

## **CORRECTIONS AND CORRECTIVE ACTIONS – INSTRUMENTS FOR THE CONTINUOUS IMPROVEMENT OF A MANAGEMENT SYSTEM**

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### **Abstract**

*Any private organization is created to bring profit to investors, and the effective implementation of the integrated management systems aims to develop long-term business and increase the overall performance of the organization. Achieving the intended results, knowing the external and internal threats, preventing or reducing unwanted effects, and reaping the desired effects determine a safe and solid long-term development of the organization by consistently offering quality products and services with an efficient and low consumption of resources, without affecting the quality of the environment or the health of the consumers. Food industry organizations that have implemented management systems (quality, food safety, environmental or integrated) must determine their opportunities for improvement and the necessary actions to ensure and increase the safety and quality of products and services, respectively the protection of the environment. These actions also include corrections and corrective actions aimed at removing, preventing, or reducing unwanted effects, improving the performance of the organization. The corrections and corrective actions, to be effective, must be appropriate to the effects of the identified non-conformities. The paper aims to highlight the role that the corrections and corrective actions have in the process of continuous improvement of the management system of food safety, quality, or the environment in food industry organizations, identifying the benefits of implementing these management tools and, especially, contributing to the goal of a sustainable and circular bioeconomy in Europe. In this sense, we analyzed how the implementation of the Integrated Quality Management System - Food Safety - Environment is perceived and achieved or, in some situations, the individual implementation of the management systems mentioned above (EN ISO 9001:2015, EN ISO 22000:2018, EN ISO 14001:2015), by the management of the companies concerned. The case studies presented in the paper are, in fact, a synthesis of data and information accumulated in the external audit process performed in organizations where certified management systems are implemented or in the process of certification according to the requirements of the standards mentioned above. The intended results established for each category of corrections and corrective actions represent their interpretations regarding their contribution to improving the performance of management systems.*

### **Keywords**

*Corrections; corrective actions; management system; quality; environment; food safety.*

## **Introduction**

Given the development of a sustainable economy, the quality of life and the environment are a global priority. We cannot talk about the quality of life and the environment without talking about the quality of products and services, about food safety and security, about environmental protection policies and actions. In this regard, numerous regulations on food processing, packaging, labeling, transport, and keeping/storage (Banu, 2007) of food products, as well as directives and regulations on environmental protection, have been issued and applied internationally. Significant for our study are the standards issued by the International Organization for Standardization (ISO), respectively: EN ISO 9001:2015, EN ISO 22000:2018, EN ISO 14001:2015, HACCP Guide (HACCP.a), but also the Guide GMP - Good Manufacturing Practices promulgated by the American Administration of Food Products and Medicine (US Food and Drug Administration).

Currently, it is not possible to talk about the management of the organization without addressing the quality of products and services offered by the organization, the quality policy, and the quality management system implemented (Olaru, 2004).

Food industry organizations that have implemented management systems such as those based on quality management, food safety, environmental (or integrated) management must identify opportunities for improvement and actions needed to ensure and increase the safety and quality of products and services (Ștețca et al., 2012), respectively the protection of the environment. These actions also include corrections and corrective actions aimed at removing, preventing, or reducing unwanted effects, improving the performance of the organization. The corrections and corrective actions, to be effective, must be appropriate to the effects of the identified non-conformities.

## **Theoretical aspects regarding management systems quality - food safety - environment**

ISO 9001 is based on several quality management principles, including a strong focus on customers, top management motivation and involvement, the process approach, and continuous improvement.

In addition to the 2008 edition (SUN CERT, 2020a), the ISO 9001:2015 standard sets out explicit requirements for taking into account the risks and opportunities associated with the organizational context and the objectives set up by the organization for long-term business development and achieving the goal of sustainable development, promotes risk-based thinking to plan and implement the processes of the quality management system so that to determine the extent of documented information. Moreover, risk-based thinking adopted by ISO 9001:2015 allows reducing regulatory requirements and replacing them with performance-based requirements, greater flexibility in process requirements, documented information, and organizational responsibilities.

