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Implementation of a food safety management system according to ISO 22000 in the food supplement industry: A case study

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ABSTRACT

This work aims to present a methodology to carry out hazard and control measures assessments to properly establish operational prerequisite programmes (oPRPs) and the HACCP plan in the food supplement industry according to the ISO 22000 standard. This study focused on the manufacture of propolis, royal jelly and vitamin C ampoules, sold as energy boosters. Seven of the 13 hazards identified in this study were significant: two hazards were in the reception step (residues of pesticides, antibiotics and/or heavy metals (code 2) and contamination by pathogens (code 3)), two in the ingredients weighing step (cross-contamination by metabisulphite (code 9) and contamination by pathogens (code 10)), one in the mixture preparation step (contamination by pathogens and/or proliferation of microorganisms (code 11)) and two in the ampoule-filling and -sealing step (cross-contamination by metabisulphite (code 12) and contamination by pathogens (code 13)). After assessing the control measures, critical control points (CCPs) were determined in the hazards with codes 2, 9 and 12, which could be managed by an HACCP plan. The remaining hazards were managed by establishing oPRPs. Implementation of the ISO 22000 standard in the food supplement industry guarantees food safety and helps improve their competitiveness in the global market.

Keywords: Food safety; ISO 22000; food supplements; operational prerequisite programmes; HACCP plan.

1. Introduction

Foodborne diseases and food safety threats are a growing public health problem. Unsafe food causes many acute and life-long diseases, ranging from diarrheal diseases to various forms of cancer. WHO estimates that foodborne and waterborne diarrheal diseases together kill about 2.2 million people annually, 1.9 million of whom are children (WHO, 2012).

In the last decade, the quality, especially the safety of food products, have become one of the most important aspects to influence national and international business and economic patterns (Aggelogiannopoulos, Drosinos, & Athanasopoulos, 2007). Globalisation of food production and procurement makes food chains longer and more complex, and increases the risk of food safety incidents (Foundation for Food Safety Certification, 2013).

Food safety started to interest consumers due to several contaminated food incidents, such as dioxin and bovine spongiform encephalopathy (BSE) (van der Spiegel, Luningy, Ziggersx, & Jongen, 2003). In the aftermath of the BSE crisis and other food scandals, the European Union (EU) introduced an initiative called 'From the Farm to the Fork' at the beginning of this century. This initiative was based on a risk analysis and traceability, and aimed to guarantee food safety. In line with this approach, the food safety policy underwent reforms in the first decade of this century to thereby guarantee a high level of safety for foodstuffs and food products marketed within the EU, and at all the production and distribution chain stages. In January 2002, the EU adopted the framework legislation in Regulation (EC) 178/2002, which contains general provisions for traceability (applicable from 1 January 2005) and establishes the European Food Safety Authority. In April 2004, the EU adopted the Food Hygiene Package, which lays down hygiene rules for foodstuffs produced in EU and non-EU countries exporting to the EU. This contains Regulation (EC) 852/2004, Regulation (EC) 853/2004, and Regulation (EC) 854/2004. Regulation 852/2004 focuses on defining the food safety objectives to be achieved, and leaves food operators responsible for establishing and operating food safety programmes and procedures based on the HACCP principles (EU, 2013).

In parallel to food safety regulation development, some standards related to food quality and safety, such as the BRC (British Retail Consortium) Global Standard for

Food Safety, IFS-Food (International Featured Standards), SQF (Safe Quality Food) Code or ISO 22000, were designed by different organisations.

In 2005, ISO developed the ISO 22000 standard for food safety management systems, which applies to all the organisations in the food chain, thus ensuring the chain's integrity. The aim of this standard was to provide an effective and harmonized food safety system to manage and ensure food safety and suitability in each link of the supply chain (Foundation for Food Safety Certification, 2013).

In the food supplement industry, as in the rest of the food industries, the actual situation of competitiveness among companies entails the necessity of new marketing strategies. The number of enterprises that are adopting quality assurance systems to improve their competitiveness in the global market is continually increasing (Karipidis, Athanassiadis, Aggelopoulos, & Giompliakis, 2009). In addition, food safety failures in both developed and developing countries have intensified interest everywhere in systematic prevention at every link in the supply chain. ISO 22000, backed by an international consensus between government and industry experts, harmonises the requirements for good food safety practice worldwide (Frost, 2006). For all these reasons, the implementation of this standard in the food industry could assure product safety and improve the competitive landscape for international trade.

