Union, 2004a, 2004b - Reg. EC 882/2004 and Reg. EC 854/2004). Therefore, the present study described the approach used for the implementation of an updated pilot checklist to support control activities on consignments of goods most frequently received at the Livorno BCP.

Materials and Methods

The pilot checklist design was conducted by a fifth-year veterinary student in training at the BCP (hereafter referred to as the trainee operator) and by a veterinary officer operating at Livorno BCP. The checklist design was based on Gawande's (2010) *Checklist Manifesto* approach. Specifically, the pilot checklist was developed through i) the definition of the scope of the checklist (target goods); ii) the revision of the legislation of interest currently in force for the selection of the general and specific requirements for the verification procedures; iii) the design of the structure and content of the pilot checklist; iv) the testing of the checklist within field control activities.

Definition of the scope (target goods) of the pilot checklist

The target goods of the pilot checklist have been selected after a preliminary evaluation of the volumes of incoming goods consignments of the product categories (POA, PNAO) for which the Livorno BCP is designated. The evaluation of the incoming consignments was made by consulting the internal annual reports on Livorno BCP check activities from 2015 to 2021 and the annual reports produced by the General Directorate for Animal Health and Veterinary Medicines of the Ministry of Health for the same period (DGSA-Ministry of Health, 2017, 2018, 2019, 2020, 2021, 2022).

Revision of the legislation of interest in force

European and national regulatory sources on general aspects of official control activities were retrieved from the Eur-Lex and Italian Official Gazette portals (<https://eur-lex.europa.eu/homepage.html>; <https://www.normattiva.it/>), respectively. The following keywords: official controls, BCP, documentary control, identity control, physical control, and official sampling were searched using the available search function. Subsequently, regulatory sources on safety, traceability, labeling requirements, and specific conditions for official controls of fisheries products, selected as target products (see section *Definition of checklist scope and regulatory framework*) were analyzed. Finally, research was conducted to identify any pre-existing checklists developed by other Italian BCPs for controlling POA consignments.

Design of the pilot checklist

A preliminary comparison was performed between the checklist provided by the Ministerial Guidelines for official control activities in BIPs, and the internal Livorno BIP checklist taking into account: i) structure and documents format; ii) organization of the verification objectives inherent to the official control procedure (documentary, identity, physical and sampling); iii) presence of scores or assessments linked to the verification objectives; iv) presence of dedicated areas for free annotations related to the objectives of the control activity. The comparison aimed to define the format of the pilot checklist, the official verification objectives in relation to the general and specific regulatory references identified, and the evaluation criteria and scores for the suitability and conformity of the good to be checked.

Pilot checklist testing during field control activities on fishery product consignments

Prior to the administration of the checklist to all personnel operating at the Livorno BCP, the first draft of the new pilot checklist was utilized during field control on incoming fishery products. During the field test, the draft of the new checklist was compiled by the trainee operator under the supervision of the veterinarian in order to verify its completeness, usability, and facilitation of the recording data/results of control activities.

Results and Discussion

Definition of checklist scope and regulatory framework

To ensure that official controls are carried out in accordance with the procedural flow described in the current legislation (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625; European Commission, 2019b, 2019c - Impl. Reg. EU 2019/2129 and Impl. Reg. EU

2019/2130), it is deemed appropriate to draft good-specific checklists based on the application of general official control procedures, complemented by specific safety and traceability aspects. In the absence of European or national standards for the design of checklists to support official controls, the pilot checklist was developed using an approach that has been successfully in a variety of different professional contexts (England *et al.*, 2011; Davidow and King, 2023).

The preliminary analysis of the volumes of imported goods consignments entering the Livorno BCPs was only focused on POA volumes, as P and PNAO, have been transferred under the responsibility of the BCPs from 2021 onwards, and only partial input volume data were available for these categories. Within the POA category, the analysis showed a clear predominance of import volumes of fishery products (78-84%) of all POA inputs over the seven-year period (2015 to 2021). The data obtained for the Livorno BCP appear to be consistent with the overall data provided by the Ministry of Health for the Italian BCPs as a whole. Fishery products are in fact the predominant commodity group in terms of volume of imports (69.7%) at the Italian borders and consequently in terms of border control activities for entry into the Union (DGSA-Ministry of Health, 2022). The import data appear also in line with the current consumption and demand projections for 2030-2035 presented by the European Parliament and the Commission, respectively. Specifically, these data confirm that the European market, which is already highly dependent on imports from third countries, will increase its dependent status to satisfy the consumption demand for fishery products (European Commission, 2019d). This considered, fish products were selected as the target goods for the implementation of the pilot checklist, based on the assumption that the document would be of potential interest to other BCPs designated for POA control at the national level.

