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FROM THE APPLICATION OF WATER SAFETY PLAN TO THE ACHIEVEMENT OF THE ISO 22000:2005 STANDARD: A CASE STUDY

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Abstract

The Water Safety Plan (WSP) model provides a completely new, cross-cutting and multidisciplinary approach for the risk assessment of drinking water pollution. The concept of "control" of the drinking water supply system (DWSS) is replaced by the concept of "under control", in order to protect human health. The key factor of the WSP approach is the identification and mitigation or, if possible, the elimination of all factors that may cause a chemical, physical, microbial and radiological risk for drinking water. Due to its characteristics, the WSP can be perfectly integrated with the Hazard Analysis Critical Control Points (HACCP) system, a food safety management system which has the same approach of the WSP for the control of CCPs in food and drink production. Based on the Codex Alimentarius indications, 7 main principles have to be followed in order to establish a HACCP plan. These 7 principles are resumed in the International Organization for Standardization (ISO) 22000:2005 management system. The aim of this study is to evaluate how the WSP implemented for the DWSS of Mortara, Italy, was integrated with the HACCP system, in order to achieve the ISO 22000:2005 standard. The novelty of this work is that this is one of the first nationwide application of the ISO 22000:2005 standard on the whole DWSS stages, from catchment to consumer. In this way, all the DWSS criticalities have been detected. Moreover, the drinking water quality control system has been improved so much to consider water by rights a food.

Key words: drinking water, Hazard Analysis Critical Control Points, ISO 22000:2005, Water Safety Plan

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1. Introduction

1.1. Water Safety Plan approach

Drinking water supply system (DWSS) utility managers have the responsibility of managing water quality risks to ensure the safety and quality of water supplied to their customers. Nowadays, managers rely on the Water Safety Plan (WSP), recently included in European Directive 2015/1787 (EC Directive, 2015). WSP is an innovative risk assessment and management approach introduced in 2004 by the World Health Organization (WHO) through guidelines for drinking water quality (Collivignarelli, 2017; Gunnarsdöttir et al., 2008; Khaniki et al., 2009; Sorlini et al., 2017; WHO, 2004; WHO, 2009; Yokoi et al., 2006). WSP ensures the safety of drinking water in the entire DWSS, from catchment to consumer (Collivignarelli, 2017; Sorlini et al., 2015, 2017). It identifies all factors that may cause a chemical, physical, microbial and radiological risk for water in order to reduce or eliminate these factors. Moreover,

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it prevents water re-contamination during storage and distribution (Collivignarelli, 2017; Giardina et al., 2016; Gibellini et al., 2017; Sorlini et al., 2017; WHO, 2009). This management intervention involves a continuous feedback loop of risk identification and evaluation of whether risks are under control, deriving from the approach used widely to ensure food safety (Setty et al., 2017).

In order to highlight the connection between drinking water and food is necessary to consider the Codex Alimentarius, i.e. the "Food Code". This is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission (CAC) in order to protect consumers' health and promote fair practices in food trade (Boutrif, 2002; Luber, 2010). Regarding to food safety, CAC has introduced the "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application" guideline (Dawson, 1995). According to Jayaratne (2008), at page 548: "HACCP is an internationally recognized process control system which involves identifying and prioritizing hazards and risks to product quality and controlling processes to reliably maintain the desired level of product quality".

The purpose of the HACCP system is to control potential hazards in food production and guarantee the safety of the products in the whole food chain (production, handling, treatment, transportation and storage), all the way to the consumer (Al-Busaidi et al., 2016; Allata et al., 2017; Bergström and Hellqvist, 2004; Casolani and Del Signore, 2016; Damikouka et al., 2007; Nordenskjöld, 2012). EC Directive (1993) and EC Regulation (2004) report that the application of HACCP system in a food production is mandatory in Europe (Damikouka et al., 2007; Khaniki et al., 2009; Nordenskjöld, 2012).

1.2. The HACCP principles and the ISO 22000:2005 standard

Based on the Codex Alimentarius indications, 7 main principles have to be followed in order to establish a HACCP plan (CAC, 1969):

• **Principle 1: perform a hazard analysis**. The target of this step is to obtain a comprehensive list of all biological, chemical and physical agents or conditions which have the potential to cause damage, the assessment and the severity of the risk associated with these hazards as well as the possible control measures for each hazard.

• Principle 2: Determine the Critical Control Points (CCPs). The Codex, at page 26, defines CCP as: "A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. The intent of the HACCP system is to focus control at CCPs" (CAC, 1969).

• **Principle 3: establish critical limit(s)** for each CCP. In some cases, more than one critical limit will be identified and measured.

• **Principle 4: establish a CCP monitoring plan** to verify that CCPs are always under control, in order to prevent the exceeding of critical limits.