There are numerous studies on the implementation of quality and food safety management systems (Cerf, Donnat, & the Farm HACCP Working Group, 2011; Christaki & Tzia, 2002; Gaaloul, Riabi, & Ghorbel, 2011; Martínez-Rodríguez & Carrascosa, 2009; Mataragas, Drosinos, Tsola, & Zoiopoulos, 2012; Mensah & Julien, 2011; Sampers, Toyofuku, Luning, Uyttendaele, & Jacxsens, 2012; Taylor, 2008), some of which are based on the ISO 22000 standard. However, there is very little information available on how to implement some important requirements of this and other food safety management systems, such as hazard assessment or control measures assessment. Poumeyrol, Rosset, Noel, and Morelli (2010) reported a methodology to carry out hazard assessment in meat pâté, but they considered only bacterial hazards.

The objective of this work was to present a methodology to carry out hazard and control measures assessments in order to properly establish operational prerequisite programmes (PRPs) and the HACCP plan in a food supplement industry.

2. Methodology

2.1. Company description and scope

This study was carried out in the company Korott, S.L, in east Spain. This company was founded in 1991 as a pharmaceutical company but, nowadays, Korott has different manufacturing plants which focus on three sectors: pharmaceuticals, cosmetics and food supplements. This work was conducted in the food supplements plant. Although the ISO 22000 standard has been completely implemented in all production lines, this work explains only the implementation of some requirements of this standard on the processing line for ampoules fabrication. The products manufactured on this line are:

- Royal Jelly Ampoules
- Mini Royal Jelly Ampoules
- Propolis, Royal Jelly and Vitamin C Ampoules
- Green Tea and Pineapple Ampoules
- Ginseng, Royal Jelly and Vitamin C Ampoules
- Valens Sport Ampoules with Taurine and L-Carnitine

This study focuses on manufacturing Propolis, Royal Jelly and Vitamin C Ampoules, which are sold as energy boosters.

2.2. Study stages

Stage 1. Devising the flow diagram

Stage 2. Hazard analysis:

- Hazard identification
- Hazard assessment
- Selection and assessment of control measures

Stage 3. Establishing operational prerequisite programmes (oPRPs).

Stage 4. Establishing the HACCP plan (identification of critical control points (CCPs), determination of critical limits for CCPs, corrective actions, responsibilities and monitoring record).

3. Results and discussion

3.1. Devising the flow diagram

Fig. 1 illustrates the main manufacturing stages of propolis, royal jelly and vitamin C ampoules.

Fig. 1

3.2. Hazard analysis

3.2.1. Hazard identification

The possible hazards identified in each step of the process are described below and are observed in Table 1.

Table 1

Step 1. Reception.

- Physical hazards: foreign bodies (pieces of wood, plastic, hair, etc.) inside packaging together with the raw material.
- Chemical hazards: residues of pesticides, antibiotics and/or heavy metals in the raw material (royal jelly).
- Biological hazards: raw material contaminated by pathogens, such as *Salmonella*, *E. coli*, etc.

Step 2. Conditioning.

- Physical hazards: if the drums, bags or boxes containing the raw material break while removing external packaging, foreign bodies can contaminate the raw material.

Step 3. Storage.

- Biological hazards: growth of microorganisms present in the raw material reaches unacceptable levels. Contamination by insects.

Step 4. Transport to the production area.

- Physical hazards: foreign bodies from tools used for transport.

Step 5. Ingredients weighing.

- Physical hazards: the foreign bodies used in this stage may contaminate the mixture of ingredients, including contact lenses, hair, etc.

- Chemical hazards: cross-contamination by metabisulphite (allergen) used to manufacture other products because the weighing room is shared by both products.
- Biological hazards: contamination by pathogens coming into contact with ingredients and personnel.

Step 6. Preparing the mixture.

- Biological hazards: contamination by pathogens and/or proliferation of the microorganisms present in the ingredients.