ISO 9001:2015 contributes significantly to the production of high-quality products and/or services and, implicitly, to the increase of customer and business partners' satisfaction, of all those interested in this issue; allows the management of the company

to adopt a development strategy based on clear principles, relatively easy to implement (Olaru, 2004);

ISO 22000:2015 sets out the requirements for a food safety management system, being a combination of the ISO 9001 quality standard with the HACCP principles (SUN CERT, 2020b; HACCP.b). The food safety management system implemented and certified by the requirements of this standard means a commitment of the organization to implement the food hygiene system, as well as confidence in the company's ability to provide "safe" food (Condrea et al., 2015).

The implementation and certification of ISO 22000:2018 at the level of a company cause customers to have confidence in the quality and safety of the food and services provided by it. At the same time, this standard helps policymakers to improve risk management in food safety processes.

"ISO 22000:2018 provides dynamic control of food safety hazards, combining: interactive communication, systems management, prior programs (PRPs) and principles of risk analysis and critical control points (HACCP)" (ASRO, 2018).

EN ISO 14001:2015 specifies the requirements of an environmental management system for organizations wishing to establish, implement, maintain and continuously improve a way of working to manage its environmental responsibilities in a way that contributes to "the "environmental pillar" of sustainable development. The expected results of an environmental management system provide value to the environment, the organization, and stakeholders.

In the ISO 14001 standard, the notion of "continuous improvement" is defined as representing "the process of developing the environmental management system to obtain the improvement of the global performance in the field of environment, in accordance with the environmental policy of the organization".

"ISO 14001:2015 focuses on achieving the desired for *sustainable development* through the efficient use of natural resources, efficient waste management, attention to climate change, degradation of ecosystems, use of the product lifecycle concept" (SUN CERT, 2020c).

EN ISO 14000:2015 standards help organizations to improve their environmental performances and achieve their established environmental protection objectives (Enesco, 2016); facilitates established relationships between top management and stakeholders; contribute to the promotion of the organization among those who are concerned about ensuring the quality of life and the environment.

## Research methodology

The case studies presented in the next section are, in fact, a synthesis of data and information accumulated in the external audit process performed in organizations with certified management systems or the process of certification.

In the first part of the research, we identified some non-conformities with the requirements of the standard EN ISO 9001:2015, respectively EN ISO 22000:2018 and EN ISO 14001:2015, as well as the corrections and implicitly the corrective actions proposed by the management of the audited organizations. The intended results established for each category of corrections and corrective actions represent their interpretations regarding their contribution to improving the performance of the management systems.

To present the following as accurately as possible, we consider it necessary to reproduce some concepts as they are included in the reference standard EN ISO 9001:2015; as follows:

- non-compliance - failure to meet a requirement;
- correction - the action of eliminating a detected nonconformity;
- corrective action - action to eliminate the cause of non-compliance and prevent recurrence;
- continuous improvement - repeated activity to increase performance;
- performance - measurable result;
- management system - set of correlated or interacting elements of an organization through which policies and objectives are established, as well as the processes through which those objectives are achieved.

## Results of the research

We structured the results of our research in three directions, specific to the analyzed management systems, as follows:

### ***A. Quality management systems.***

#### ***Audited field of activity: restaurant***

Audited areas: food block, serving space

Inadequate situations found at the time of the audit:

1. The ceiling in the raw material storage area (refrigerator and freezer area) showed traces of infiltration.
2. The raw material elevator was not sanitized. Storage conditions for products with hygroscopic potential (flour, semolina, sugar, etc.) were not monitored.
3. The filter locker room does not have all smooth/washable surfaces and is not properly compartmentalized for separating work equipment and street clothes.
4. The vanilla and chocolate toppings were not kept under the specified conditions by the manufacturer ("after opening, store in the refrigerator").
5. The restaurant menu did not refer to the presence of allergens in food products.
6. Some thermometers used in the food block were not identified and it was not possible to prove the metrological verification of the metal rod thermometer used in the kitchen.

For the situations presented, the following *non-compliances* with the requirements of the standard EN ISO 9001:2015 (SR EN ISO 9001:2015) are identified and formulated:

*Requirement 7.1.3 - Infrastructure*

1. The ceiling in the raw material storage area (refrigerator and freezer area) does not meet the appropriate conditions to avoid physical contamination of the products.
2. The filter locker room does not have all smooth/washable surfaces and is not properly compartmentalized for separating work equipment and street clothes.