• **Principle 5: establish the corrective action** to be taken when monitoring indicates that a particular CCP is no longer under control.

• **Principle 6:** establish procedures of verification to confirm that the HACCP system is working effectively.

• **Principle 7: introduce documentation** concerning all procedures **and records** appropriate to these principles and their application.

The systematically application of HACCP principles guarantees that water quality risks are controlled as close to their sources as possible (Jayaratne, 2008). The 7 principles can be applied through the implementation of 12 preparatory steps: (i) assemble HACCP team; (ii) describe product; (iii) identify intended use; (iv) construct flow diagram; (v) confirm flow diagram; (vi) conduct a hazard analysis; (vii) determine the critical control points (CCPs); (viii) establish critical limits for each CCP; (ix) establish a CCPs monitoring plan; (x) establish corrective actions; (xi) validation and verification of HACCP plan; (xii) establish documentation and record keeping. The 7 principles mentioned above are taken up in the ISO 22000 (2005) "Food safety management systems - Requirements for any organization in the food chain" quality management system, published by ISO Committee TC34 on the first of September 2005. Starting from the assumption that a consumer health hazard may occur at any stage of the production/distribution chain, ISO 22000 standard has been designed in order to ensure that there are no weak links in the food supply chain (Allata et al., 2017; Færgemand, 2008; ISO 22000, 2005). It therefore involves both the companies directly concerned (producers and distributors of the product) and those involved indirectly (i.e. packaging manufacturers or cleaning companies) (De Gregorio et al., 2010).

The structure of ISO 22000 (2005) standard is based on the combination of three elements: the principles of HACCP, the Prerequisite Programs (PRPs) and the operational Prerequisite Programs (oPRPs). PRPs, at page 16, are defined as "practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety" (ISO 22000, 2005). PRPs provide a foundation for an effective HACCP system and reduce the likelihood of certain hazards. Instead, the oPRPs are PRPs identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the proliferation of food safety hazards in the product(s) or in the processing environment. The system planning of the ISO 22000 (2005) standard is shown in Fig. 1.

The primary goal of this study is to highlight how the DWSS utility manager of Mortara, Italy, has adapted the already implemented WSP (2016) to the HACCP system, modifying and/or integrating the WSP hazard analysis with the principles reported in the Codex Alimentarius, in order to achieve the ISO 22000 (2005) standard. This upgrade process perfectly follows the objectives set by the European Commission.

As a matter of fact, at the beginning of February 2018, a proposal to amend EC Directive (1998) was presented. The focus of this proposal is to review the list of parameters to define drinking water as "safe". In particular article 10, now revised and entitled "Domestic distribution risk assessment", introduces the obligation to conduct a risk-based approach for the products and materials intended for contact with drinking water.

Furthermore, the proposal requires Member States to ensure regular monitoring of parameters such as lead and legionella and establishes rules on the admissible quantities of certain substances in water (EC Directive, 2018).

2. Material and methods

2.1. The HACCP system and the WSP: connection between drinking water and food

Access to drinking water, healthy and clean, is a human right and a fundamental health indicator. In Italy, the quality parameters to be observed for drinking water are defined in Legislative Decree 31 (2001), transposition of the Council Directive 98/83/EEC, which establishes the conformity compliance points, the control Bodies and the procedures by which the controls are to be carried out. Furthermore, as reported in Legislative Decree 31 (2001), DWSS utility managers and water kiosk managers must apply the HACCP system (EC Regulation, 2004) and must monitor the maintenance of water potability parameters through the adoption of self-control plans (MHC, 2011). In fact, HACCP is a food safety management system that can also be applied to drinking-water supply (Khaniki et al., 2009). In this perspective, the HACCP is a basic concept that underlies the WSP (Setty et al., 2017). Compared to food production chain, there are three main features in the drinking water treatment process:

1. Variable qualitative features of raw water. While quality checking of products and materials for food use can guarantee a qualifying level, which keeps constant along the whole food chain, water suppliers have to deal with a variation of water quality, based on the source of supply.

2. Need for continuous treatment and supply. Each food product is separately handled by production lots and is therefore easily traced. Instead, raw water is generally treated and supplied continuously to the consumer. Therefore, it is not possible to apply the lot concept as it is. Besides, re-contamination and regrowth could happen in the distribution system, after water treatment and purification.

3. Respecting numerous qualitative and organoleptic parameters for drinking water. Although the HACCP system covers only the health hazards, utilization hazards such as bad colour, bad taste and odour must be considered because they are unacceptable to water consumers (Yokoi et al., 2006).