Step 7. Ampoules-filling and -sealing.

- Chemical hazards: cross-contamination by metabisulphite used to manufacture other products since the filling machine is shared by both product types.
- Biological hazards: contamination by pathogens.

From this step, it was considered that there were no hazards because the product is packaged and does not require special storage conditions.

3.2.2. Hazard assessment

The hazards identified were assessed according to the severity of known or potential adverse health effects and to probability of occurrence. An estimated method based on the company's experience, as well as on technical reports (Agencia Catalana de Seguridad Alimentaria, 2013; Schmidt & Newslow, 2013) was defined by setting different levels of severity and different levels of likelihood, and by assigning a value to each level. Likelihood was evaluated based on the company's experience (historical background, customers' and consumers' claims and non-conformities) by establishing the following criteria:

- Low Probability = Occurrence may be ≤ 3 times per year. Value = 1.
- Medium Probability = Occurrence may be between 4 and 10 times per year. Value = 2.
- High Probability = Occurrence may be more than 11 times per year. Value = 5.

Severity was assessed according to the following criteria:

- Low Severity = The hazard can provoke only minor health problems. Value = 1.
- Medium Severity = The hazard may provoke some health problems in immuno-compromised/allergic individuals, or may involve medical consultation. Value = 2.

- High Severity = The hazard may provoke significant problems, not only in immuno-compromised/allergic individuals, but also in healthy people, which may involve hospitalisation or potential chronic disease. Value = 5.

Table 2 shows the assessment of each hazard. A hazard was considered significant if the probability (P) value by the severity (S) value (P x S) was over 4. Of the 13 hazards identified, seven were significant (P x S = 5).

The hazards that were non-significant (P x S < 4) did not move on to the next step in this study, although all these hazards could be managed by different control measures, some of which are included in the pre-requisites programmes (data not shown).

Table 2

3.2.3. Selection and assessment of control measures

The following control measures were defined for all the significant hazards (codes 2, 3, 9, 10, 11, 12 and 13; see Table 2):

Hazard with code 2:

The control measure for this hazard was to establish a raw material control throughout the suppliers. The raw material specifications are provided in detail on a technical sheet that has to be accepted by the supplier. In addition, the supplier must provide a certification of analysis of each product batch dispatched to demonstrate that all the requirements have been met.

Hazard with code 3:

The control measures are those described for hazard with code 2. In addition, microbial analyses of the raw material are carried out (*E. coli*, *Enterobacteriaceae*, *Staphylococcus aureus*, and *Salmonella* spp., mesophilic, and moulds and yeasts counts).

Hazard with code 9:

The measure that controls this hazard is described in a standard operating procedure (SOP) that contains a systematic cleaning of working tools. The staff involved in these activities knows this SOP.

Hazard with code 10:

The measure mentioned for hazard 9 also applies to control this hazard. Other measures are: staff complies with hygiene rules; controlling the air quality inside the weighing room by filters H and G; controlling the temperature and relative humidity in

the room by the air conditioning system; finally, controlling microbial quality through microbial analyses, as detailed for hazard with code 3.

Hazard with code 11:

The last four control measures mentioned for hazard 10 are applied to control this hazard. In addition, there is a SOP that describes the systematic cleaning of mixing tanks, which the staff involved in these activities knows. Other measures are pH control, which must be between 3.6 and 4.5, and a_w must be lower than 0.81.

Hazard with code 12:

This measure is the systematic cleaning of the filling machine as described in a SOP that the staff involved in these activities knows.

Hazard with code 13:

The same measure control for hazard 12 is applied. In addition, microbial analyses of the product are carried out.

According to ISO 22000, the control measures were classified according to whether they should be managed through Operational Prerequisite Programmes (oPRPs) or by the HACCP plan. This classification was made by assessing the measures relating to seven variables according to the criteria and the values described in Table 3.

Table 3

Each control measure was scored for the seven variables. If the final score was > 14, it would be managed by the HACCP plan. If the final score was ≤ 14, it would be managed by oPRPs. Table 4 shows the results of the control measures assessment.