The analysis of the regulatory framework led to the selection of a total of 18 European and four national regulatory sources details are provided in *Supplementary Table 1*.

The research conducted did not identify the existence of any other similar published documents. Thus, the pilot checklist was implemented based on the ministerial and Livorno BIP internal checklists.

Design of the pilot checklist.

A checklist is depicted either as a “read-do” or a “do-confirm” checklist (Gawande, 2010). Specifically, a “read-do” checklist which is used concurrently with the control activities and allows the operator to perform the tasks and check them off as they are completed. In contrast, a “do-confirm” checklist is used as an *a posteriori* support tool to verify that an activity performed from memory and experience has been thoroughly completed and all relevant aspects have been verified. Moreover, according to Davidow and King (2023), it can be designed as a “static” sequential list of verification objectives or as a “dynamic” tool designed according to an operational control flowchart with decision points.

In this respect, the ministerial checklist was attached to the guidelines to be applied either simultaneously with the control activity, in a “read-do” mode, by checking the verification objectives in the order given, or in a “do-confirm” mode, following the control. Structurally, it was developed as a static technical list in which the verification objectives included in the control activity are sequentially presented. It was provided with a check-box to be filled in to confirm that the corresponding verification objective has been completed (*Supplementary Table 2*). The internal checklist was instead structured only as a “read-do” dynamic operational checklist designed on the workflow of the official control procedure described in L. Decree n. 80 of 2000 (Italian Republic, 2000) implementing Council Dir. 97/78/EC.

In terms of content, in the ministerial checklist, the verification objectives are almost exclusively related to documentary check verifications offering partial support during control activities. The verification objectives are described in general terms that do not always allow an immediate association with a specific control action on the consignment. However, several objectives are accompanied by additional explanations and examples to assist the official veterinarian in understanding the action to be referred to. Moreover, it has to be emphasized that all the verification objectives are linked to specific regulatory references (*Supplementary Table 2*). Conversely, the

internal checklist is designed with a clear division into sections relating to the different control phases (documentary, identity, physical and sampling) with specific verification objectives available for all the phases (*Supplementary Table 3*). It is provided with a decision box added at the end of the first section to record the outcome of the documentary check before proceeding with the selection of the subsequent control activities to be conducted (seal limited identity check vs full identity check and physical check). The verification objectives refer to specific control activities and are linked to fields for check-box style filling or open fields for the recording of notes and data by the veterinarian in charge. Furthermore, the existence of specific areas for the signature of the official veterinarian can be highlighted for each control operation involving the official assumption of responsibility for the control performed. Regarding the regulatory references throughout the document, unlike the ministerial checklist, they are not linked to the individual objectives. However, they are present in each section.

With respect to the presence of scores or assessments linked to the verification objectives the ministerial checklist does not include any area dedicated to the registration of the conformity/non-conformity of the consignment or of the favorable/not favorable (F/NF) outcome of the control, both of which are instead included in the Livorno BIP's internal checklist (*Supplementary Table 3*). Neither checklist has numerical scores associated with the verification objective, although the presence of an F/NF judgment annotation in the internal checklist facilitates both the verification activity and the final decision on the consignments. Finally, both checklists include spaces for commenting on the results of the checks in relation to the objectives; in particular, the ministerial checklist provides examples for several objectives in the comment section.

At the end of the comparative analysis, following the structure implemented in the previous internal checklist, the pilot checklist was developed as a dynamic document (*Supplementary Table 4*) based on the workflow of control activities described within the current regulations (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625; European Commission, 2019c – Impl. Reg. EU 2019/2130). The pilot checklist is divided into sections including all the phases of official control (documentary, identity, physical check). A decision box has been included at the end of the first section on documentary checks, analogously to the internal checklist, to select the subsequent control activities to be performed according to the risk assessment applied to the consignment (European Commission, 2019b - Impl. Reg. EU 2019/2129). The choice of a dynamic checklist was dictated by the need to provide a document that would facilitate the official veterinarian in applying the workflow described in the Regulations through a complex process involving decision points as described by Davidow and King (2023). The establishment of a checklist in a dynamic format meets the requirements of Reg. EU 2017/625 for the updating of documented procedures containing operational instructions for staff performing official controls (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Article 12).