2.2. Mortara (Pavia) drinking water supply system

A WSP was implemented for the DWSS of Mortara, a town of 15500 inhabitants located in northern Italy (province of Pavia). The water supply system consists of three drinking water treatment plants (DWTPs), each treating groundwater (drawn at 200 m depth, through wells, by a confined aquifer) containing the main following contaminants: arsenic, iron, manganese and ammonia. Two of the three DWTPs have the sequence of treatments reported in Fig. 2.

Pre-oxidation is carried out with air. This process allows to oxidize iron ($Fe^{2+} \rightarrow Fe^{3+}$) and ensure aerobic conditions for the next phase. Biofiltration is carried out on a quartzite support mixed with pyrolusite. The latter is produced by coating the sandy material with MnO₂, in order to catalyze the oxidation of manganese. The sandy support is also used for the development of nitrifying biomass that works on inorganic nitrogen compounds (NH₄⁺). The iron precipitates (Fe(OH)₃) are also retained in this phase.

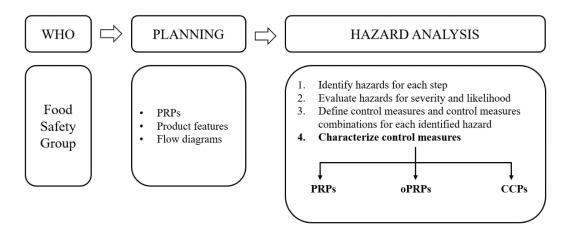


Fig. 1. System planning according to ISO 22000 standard

The FeCl₃ dosage ensures the arsenic and residual MnO₂ precipitation. These precipitates are retained in the mixed Granular Activated Carbon (GAC)/sand filtration. Finally, NaClO dosage guarantees chlorine coverage in the distribution network. The third plant does not have FeCl3 dosage and mixed GAC/sand filtration treatment because the natural iron content in the raw water is enough for arsenic removal. The 2014-2017 averages of monitored data of the Mortara DWSS are reported in Table 1. Treated water flows into an 84-km interconnected distribution network (Sorlini et al., 2017). The implemented WSP was adapted to the HACCP system steps (described afterwards) in order to obtain the ISO 22000 certification for all the DWSS stages.

2.3. Description of the HACCP implementation steps

2.3.1. Assemble HACCP team (step 1)

The HACCP team is responsible for the planning, development, verification and implementation of the HACCP system. The DWSS utility manager has to appoint a Food Safety Group (FSG), consisting of Operative Director, Security Manager and Plants Foreman. The FSG composition owns а combination of knowledge and multidisciplinary experience in the development and implementation of the food safety management system relating to products, processes and hazards for food safety.

2.3.2. Describe product (step 2)

According to the implemented WSP, the DWSS utility manager has to describe and document drinking water features, building materials and products that may be in contact with water, in order to conduct the hazard analysis. The description includes: biological, chemical and physical features; raw water composition and characteristics of additives and processing aids; supply source; treatment methods; distribution methods; storage conditions; preparation and/or manipulation before use or processing; acceptance criteria relating to food safety or purchased materials specifications suitable for the intended use. For the choice of materials, the DWSS utility manager can take into account the legislative and regulatory requirements related to the drinking water distribution (Legislative Decree 31 (2001)).

2.3.3. Identify intended use (step 3)

The DWSS utility manager has to supply drinking water for both sanitary (toilet facilities) and food use, through the distribution network. Furthermore, the DWSS utility manager is responsible for the delivered service up to the end-user delivery point (counter). Poor post-counter handling could bring to a worsening in the distributed water potability features. The service is also aimed at particularly vulnerable users such as hospitals, old people's home, kindergartens, schools etc. In compliance with the provisions of Legislative Decree 31 (2001), the maintenance of water health parameters is considered in the risk assessment, as well as an adequate protection for the expected and predictable water uses.

2.3.4. Construct flow diagram (step 4 & step 5)

The FSG has to develop a flow diagram for the DWTPs, in order to describe the key steps in the water treatment process. Moreover, flow diagrams must be revised periodically.

2.3.5. Conduct a hazard analysis (step 6)

The FSG has the task of carrying out the hazard analysis in order to determine the hazards that need to be controlled, the degree of control needful to ensure food safety and which combination of control measures is required. For each phase identified through flow diagrams, the FSG detected all the hazardous events (i.e. any event that introduces hazards to the water supply) that may lead to a food safety water hazard. Furthermore, each hazardous event must be associated with the related hazards (i.e. any physical, chemical, biological or radiological agent that has the potential to cause harm to public health) that may cause a water physical, chemical, microbial or radiological contamination. In this assessment, the FSG has also to consider hazard events that are not readily apparent, such as changes in weather conditions or pipelines aging, also considering past events and historical information.