The improvement actions proposed by the audited organization are:

- *The correction:*

- a. Repairment of the ventilation system, the ceiling in the raw material area, and the locker room surfaces.
- b. Proper compartmentalization of the filter locker room to separate the work equipment from the street equipment.

- *Corrective actions:*

- a. Allocation of resources needed to carry out repairs and compartmentalization of the locker room.
- b. Training of the process manager with the requirements established by the organization to avoid physical contamination of the products and with the requirement 6.3 of the reference standard.

*Intended results:* The appropriate infrastructure will reduce the risk of physical and / or biological contamination of products, will ensure the level of quality and food safety of culinary products offered to consumers.

*Requirement 8.5.4 - Storage*

Some products used in the preparation process (vanilla topping and dessert sauce) were not kept, at the time of the audit, under the conditions specified by the manufacturer ("*after opening, stored in the refrigerator*").

The improvement actions proposed by the audited organization are:

- *Correction:* Store all products and ingredients according to the suppliers' specifications.

- *Corrective actions:* Training of production site personnel on storage conditions for products and raw materials according to product specifications.

*Intended results:* Proper storage of raw materials, products, and ingredients will reduce the risk of non-compliant products, will ensure production with optimized costs, will ensure the quality level of culinary products offered to consumers.

*Requirement 7.1.4 - Process operation environment*

1. No documented information shall be kept on monitoring the storage conditions of products with hygroscopic potential (flour, semolina, sugar, spices, etc.).
2. The cleaning and sanitation program does not refer also to the elevator for raw materials.

The improvement actions proposed by the audited organization are:

- *Correction:*

- a. Recording the monitored temperature and humidity in the storage area of the grocery products following the internal procedure.
- b. Revision of the cleaning and sanitation program to include the elevator of the raw materials.

- *Corrective actions:*

- a. Training of process managers with requirement 7.1.4 of the framework.
- b. Training of process managers on the registration of monitored parameters in the storage space of the grocery products following the internal procedure.

- c. Training of process managers with the revised cleaning and sanitation program and with the requirements for monitoring the performance of the planned works.

*Intended results:* The appropriate working environment will reduce the risk of physical and / or biological contamination of the products, will ensure the quality and food safety level of the culinary products offered to consumers.

*Requirements 8.2.1, 8.2.2 - Communication with the client; determining the requirements for products and services*

No clear way has been established to inform consumers about the presence of allergens in food products.

The improvement actions proposed by the audited organization are:

- *Correction:* Revising the menu to supplement with all the ingredients used in the preparation of each culinary product, including those with a potential allergen.
- *Corrective actions:* Training the process manager with requirements 8.2.1 and 8.2.2 of the reference standard.

*Intended results:* The correct information of consumers regarding the ingredients used in the preparation of culinary products, including allergens will increase the level of consumer satisfaction, but also the degree of safety in consumption.

*Requirement 7.1.5 - Monitoring and measurement resources*

Not all thermometers used are identified and evidence of the metrological verification of the metal rod thermometer used in the kitchen could not be found.

The improvement actions proposed by the audited organization are:

- *Correction:* All the R.M.Ms used will be properly identified, the stage of the metrological verifications will be proved.
- *Corrective actions:* Training of the process manager with the requirement 7.1.5 of the reference standard and with the applicable internal procedure.

*Intended results:* The use of appropriate measurement and monitoring resources will result in effective measurement or monitoring of the compliance of the products or services with the customer, legal, or other applicable regulatory requirements.

**B. Food safety management systems**

**I. Audited field of activity: bovines' slaughterhouse**

Audited area: production, cattle slaughter line

Inadequate situations found at the time of the audit:

1. A bird's nest was observed at the entrance to the slaughterhouse, in the personal access area.
2. At the entrance to the filter locker, the audit team was offered only protective robes.
3. The saw-knife and the carcasses resulting from evisceration have not been considered as sanitation sampling areas in the self-control program.
4. 14°C were recorded in the semi-carcass cooling/swindling space, above the maximum level set.
5. No records were found concerning the hygiene of the means of transport for finished products which are delivered to outlets.
6. No map of drinking water taps or safety records for insecticides and raticides used were available.