Among the 7 significant hazards studied in this step, only the control measures of 3 hazards (codes 2, 9 and 12) reached values of over 14. Therefore these hazards were managed by the HACCP plan, as described below. The rest were controlled with oPRPs, as shown in the following point.

Table 4

3.3. Establishing operational prerequisite programmes (oPRPs)

According to the ISO 22000 standard, oPRPs contain the following information: food safety hazard, control measure, monitoring procedures, corrective actions, responsibilities and monitoring records.

An example of oPRPs for the hazard with code 11 is provided below:

Hazard code 11: Contamination by pathogens while preparing the mixture.

Control measure 1: staff comply with the good hygiene practices, which include hygiene rules, and those related to clothing and behaviour. Information is contained in SOPs CN-GC 800 (Personnel hygiene manual), CN-GC 804 (Personnel clothing), and CN-LE 805 (Facility cleaning). These codes correspond to internal company references.

- *Monitoring procedures:*

  Visual checking the degree of staff's fulfilment of the good hygiene practices according to the three above-mentioned SOPs, and filling in a checklist.

  Reviewing the production orders to check if there has been any incident.

- *Corrective actions:*

  If the checklist shows some deviation, staff will receive new training according to SOP CN-GC 103 (Personnel training).

- *Responsibilities:*

  The Production Department is responsible for the fulfilment of the good hygiene practices. The Quality Assurance Unit (QAU) is in charge of training courses, and of revising SOPs and production orders.

- *Monitoring records:*

  Checklists, production orders and non-conformity reports.

Control measure 2: Quality of air controlled by filters H and G.

- *Monitoring procedures:*

  Using the air conditioning system according to SOP CN-F 712 (Air conditioning system operation).

  Carrying out an environmental analysis according to SOP CN-GC 416 (Surface sampling and environmental analysis).

- *Corrective actions:*

  If the results of the environmental analyses are not correct, the corrective actions involve increasing the frequency with which filters are replaced and amending SOP CN-LE 623 (Air conditioning system maintenance).

- *Responsibilities:*

  The Maintenance personnel and the QAU shall ensure proper environmental conditions.

- *Monitoring records:*

  Maintenance reports of changes and revisions of filters, supporting documentation related to the efficiency of filters, analyses reports and non-conformity reports.

Control measure 3: Controlling temperature and relative humidity.

- *Monitoring procedures:*

  Maintaining the air conditioning system according to SOP CN-LE 712, periodical measurements of temperature (T) and relative humidity (RH) in production rooms to check that their values are correct.

- *Corrective actions:*

  If the T and/or RH values are beyond the acceptable limits, the Maintenance personnel shall repair the air conditioning system.

- *Responsibilities:*

  The Production Department and the Maintenance personnel are responsible for checking T and RH, and system maintenance, respectively.

- *Monitoring records:*

  Control sheets and non-conformity reports.

Control measure 4: Systematic cleaning of mixing tanks as described in SOP CN-LE 608 (Tank cleaning).

- *Monitoring procedures:*

  Reviewing production orders to check if there has been any incident.

  Checking if tanks have been properly cleaned.

- *Corrective actions:*

  If cleaning is not appropriate, the corrective action is to change SOP CN-LE 608 and to clean tanks properly.

- *Responsibilities:*

  The Production Department is responsible for cleaning and reviewing. The QAU is responsible for reviewing production orders.

- *Monitoring records:*

Production orders, cleaning revision reports or checklists, and non-conformity reports.

Control measure 5: pH control

- *Monitoring procedures:*

  Measuring pH according to SOP CN-GC 313 (pH measurement).

- *Corrective actions:*

  Product rejection if the pH values do not fall within the range established for the mixture.

- *Responsibilities:*

  The Production Department is responsible for carrying out the pH control. The QAU is responsible for treating the rejected product.

- *Monitoring records:*

  Production orders with pH values and non-conformity reports.

Control measure 6: Controlling a_w

- *Monitoring procedures:*

  Measuring a_w according to SOP CN-GC 347 (a_w measurement).

- *Corrective actions:*

  Product rejection if the a_w values do not fall within the range established for the mixture.

- *Responsibilities:*

  The Production Department is responsible for carrying out the a_w control. The QAU is responsible for the treating the rejected product.