The risk associated with each hazard may be described by identifying the likelihood of occurrence (i.e. the frequency with which a hazard or hazardous event can occur) and evaluating the severity of the consequences (i.e. the severity or intensity of the impact that the hazard may cause on both human health and the sanitary quality of the distributed water).

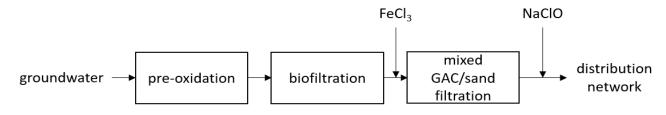


Fig. 2. Block diagram of Mortara DWTPs

| 2014-2017 Monitoring Data | Raw Water | OUT Pre- oxidation | OUT biofiltration | OUT GAC/sand filtration | Italian Regulation Limits (EC Directive, 2001) |
|------------------------------|-----------|-----------------------|-------------------|----------------------------|---|
| | | | Plant 1 | | · |
| Fe [µg/L] | 77 | 72 | 28.5 | 25 | 200 |
| Mn [µg/L] | 98 | 97 | 5.6 | 1.1 | 50 |
| As _{TOT} [µg/L] | 10.5 | 10 | 9.7 | 7.5 | 10 |
| NH4 ⁺ [mg/L] | 0.8 | 0.9 | 0.3 | 0.01 | 0.5 |
| | | | Plant 2 | | - |
| Fe [µg/L] | 69 | 66.5 | 10.5 | 44.3 | 200 |
| Mn [µg/L] | 94.5 | 95 | 1 | 1.03 | 50 |
| Astot [µg/L] | 9.7 | 10.1 | 9.6 | 7.5 | 10 |
| NH4 ⁺ [mg/L] | 0.7 | 0.8 | 0.03 | 0.01 | 0.5 |
| | | | Plant 3 | | |
| Fe [µg/L] | 76.5 | 79.5 | 23 | | 200 |
| Mn [µg/L] | 164.5 | 176.5 | 1 | No GAC/sand | 50 |
| Astot [µg/L] | 5.2 | 5.6 | 5.5 | filtration treatment | 10 |
| NH4 ⁺ [mg/L] | 0.4 | 0.3 | 0.04 | | 0.5 |

Table 1. 2014-2017 averages of monitored data of the Mortara DWSS

The likelihood of occurrence is assigned taking into account the DWSS utility manager experience, past events and monitoring data, both internal and external. The risk is calculated as the product of the likelihood and the severity of the consequences, according to the semi-quantitative risk matrix approach shown in Table 2.

The risk calculation is based on a semiquantitative approach because it derives from a product between two factors, whose values are however established by the team taking into account the user's food safety requirements and the intended drinking water use. The risk assessment is initially carried out considering the worst possible scenario for the water system, i.e. assuming the absence of control measures and the absence of other downstream treatments, in order to highlight all the DWSS possible risks.

Based on the hazard analysis, the DWSS utility manager has to choose an appropriate combination of control measures to prevent, eliminate or reduce the food safety hazards. Therefore, based on the established control measures, the PRPs must be defined and cataloged within a monitoring plan.

Subsequently, the control measures are submitted to a validation process with the aim of verifying that they are effective and able (also in combination) to ensure the control of the identified hazards. In case of negative validation, the control measure and/or their combination are modified and evaluated again. Therefore, after identifying and appropriately validating all the control measures, the FSG reassess the risks considering the effectiveness of the control measures in place. The risks are recalculated in terms of the severity of consequences and likelihood of occurrence, considering that the latter, compared to the initial one, is as much smaller as the effectiveness of the control measures associated with each hazard is greater. 2.3.6. Determine the oPRPs and CCPs (step 7)

After identifying and appropriately validating all the control measures, and after establishing which control measures can be considered as PRPs, the FSG has to divide them into categories to determine if they must be managed as oPRPs or as CCPs. The CCPs assessment is carried out using a logical approach, defined as "decision tree" and schematized through the flow chart shown in Fig. 3.

| | | | | Severity/consequence | | | | | | | |
|--------|--------------------------------|---|-------------------------------|----------------------|-----------------|--------------|-----------------------|--|--|--|--|
| | | | Insignificant or no impact | Minor impact | Moderate impact | Major impact | Catastrophi impact | | | | |
| | | | 1 | 2 | 3 | 4 | 5 | | | | |
| cy | Rare (once every 5 years) | 1 | 1 | 2 | 3 | 4 | 5 | | | | |
| nen | Unlikely (once a year) | 2 | 2 | 4 | 6 | 8 | 10 | | | | |
| od/ fr | Moderate (once a month) | 3 | 3 | 6 | 9 | 12 | 15 | | | | |
| seliho | Likely (once a week) | 4 | 4 | 8 | 12 | 16 | 20 | | | | |
| Lil | Almost certain (once a day) | 5 | 5 | 10 | 15 | 20 | 25 | | | | |
| Ris | k score | | <6 | 6-9 | 10-15 | >15 | | | | | |
| Ris | k rating | | Low | Medium | High | Very high | | | | | |

Table 2. Semi-quantitative risk matrix approach (adopted from WHO, 2009)

If a PRP is classified as oPRP, it must be managed by identifying a control measure, a monitoring procedure and corrective actions.