For the situations presented, the following *non-conformities* in reference to the EN ISO 22000:2018 (SR EN ISO 22000:2019) standard shall be identified and made:

*Requirement 8.2 – Preliminary Programs (PRP)*

1. Sufficient protection against pests (e.g. bird's nest in the personal access area) is not provided.
2. On the visit to the slaughterhouse, the visitors' equipment was not complete (lack of caps, suitable disposable footwear).
3. The location of drinking water taps is not documented.
4. Safety records for insecticides and raticides used in the disinfection, extermination, and de-ratification process are not available.

The improvement actions proposed by the audited organization are:

- *Correction:*

- a. Pest eradication in the food processing areas.
- b. Purchase and equipping visitors with full-use disposable protective equipment.
- c. Drawing up the map of the water taps.
- d. Procurement of safety records for insecticides and raticides used.

- *Corrective actions:*

- a. Allocating resources necessary for pest protection and the purchase and equipping of visitors with full-use single-use protective equipment.
- b. The training of the staff in charge of applying the "Pest Control" procedure.
- c. Training of the food safety Team Leader with measures to prevent cross-contamination and personal hygiene and with the requirements of 8.2.2 and 8.2.3 of the reference standard.
- d. Training of production personnel with safety records for insecticides and raticides used in the disinfection, extermination, and de-ratification process.

*Intended results:* Proper implementation of preliminary programs throughout the production process will reduce the risk of physical, chemical, and/or physiological contamination of products, food safety requirements.

*Requirement 8.5.4.2 – Determination of critical limits and action criteria*

Acceptable levels have not been established for all documented PRPOs for pig slaughter (e.g. knife/saw sterilization, carcass sanitation tests after evisceration).

The improvement actions proposed by the audited organization are:

- *Correction:* Documentation and completion of PRPO with acceptable levels.

- *Corrective actions:* Training the food safety team to document and supplement PRPOs with acceptable levels.

*Intended results:* The application of appropriate control measures prevents significant hazards to food safety, effective control of manufacturing processes or products

*Requirement 9.1.1; 9.1.2 – Monitoring, measurement, analysis, and evaluation*

At the time of the audit, the whole temperature in the semi-carcass cooling/swindling space exceeds the maximum set level of 10-12°C (14°C recorded).

The improvement actions proposed by the audited organization are:

- *Correction:* Correct electronic temperature setting in the semi-carcass cooling/swindling room.

- *Corrective actions:* Training of the staff responsible for setting and monitoring the correct temperature.

*Intended results:* The use of appropriate methods ensures that valid results are obtained from the measurement and monitoring process.

*Requirement 7.5.3.2 – Control of documented information*

Although the means of transport for the finished products are in the appropriate condition, documented information as evidence of the hygiene of the respective means of transport following the specific procedure was not available at the time of the audit.

The improvement actions proposed by the audited organization are:

- Correction: Completion and retention of the hygiene sheets following the specific internal procedure.
- Corrective actions:
  - a. Training drivers to keep evidence of the sanitation process of the means of transport.
  - b. Training of the staff responsible for verifying the storage of records.

*Intended results:* The recording and storage of appropriate documented information is evidence of the conformity of processes or products, as appropriate.

**II. Audited field of activity: collection of cow's milk and goat's milk**

Areas audited: milk production holdings located on farms, collection center

Inadequate situations found at the time of the audit:

1. The qualitative reception stage of the milk collected at the production holdings and the transport up to the collection center has been omitted when drawing up the flow chart, no hazards have been identified and acceptable limits have not been established for these two stages of the manufacturing process.
2. The food safety team did not check on the spot the accuracy of the flow chart.
3. No records of the qualitative reception stage carried out at the milk production holdings were found.
4. In the collection center, in the area of the storage tanks, the ceiling had cracks, the electrical panel in the storage space was slightly detached from the wall, and the flow meter preset was not in working order.
5. The sanitation plan did not include the activity of washing tanks and supplier machines with the WAP installation. Milk transfer hoses were kept on the pavement. The flykiller wasn't sanitized. The sanitization of the tanks had not been carried out through sanitation tests.
6. No analysis bulletins of the drinking water were available.

For the situations presented, the following non-conformities to the EN ISO 22000:2018 (SR EN ISO 22000:2019) standard shall be identified and made:

*Requirement 8.5.1.5.1 – Elaboration of flow charts*

The flow chart does not include the sequence and interaction of all stages, i.e. the qualitative reception of the milk in milk production holdings and transporting it to the collection center.