- *Monitoring records:*

  Production orders with a_w values and non-conformity reports.

Control measure 7: Microbial analyses.

- *Monitoring procedures:*

  The microbial analysis of the product according to the procedures described in SOPs CN-GC 405 (mesophilic counts), CN-GC 407 (*E. coli* analysis), CN-GC 410 (moulds and yeasts counts), CN-GC 411 (*Enterobacteriaceae* counts), CN-GC 413 (*Staphylococcus aureus* analysis), CN-GC 414 (*Salmonella* spp. analysis).

- *Corrective actions:*

  If the microbial analyses show that the product is contaminated, it is rejected according to SOP CN-GC 601 (Treating rejected product).

- *Responsibilities:*

  The Production Department is responsible for carrying out the microbial analyses. The QAU is responsible for treating the rejected product.

- *Monitoring records:*

  Analyses reports and non-conformity reports.

3.4. Establishing the HACCP plan

The HACCP plan contains the following information: identification of critical control points (CCPs), control measures, determination of critical limits for CCPs, monitoring procedures, corrective actions, responsibilities and monitoring records.

The HACCP plan is shown below with an example for the hazard with code 12:

Hazard code 12: Cross-contamination by metabisulphite during the ampoules-filling and -sealing step.

- *Identifying critical control points:*

  This task has been performed in a previous step (section *3.2.3.*)

- *Control measure:*

  Systematic cleaning of the filling machine described in SOP CN-LE 607 (Filling machine cleaning) that the staff involved in these activities knows.

- *Critical limit:*

  Cleaning has to be done properly so that no product remains are found in the filling machine.

- *Monitoring procedures:*

  Validating the cleaning process of the filling machine according to the VLSARONG protocol.

- *Corrective actions:*

  If cleaning is not appropriate, the corrective action is to change SOP CN-LE 607, if necessary, and to clean the filling machine properly.

If cross-contamination exists, all the products affected must be discarded in accordance with SOP CN-GC 601.

- *Responsibilities:*

The Production Department is responsible for cleaning and reviewing. The QAU is responsible for treating the rejected product.

- *Monitoring records:*

Cleaning revision reports and non-conformity reports.

4. Conclusions

This study sets out a methodology that is applied to a practical example to carry out hazard and control measures assessment in order to properly establish operational prerequisite programmes (oPRPs) and the HACCP plan.

Thirteen different hazards have been identified in the manufacturing line of ampoules made with propolis, royal jelly and vitamin C. Only seven were significant: two hazards in the reception step (residues of pesticides, antibiotics and/or heavy metals (code 2), and contamination by pathogens (code 3)), two in the ingredients weighing step (cross-contamination by metabisulphite (code 9) and contamination by pathogens (code 10)), one in the mixture preparation step (contamination by pathogens and/or proliferation of microorganisms (code 11)) and two in the ampoules-filling and -sealing step (cross-contamination by metabisulphite (code 12) and contamination by pathogens (code 13)). After assessing the control measures, CCPs were determined in the hazards with codes 2, 9 and 12, which could be managed by an HACCP plan. The rest of the hazards were managed by establishing oPRPs. With this study, the company achieved the ISO 22000 certification, thus guaranteeing food safety, which may contribute to increase its share market and to enter new markets.

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Table 3

Criteria to assess control measures.

Code	Variable	Criteria	Value
V1	Effect on hazards	It eliminates the hazard	1
		It minimises the hazard, but does not eliminate it	3
V2	Feasibility for monitoring	Continuous measurement or in real time	1
		Discontinuous measurement	3
V3	Place within the system relative to other control measures	Initial control measure or a previous one to other measures established for the same hazard	1
		Final control measure	3
V4	Likelihood of failure	The measure did not fail last year	1
		The measure failed 1 to 5 times last year	3
V5	Severity of the consequence(s) in the case of failure in its functioning	It may involve medical consultation, but not hospitalisation	1
		It may involve hospitalisation	3
V6	Specificity of the control measure	Discrimination of the hazard in real time	1
		It provides information for further analysis and minimization of the hazard	3
V7	Synergistic effects	Complementary control measure	1
		Non-complementary control measure	3

Table 4

Control measures assessment. (Variables V1 to V7 are described in Table 3). oPRPs: Operational prerequisite programmes; CCP: Critical control point.