2.3.7. Establish a CCPs critical limits (step 8), monitoring plan (step 9) and corrective actions (step 10)

For the identified CCPs, the FSG has to establish the critical limit and ensure the compliance with the level of acceptability, the measurability of the critical limit and the documentation relating to the criteria for the limit selection. The monitoring methods and their frequencies ensure that the critical limit is not exceeded in order to prevent the distribution of potentially polluted drinking water.

2.3.8. Validate/verify HACCP plan (step 11)

The FSG has to define a verification plan where, for each control measure, the methods, the phase or sampling point, the frequencies and the responsibilities for the verification activities are defined.

2.3.9. Establish documentation and record keeping (step 12)

The DWSS utility manager maintains hardcopy and electronic record keeping and tracking systems, asset information management databases and a water quality database in accordance with its ISO accreditation systems, as well as the traceability of the reagents used in DWTPs. The water distribution network is also documented by the indication of the traces, the pipeline diameters and of the construction materials.

3. Results and discussion

3.1 Results

As already reported, the hazard analysis applied for the WSP has been adapted to the HACCP system. The DWTPs flow diagram were constructed to describe the key steps in the water treatment process and include: sequence and interaction of all operational phases; water and reagents inlet in the flow; types of treatments and respective backwashes and discharge points in municipal sewage system. Processes stages are directly managed by DWSS utility manager or by accredited companies. Annually, through internal audits, the FSG verifies the accuracy of flow diagrams by on-site verification. An example of DWTP flow diagram is reported in Fig. 4.

For each phase identified through flow diagrams, the FSG detected all the hazardous events that may lead to a food safety water hazard. Tables 3 and 4 show an example of risk assessment, respectively before and after the validation of the control measures. Both tables reported the same hazardous events, chosen as examples.

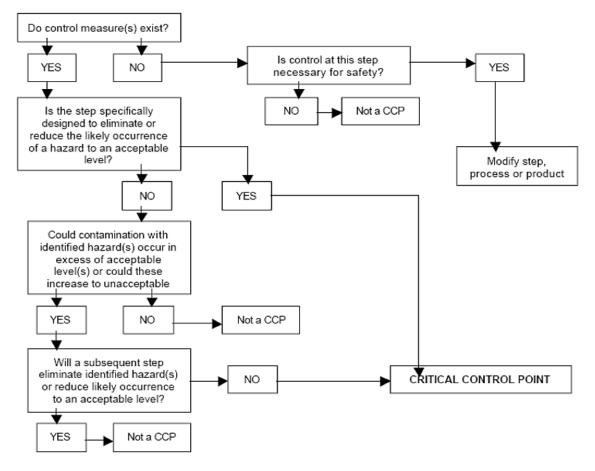


Fig. 3. The decision tree for determination of CCPs (adapted from CAC, 1969)

From the application of the WSP to the achievement of the ISO 22000:2005 standard: A case study

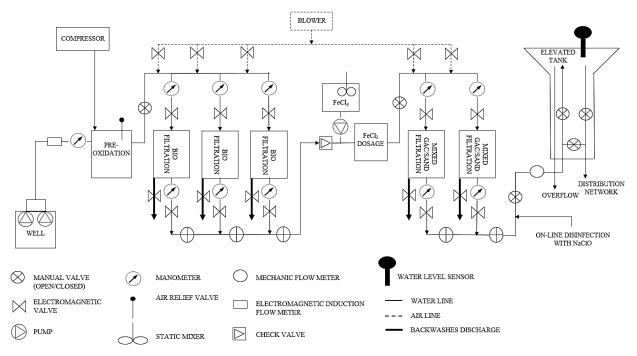


Fig. 4. Example of Mortara DWTP flow diagram

| Process step | Hazardous event | Related hazard | L (a) | S (b) | R score (c) | R rating (before considering controls) |
|-------------------------|--------------------------------|-----------------------------|-------|-------|-------------|--|
| Basin | Changes in weather conditions | Chemical | 1 | 4 | 4 | Low |
| Well | Pump failure | Insufficient water | | | | Not applicable |
| Mixed GAC/sand | Activated carbon exhaustion | Physical | 3 | 2 | 6 | Medium |
| filtration | CARRESTOR | Chemical | 3 | 4 | 12 | High |
| Disinfection | Disinfectant underdosage | Microbial | 2 | 5 | 10 | High |
| Distribution network | Vandalism | Chemical/physical/microbial | 1 | 5 | 5 | Low |