The improvement actions proposed by the audited organization are:

- *Correction:* Review of the flow chart so that it includes all stages, including the qualitative reception of the milk in milk production holdings and transporting it to the collection center.
- *Corrective actions:* Training of the food safety team staff with the requirement 8.5.1.5.1 of the reference standard.

*Intended results:* Adequate and complete flow charts provide an appropriate analysis of the risks to food safety hazards.



*Requirement 8.5.1.5.2 – On-the-spot confirmation of the flow charts*

The accuracy of the flow chart has not been verified on the spot.

The improvement actions proposed by the audited organization are:

- *Correction:* Check the accuracy of the flow chart on the spot.
- *Corrective actions:* Training the food safety team staff with requirement 8.5.1.5.2 of the reference standard.

*Intended results:* The accuracy of the flow diagrams confirmed on-site by the food safety team ensures the effectiveness of the food hazard assessment.

*Requirement 8.5.2.2–Identification of hazards and determination of acceptable levels*

No hazards have been identified and acceptable levels have not been established for the reception of the milk at milk production holdings and the transport up to the collection center.

The improvement actions proposed by the audited organization are:

- *Correction:* Identification of hazards and establishing acceptable levels for the qualitative reception of the milk at production holdings and transporting it to the collection center and the review corresponding to the risk analysis sheet.
- *Corrective actions:*
  - a. Training of the food safety team staff regarding the standard requirement 8.5.2.2.
  - b. Training of the staff involved in the processes of qualitative reception of the milk at production and transport holdings to the collection center with the revised risk analysis sheet and established control measures.

*Intended results:* The identification and documentation of all food safety hazards, for all stages of the manufacturing process, allows the effective hazard assessment and the establishment of appropriate control measures.

*Requirement 8.5.4.3 – Monitoring systems at the CCP level*

No documented information shall be kept as evidence of the qualitative reception of the milk on production holdings following the specific internal procedures.

The improvement actions proposed by the audited organization are:

- *Correction:* Completion and retention of records as evidence of the qualitative reception stage of the milk in the production holdings following specific internal procedures.
- *Corrective actions:*
  - a. Training of the food safety team staff with requirement 8.5.4.3 of the reference standard.
  - b. Training of the staff involved in the processes of qualitative milk reception on production holdings with the specific internal procedure applicable to the process of qualitative milk reception.

*Intended results:* The establishment and proper implementation of the method and frequency of monitoring critical control points ensures the immediate detection of any failure to meet critical limits to isolate and quickly assess the potentially unsafe product.

*Requirement 8.2 – Preliminary Programs (PRP)*

Washing of the tanks with the WAP installation was not properly documented and planned. Milk transfer hoses were kept inappropriately (on the pavement). The flykiller was unhygienic. No objective evidence was found demonstrating the effectiveness of the tank sanitation process or the quality of the drinking water.

The improvement actions proposed by the audited organization are:

- *Correction:*

- a. Review of the sanitation plan to introduce the tank washing phase with the WAP installation.
  - b. Making support for transfer hoses.
  - c. Hygiene of the flykiller according to the sanitization plan.
  - d. Compliance with the self-control program.
- *Corrective actions:* Training of the staff with requirement 8.2 of the reference standard and with specific internal procedures related to the preliminary programs.
- Intended results:* Proper implementation of preliminary programs throughout the production process will reduce the risk of physical, chemical and / or physiological contamination of products, food safety requirements.

### ***C. Environmental management systems***

#### ***Audited field of activity: processing of pork meat, distribution, and marketing of pork and pork preparations***

Areas audited: carmangery, butcher shop, retail shops

Inadequate situations found at the time of the audit:

1. The organization has not identified the environmental aspects resulted from the parking of authorized vans for the transport of meat products and the environmental aspects resulted from their sanitization process.
2. It was not possible to prove the washing and hygiene of the approved equipment for the transport of meat products.
3. The collection of animal waste not intended for human consumption is not carried out uniformly in all locations of the organization.
4. Although procedures have been established for the management of emergencies with an impact on food safety (interruption of electricity, fire), not all potential emergencies that may have an impact on the environment have been identified.
5. Wastewater quality monitoring shall not be carried out at the frequency set out in the environmental authorization.