		Variable scoring								
Hazard Code	**Control measure**	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**Score**	**oPRPs /CCP**
2	Raw material and suppliers control	3	1	3	1	3	1	3	15	CCP
3	Raw material and suppliers control	3	1	1	1	3	1	1	11	oPRPs
	Microbial analyses	1	3	3	1	3	1	1	13	oPRPs
9	Systematic cleaning of working tools	3	3	3	1	3	1	1	15	CCP
10	Systematic cleaning of working tools	3	3	1	1	3	1	1	13	oPRPs
	Good hygiene practices	3	3	1	1	3	1	1	13	oPRPs
	Quality of air controlled by filters H and G	3	1	1	1	1	1	1	9	oPRPs
	Control of temperature and relative humidity	3	1	1	1	1	1	1	9	oPRPs
	Microbial analyses	1	3	3	1	3	1	1	13	oPRPs
11	Good hygiene practices	3	3	1	1	3	1	1	13	oPRPs
	Quality of air controlled by filters H and G	3	1	1	1	1	1	1	9	oPRPs
	Control of temperature and relative humidity	3	1	1	1	1	1	1	9	oPRP
	Systematic cleaning of mixing tanks	3	3	1	1	3	1	1	13	oPRPs
	Control of pH	1	3	1	1	3	1	1	11	oPRPs
	Control of a_w	1	3	1	1	3	1	1	11	oPRPs
	Microbial analyses	1	3	3	1	3	1	1	13	oPRPs
12	Systematic cleaning of the filling machine	3	3	3	1	3	1	3	17	CCP
13	Systematic cleaning of the filling machine	3	3	1	1	3	1	1	13	oPRPs
	Microbial analyses	1	3	3	1	3	1	1	13	oPRPs

Table 1

Hazard identification.

STEP	HAZARD	Code
1. Reception	*Physical*: Presence of foreign bodies (pieces of wood, plastic, etc.)	1
	Chemical: Residues of pesticides, antibiotics and/or heavy metals.	2
	Biological: Contamination by pathogens (*Salmonella*, *E. coli*, etc.)	3
2. Conditioning	*Physical*: Foreign bodies	4
3. Storage	*Biological*: Proliferation of microorganisms	5
	Biological: Contamination by insects	6
4.Transport to production area	*Physical*: Foreign bodies from tools used for transport.	7
5. Ingredients weighing	*Physical*: Foreign bodies	8
	Chemical: Cross-contamination by metabisulphite (allergen).	9
	Biological: Contamination by pathogens	10
6. Preparing the mixture	*Biological*: Contamination by pathogens and/or proliferation of microorganisms	11
7. Ampoules-filling and -sealing	*Chemical*: Cross-contamination by metabisulphite.	12
	Biological: Contamination by pathogens	13

Table 2

Hazard assessment.

Step	Hazard	Code	Probability (P)	Severity (S)	P x S
1. Reception	Presence of foreign bodies (pieces of wood, plastic, etc.)	1	1	1	**1**
	Residues of pesticides, antibiotics and/or heavy metals.	2	1	5	**5**
	Contamination by pathogens (*Salmonella*, *E. coli*, etc.)	3	1	5	**5**
2. Conditioning	Foreign bodies.	4	1	1	**1**
3. Storage	Proliferation of microorganisms	5	1	2	**2**
	Contamination by insects	6	1	1	**1**
4.Transport to production area	Foreign bodies from tools used for transport.	7	1	1	**1**
5. Ingredients weighing	Foreign bodies	8	1	1	**1**
	Cross contamination by metabisulphite (allergen).	9	1	5	**5**
	Contamination by pathogens	10	1	5	**5**
6. Preparing the mixture	Contamination by pathogens and/or proliferation of microorganisms.	11	1	5	**5**
7. Ampoules-filling and -sealing	Cross contamination by metabisulphite.	12	1	5	**5**
	Contamination by pathogens.	13	1	5	**5**