(a) L = likelihood; (b) S = severity; (c) R = risk

Table 4. Example of risk assessment after the validation of the control measures

| | R rating (before | | | Validation | | | | | R rating |
|-------------------------------------|-------------------------------|--|--|------------|-------------------|---|---|------------|------------------------------------|
| Hazardous event | considering controls) | Control measure | Monitoring plan | E (d) | NE ^(e) | L | S | R score | (after considering controls) |
| Changes in weather conditions | Low (Chemical hazard) | Presence of a clay layer that waterproof the aquifer | Natural measure | X | | 1 | 4 | 4 | Low |
| Pump failure | Not applicable | \ | \ | \ | | \ | \ | \ | \ |
| | n Medium (Physical hazard) | Periodic activated carbon replacements | PRP n.8: plants maintenance | Х | | | | 3 | Low |
| Activated carbon exhaustion | | in/out pressures verification | PRPo n.3: pressures verification | Х | | 1 | 3 | | |
| | | Downstream elevated tank that allows the sediment deposit | See downstream phase | X | | | | | |

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| | High | Periodic activated carbon replacements | PRP n.8: plants maintenance | Х | X | | 4 | 4 | Low |
|-----------------------------|---------------------------------------|---|--|---|---|---|---|---|-----|
| | (Chemical hazard) | | PRPo n.3: pressures verification | X | | 1 | 4 | 4 | LOW |
| Disinfectant underdosage | High (Microbial hazard) | Disinfectant dosing control | PRP n.1: continuous disinfection | Х | | 1 | 5 | 5 | Low |
| | Low | Active remote control | PRP n.2: site protection | Х | | | | | |
| Vandalism | Low (Chem./Phys./Micro. hazard) | Locked building that prevents unauthorized entry | PRP n.2: site protection | Х | | 1 | 5 | 5 | Low |

(d) E = effective; (e) NE = not effective

As reported in the previous Tables 3 and 4, a hazardous event related to the catchment area may be the change in weather conditions. This event may involve both chemical and physical contamination, due essentially to rapid changes in the quality of the source water. According to the information reported by the DWSS utility manager, the likelihood of occurrence is once every 5 years (rare, 1). Instead, the severity of consequences is 4 (major regulatory impact). So, the calculated risk is low $(1 \times 4 = 4)$. In this case the control measure, that is the presence of a clay layer that waterproof the aquifer, is natural and cannot be classified as a PRP. Therefore, after the validation of this control measure, the risk remained unchanged.

Instead, at the catchment, the pump drawing water from the well to the treatment plant could malfunction. In this case, there is no water supply to the plant and is impossible to carry out a risk assessment: the supply interruption involves that there are no hazards for the food safety of water. Furthermore, at the disinfection, the reported hazardous event is the disinfectant underdosage. This event is associated with a microbial contamination hazard, due to the ineffectiveness of the treatment and the consequent presence of bacteria content in the water outlet from the disinfection step. The microbial contamination has a severity of consequences of 5 (public health impact). Moreover, according to the DWSS utility manager information, the likelihood of occurrence of the disinfectant underdosage is once a year (unlikely, 2). So, the calculated risk is high (2 x 5 = 10). The control measure applied in this case concerns the disinfectant dosing control, applied through the oPRP concerning the continuous disinfection process (described afterwards in the step 7). The effectiveness of this control measure has allowed to bring the risk to a level 5 (low), reducing the likelihood of occurrence to once every 5 years (rare, 1). After identifying and appropriately validating all the control measures, and after establishing which control measures can be considered as PRPs, the FSG had to divide them into categories to determine if they must be managed as oPRPs or as CCPs. Considering the examples reported in Table 5, the first detected oPRP is FeCl₃ dosing (Q1: yes; Q2: yes), the second is pressures verification (Q1: yes; Q2: yes; Q5: no) and the third is continuous disinfection process (Q1: yes; Q2: no; Q3: yes; Q4: no; Q5: no). The oPRPs are managed as shown in Table 5.