For the situations presented, the following *non-conformities* to the EN ISO 9001:2015 (SR EN ISO 9001:2015) standard shall be identified and formulated:

#### ***Requirement 6.1.2 – Environmental aspects***

The identification and evaluation sheet for direct and indirect environmental aspects under normal, abnormal and emergency working conditions/01.10.2019 does not contain all the environmental aspects resulted from the work carried out, according to the field of activity and from the perspective of the life cycle (e.g. environmental aspects resulting from the parking/garage activity authorized for the transport of meat products and their sanitization process).

The improvement actions proposed by the audited organization are:

- *Correction:* Direct and indirect environmental aspects will be reassessed under normal, abnormal, and emergency working conditions from a life-cycle perspective, including for the meat transport process.
- *Corrective actions:* Training of the process manager in regard to requirement 6.1.2 of the reference standard; awareness of the organization's staff with the environmental aspects and environmental impacts re-evaluated.

*Intended results:* The identification of all environmental aspects resulting from the company's activities ensures the establishment of adequate operational control

measures to eliminate, reduce or control the impact of those activities on the environment, which improves the quality of the environment.

*Requirement 8.1 – Operational control*

1. It has not been possible to demonstrate the application of operational control for certain processes carried out in the organization (washing and sanitization of the vans authorized for the transport of meat products).
2. A defined method for the collection of animal waste not intended for human consumption has not been established.

The improvement actions proposed by the audited organization are:

- *Correction:*

- a. Application of operational control for all processes carried out in the organization, including sanitization of the vans authorized for the transport of meat products.
- b. Review specific working instructions and defining of a procedural method for the collection of animal waste generated by the organization.

- *Corrective actions:* Training the staff of the organization involved in carrying out the operational control with requirement 8.1 of the reference standard and with the need to maintain all documented operational control information following internal procedures.

*Intended results:* Carrying out effective operational control determines the control of the environmental aspects with significant impact generated by the organization.

*Requirement 8.2 – Emergency preparedness and response capacity*

No procedures have been established for the management of all emergencies and potential accidents that may have an impact on the environment (e.g. earthquake).

The improvement actions proposed by the audited organization are:

- *Correction:* Establishing and implementing procedures for managing all emergencies that may have an impact on the environment, including earthquakes.

- *Corrective actions:*

- a. Training the process manager with requirement 8.2 of the reference standard;
- b. Training of the staff in the organization with all procedures for emergency management, including for an earthquake;
- c. Periodic testing of the elaborated emergency plans, including earthquakes.

*Intended results:* The management of all emergencies that may have an impact on the environment prevents or mitigates the consequences of an emergency.

*Requirement 9.1.1 - Monitoring, measurement, analysis, and evaluation; generalities*

The frequency of monitoring the quality of wastewater is not always observed.

The improvement actions proposed by the audited organization are:

- *Correction:* Timely transmission of orders for sampling to determine wastewater quality.

- *Corrective actions:* Training the process manager with the requirement 9.1.1 of the reference standard and with the monitoring chapter of the environmental permit of the organization.

*Intended results:* Compliance with the parameter monitoring frequency ensures that valid results are obtained from the measurement and monitoring process and following regulatory requirements.

## Conclusions

Through the elimination of unwanted effects, as well as their causes, the corrective actions make up viable continuous improvement instruments for management systems, to improve the organization's general performance, and, implicitly, fulfilling the circular and sustainable bioeconomy desiderate.

The intended results, identified for each implemented correction/corrective action contribute to achieving the intended general results, declared in the standards specific for each management system, namely:

- ✓ For the quality management system, in conformity with EN IS 9001:2015:
  - a. Consistent provision of products or services that meet applicable customer requirements, legal and regulated;
  - b. Increasing customer satisfaction through the effective application of SMC;
  - c. Ensuring compliance with customer requirements, legal and regulated.
- ✓ For the food safety management system, in conformity with EN ISO 22000:2018:
  - a. Consistent provision of safe food and products and services that meet applicable customer, legal and regulatory requirements;
  - b. Taking into account the risks and opportunities associated with its context and objectives;
  - c. Ensuring compliance with the specified requirements of the SMSA.
- ✓ For the environmental management system, in conformity with EN IS 14001:2015:
  - a. Increase environmental performance;
  - b. Fulfillment of compliance obligations;
  - c. Achieving environmental objectives.

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