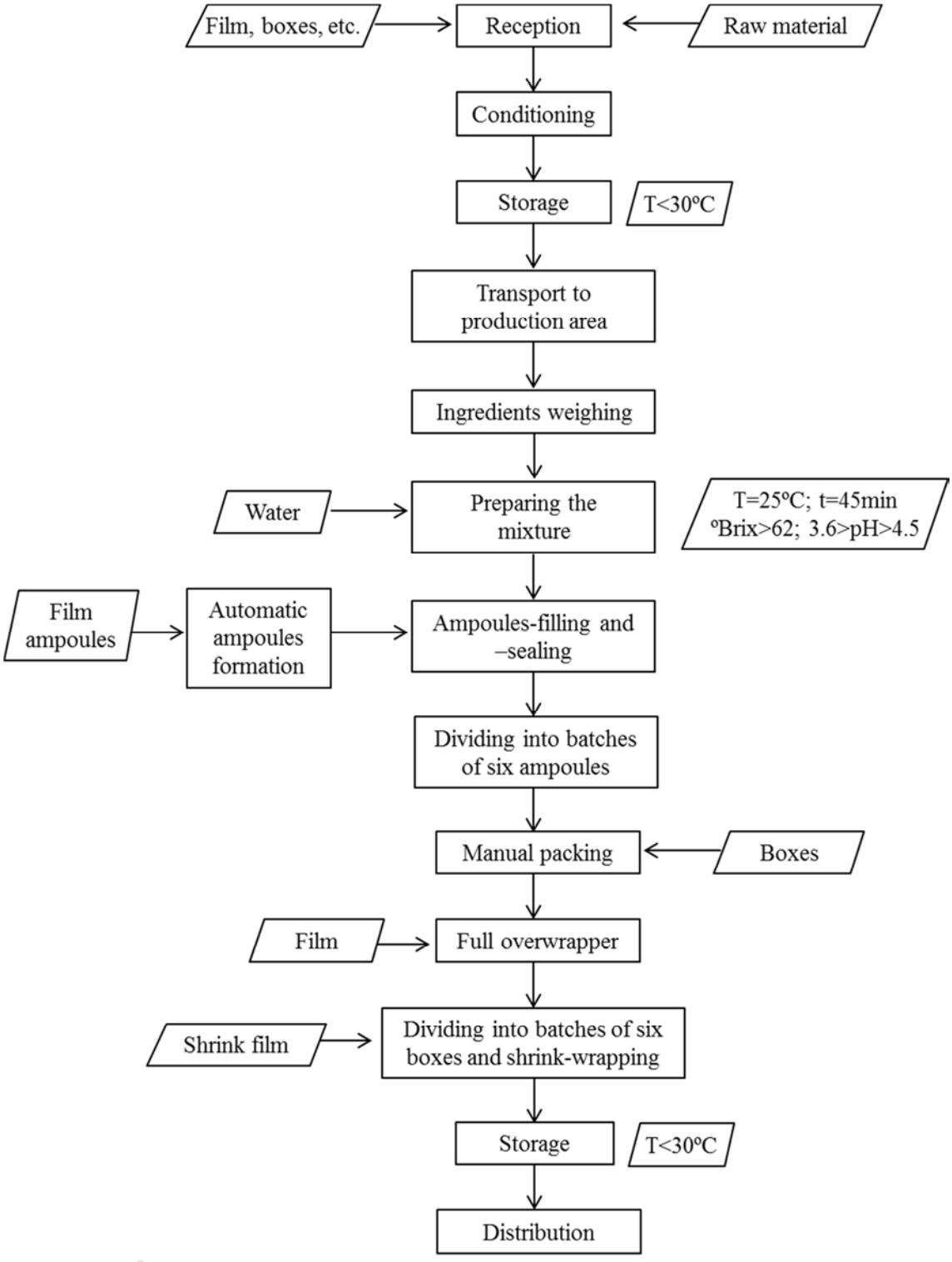

Fig. 1 (Isabel Fernández-Segovia)

Highlights

- A methodology to perform hazard and control measures assessments is shown.
- The work was done on propolis, royal jelly and vitamin C ampoules processing line.
- Seven of the thirteen hazards identified in this study were significant.
- The critical control points determined in three hazards were managed by HACCP plan.
- The other four hazards were managed by operational prerequisite programmes.