For example, the continuous disinfection process is carried out by using an automatic metering pump (0.1 mgNaClO/L \pm 0,05 supplied). Further control measures are the exposure of pump settings, quantity of reagent and solution preparation methods in the DWTPs area. The monitoring procedure of the continuous disinfection process provides the pump connection to telecontrol, in order to verify the pump functionality. Furthermore, alarm triggering is sent to operators via e-mail notification. In addition, as further evidence of control, system accesses are recorded in the telecontrol system. Finally, Plants Foreman records the preparation of the solution, the maximum storage time and the settings of the metering pump on a dedicated document. The corrective actions are the restoring of the pump functionality (in presence of anomalies), water microbial analysis (if the dosage remains inactive for more than a week) and possible NaClO by hand dosage in the absence of normal dosage for more than one week. Comparing with the DWSS utility manager, the FSG has identified only one CCP, that is the monitoring of the residual chlorine in the distribution network (Q1: yes; Q2: no; Q3: yes; Q4: no; Q5: yes). In fact the continuous disinfection process, if not correctly managed, can lead to a chemical contamination of the water distributed to the users. This contamination can be determined by an excess of chlorine in the treated water or by the possible formation of disinfection by-products (THM) in the presence of precursors. The CCP is managed as shown in Table 6. As reported in Table 6, the FSG has established a CCP critical limit equal to 0.2 mgCl/L, as recommended by EC Directive (2001).

The FSG has also established a monitoring system for the control of residual chlorine in the distribution network. The calibration of the metering pump is carried out annually. Instead, the verification of the metering pump calibration by measuring the residual chlorine is carried out monthly, or as result of each variation of the chlorine dosage.

| Hazardous event | oPRP | Control measure/s | Monitoring procedure | Corrective actions | | |
|-----------------------------------|-----------------------------|--|--|---|--|--|
| Reagent overdosing | FeCl ₃ dosing | • Automatic metering pump (1 mgFeCl ₃ /L ± 0.5 supplied) | Pump connected to telecontrol Alarm triggering send via email to operators Telecontrol system access registration Registration of the solution preparation, maximum storage time and metering pump settings | Restoring pump functionality Chemical analysis of the water outlet from the treatment Possible FeCl₃ by hand dosage in the absence of normal dosage for more than one week | | |
| Activated carbon exhaustion | Pressures verification | • DWTPs in/out pressures verification | Pressure switch connected to telecontrol Alarm triggering send by email to operators Telecontrol system access registration | Backwash performance check or possible by hand backwash DWTPs performing test (pumps) Possible filter material replacement | | |
| | | • Automatic metering pump (0.1 mg NaClO/L ± 0.05 supplied) | Pump connected to telecontrol | • Restoring of the pump functionality | | |
| Disinfectant | Continuous | • Peristaltic pump settings exhibited in the DWTPs | • Alarm triggering sent by email to operators | • Water microbial analysis | | |
| | disinfection process | • Quantity of reagent and solution preparation methods exhibited in the DWTPs | Telecontrol system access registration Registration of the solution preparation, maximum storage time and metering pump settings | • Possible NaClO by hand dosage in the absence of normal dosage for more than one week | | |

Table 5. oPRPs management plan

Table 6. CCP management plan

| ССР | Monitoring of the residual chlorine in the distribution network | | |
|-----------------------------------|---|--|--|
| Control measure | Chlorine dosage (max 0,2 mgCl/L) with calibrated metering pump | | |
| Critical limit | 0,2 mgCl/L | | |
| CCP monitoring | Metering pump calibration | | |
| CCP verification | Calibration check with residual chlorine measure | | |
| Monitoring person in charge | Plants Foreman | | |
| Analysis results person in charge | Operative Director | | |
| Corrective actions | chlorine dosage adjustment | | |
| Corrective actions | • metering pump calibration | | |

The Operative Director undertakes the corrective actions listed in Table 6 if the critical limit is exceeded. The undertaken actions ensure the identification of the cause of non-compliance and the restoration of the control over the CCP. The FSG also prepares a documented procedure to prevent the consumption and/or the distribution of potentially polluted drinking water.

For the control measures identified, a verification plan was developed establishing the verification activity, method, phase/sampling point, the frequency of verification and the responsibility of verification. An extract of the verification plan adopted is reported in Table 7.

For example, regarding to CCP, the verification activities concern microbial parameters and chlorine dosage verification. The verification method of the microbial parameters is the sampling and laboratory sample analysis. Instead, the verification method of the chlorine dosage verification is the residual chlorine analysis. Both verification activity is carried out at the outlet of elevated tank and are under the responsibility of Plants Foreman.