Within each section, aligned with the format proposed in the ministerial checklist, the verification objectives are presented in sequential order and have been arranged in the form of checkboxes individually associated with reference regulatory sources. The inclusion of specific verification objectives for each section, promotes standardisation, uniformity, and transparent recording of the verifications carried out. The direct association of each objective with the relevant regulatory source ensures that the verification is carried out in accordance with the regulations and in the area of competence for which the border control is designated (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Article 47).

Additionally, similarly to the previous internal checklist, F/N judgement scores have been associated with the verification objectives to facilitate the official veterinarian in the formulation of the final decision on the consignments (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Article 55). It has to be noted that the implemented assessment scoring does not allow for intermediate indications. This means that even partial non-compliance with the verified objective results in a negative judgement for the specific objective. Therefore, the conformity remains assessed

with an unfavourable verdict until all assessments have been fully resolved (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Article 66).

Finally, for each section, spaces have been provided for the annotation of the evidence collected at the same time as the verification of the objectives, to facilitate the subsequent completion of the CHED-P and data transfer to the IMSOC system (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Article 56).

Pilot checklist testing during field control activities on fishery product consignments

Once fully implemented, the first draft of the pilot checklist was used during the control of a total of 64 consignments of fishery products, of which 33 were subject to documentary and identity (seal) checks, 20 to documentary, full identity, and physical checks, and 11 to the full procedure, including sampling. In this regard, it is important to note that the field test did not have the characteristics of a performance test being conducted only on a small number of consignments in comparison to the overall volume of imported goods entering the Livorno BCP. It was, in fact, designed only to test the clarity and ease of use in collection objectives, also by trainee operators. Therefore, the controlled consignments, although limited in number and not perfectly responsive to the variability of seafood consignments encountered in border control activities, appear relevant to the purpose. The field test highlighted minor areas for improvement in terms of clarity of the verification objectives and facilitation of control activities. Revised objectives are bolded in *Supplementary Table 4* for completeness. Specifically, in the documentary checks section, the objective relating to verifying the conformity of the official certificate accompanying the consignment did not include the possibility of noting whether the certificate was an original or a copy. In fact, this note is relevant because the certificate, which can initially be sent as a verified copy of the original, must be received and kept by the BCP in its original form before the official control activity can be formally concluded with the issuance of a decision of admission or non-admission to import (European Parliament and Council of the European Union, 2017 - Reg. EU 2017/625, Article 50). The verification objective has therefore been amended to allow the official veterinarian to note the information down. For the section on identity check, the field testing showed that the reported objectives, although clear, were not logically ordered leading to a deceleration of the control activity. The verification objectives have therefore been rearranged so as to proceed sequentially from verification of general mandatory food labeling requirements to specific labeling requirements for fish products. Similarly, within the physical control section, the use of the checklist highlighted the possibility of simultaneously verifying objectives under separate headings, with redundancy in the data collected. Therefore, to align the documented procedure with the actual control activity, two objectives related to the verification of the conditions of transport and the maintenance of the cold chain have been merged.

Conclusions

According to the current European legislation, in order to ensure uniformity of border controls, it is necessary to standardize control activities by implementing documented procedures and operational support tools for all categories of consignments entering the Union.

In this context, the updated pilot checklist, developed in this study based on the workflow of the official control procedure described in the current regulations, represents technical support for control activities and the collection of evidence for the issuance of the final decision on fishery consignments entering the BCP. The results obtained from the field testing confirmed not only the completeness and usability of the document, but also its ability to act as a facilitating tool during checks. The approach used in this study could be extended for the development of similar checklists designed for controlling other product categories.

In this respect, it should be noted that to validate the checklist, the document needs to be further assessed following its use by all veterinary staff operating in the Livorno BCP. In particular, for validation purposes, a performance test based on the analysis model proposed for quality system assessment (ISO, 2015) could be proposed.

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Online supplementary material:

Supplementary Table 1. European and Italian regulatory sources selected for the implementation of the experimental checklist. The publication reference has been added to each source in the Regulatory Source column.

Supplementary Table 2. Checklist produced by the Ministry of Health as an annex to Ministerial Guidelines for the Standardization of Official Control Activities at border inspection posts (Ministry of Health, 2016).

Supplementary Table 3. Internal checklist form adopted by the former border inspection post of Livorno for the standardization of the official control activities on the incoming consignments.

Supplementary Table 4. Final experimental checklist, and amendments to the initial experimental checklist prototype are highlighted in bold.