3.2 Discussions

Tanks to the application of the WSP, the DWSS utility manager has obtained several benefits:

- reduction of public health risk, due to the identification of the criticalities of the DWSS;
- better compliance of water quality parameters with regulatory requirements, due to the passage from a retrospective to a preventive approach;
- greater confidence on health authorities and stakeholders, also thanks to the achievement of the ISO 22000:2005 standard;
- better management of resources due to intervention planning;
- better use of personnel, due to professional training courses.

| Verification plan | | | | | | | | |
|---|------------------------------|---|--|--|-------------------|--|--|--|
| Control measure | Verification activity | Method | Phase/ sampling point | Frequency | Responsibility | | | |
| FeCl ₃ dosing (oPRP) | Chemical parameters | Sampling and laboratory sample analysis | Mixed GAC/sand filtration | See yearly analytical plan | Plants Foreman | | | |
| Pressures verification (oPRP) | Chemical parameters | Sampling and laboratory sample analysis | Biofiltration - Mixed GAC/sand filtration | See yearly analytical plan | Plants Foreman | | | |
| Continuous disinfection process (oPRP) | Microbial parameters | Sampling and laboratory sample analysis | Elevated tank outlet | See yearly analytical plan | Plants Foreman | | | |
| Distribution network | Microbial parameters | Sampling and laboratory sample analysis | Elevated tank outlet | See yearly analytical plan | Plants Foreman | | | |
| residual chlorine monitoring (CCP) | Chlorine dosage verification | Residual chlorine analysis | Elevated tank outlet | Monthly; after dosage adjustment | Plants Foreman | | | |

Table 7. Extract of verification plan

However, a WSP also presents a series of critical issues in the implementation procedure. The first critical issue concerned the difficulty in identifying all the hazard events and the related hazards, according to the indications provided by the WHO guidelines (WHO, 2009). The second critical issue concerns the definition of the risk score, performed by analyzing each DWSS treatment individually and assuming the absence of control measures and downstream treatments.

Finally, as the WSP model proposes a step-bystep risk assessment, the last critical issue concerns the lack of a "simplified" procedure, specific for Small Water Supplies (SWSs) where problems of scarcity of resources must be considered.

Certainly, the introduction of a WSP can support the identification of simple and cost-effective actions to be taken in order to protect and improve SWSs. However, specific WSPs that consider only the hazards that really can occur and, therefore, the respective control measures, might be more efficient in SWSs.

As stated above, it is clear that the most important common element to the WSP and HACCP is the risk analysis. As already reported by Mayes (1998), it must be stated that risk analysis and HACCP are two separate subjects with different outputs. The output of risk analysis is a numerical estimate of the occurrence of a particular hazardous event. The output of a HACCP study will be a list of significant hazards together with Critical Control Points, Critical Limits, Monitoring Procedures, Corrective Actions, etc. However, the potential benefits of the use of some elements of risk assessment in HACCP (i.e. increased scientific basis for hazard analysis, clear relationship between hazards, Critical Limits and public health impacts, greater transparency in decision making) cannot be achieved without the general application of validated risk assessment tools.

A possible critical issue of hazard analysis, as reported by Toropilová and Bystrický (2015), may be due to the fact that HACCP is implemented mainly with the objective of satisfying the requirement of authorities or is seen as a task that is mandatory. Establishing HACCP in such scenario gives very little chance of it becoming a meaningful exercise and there is a real risk that it will be seen as a burden by all personnel. In the situation when both the production and the consumer environments are changing, any lag in HACCP development may cause loss of its functionality.

In this perspective, the HACCP system can be compared with dikes built to protect against floods. If they are constructed poorly, it may not be visible but water would find its way. Therefore, constructions rules must be set and observed. If construction is built properly, it deteriorates in time anyway and therefore regular control and maintenance is vital to keep them functional. However, those poorly built will deteriorate faster (Toropilová and Bystrický, 2015).

4. Conclusions

The purpose of the WSP is to make tap water even safer, revolutionizing the control system on drinking water with a model that provides a global system of risk management extended to the entire water supply chain. This new approach allows to decide, on the basis of a concrete and accurate risk assessment, which parameters have to be monitored more frequently or how to extend the list of substances to be kept under control in case of public health concerns.

Thanks to the application of the WSP, the DWSS utility manager implemented a management system for food safety and hygiene according to the ISO 22000:2005 standard, through the application of the principles established in the Codex Alimentarius.

The ISO 22000:2005 standard was achieved in September 2017 for the whole DWSS of Mortara (Pavia). This is a particularly important aspect as it is one of the first nationwide application of the ISO 22000 quality management system on the whole DWSS stages, from catchment to consumer. The consumer satisfaction is a key-factor, but often taken insufficiently into account by the DWSS utility managers. The right of consumers to information about drinking water quality is essential and represents a regulatory obligation. Furthermore, questions raised by consumers, referring to the water quality or to other aspects of the water service, can identify specific aspects of improvement and highlight the effectiveness of the implemented management system. In this context, the active participation of consumer representatives is a particularly useful tool.

Finally, future goals concern the realization of supporting programs, i.e. activities that support the development of people's skills and knowledge, commitment to the WSP-HACCP approach and capacity to manage systems to deliver safe water.

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