



Food Regulatory Affairs Manager

QP Code: FIC/Q9002

Version: 1.0

NSQF Level: 6

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Qualification Pack

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FIC/Q9002: Food Regulatory Affairs Manager

Brief Job Description

A Food Regulatory Affairs Manager is responsible for designing, developing, implementing and changing food regulatory systems in the organisation. S/he acts as a liaison between organisation and government regulatory agencies and authorities to ensure that the products produced and distributed comply with regulatory standards.

Personal Attributes

A Food Regulatory Affairs Manager must have the ability to read, write, communicate, mathematical ability to calculate, organizational & analytical skills, ability to plan, organize and prioritize, concentration, physical stamina, handling pressure, team work, mechanical aptitude and trouble shooting skills, understanding on food safety standards and requirements, personal and professional hygiene.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. [FIC/N9011: Design, develop and implement regulatory system](#)
2. [FIC/N9012: Manage change in food regulatory system](#)
3. [FIC/N9013: Prepare representations to regulatory authorities and for new product registrations](#)

Qualification Pack (QP) Parameters

Sector	Food Processing
Sub-Sector	Fruits and Vegetables, Food Grain Milling, Dairy Products, Meat and Poultry, Fish and Sea Food, Bread and Bakery, Alcoholic Beverages, Aerated Water/Soft Drinks, Soya Food, Packaged Foods
Occupation	Quality Assurance
Country	India
NSQF Level	6
Aligned to NCO/ISCO/ISIC Code	NCO-2004/NIL

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Minimum Educational Qualification & Experience	Post Graduate (Food Technology/Food Science (Preferably)) with 5-10 Years of experience Minimum 8 years experience in a food processing unit in a food regulatory role
Minimum Level of Education for Training in School	
Pre-Requisite License or Training	1. Food Safety Standards and Regulations (as per FSSAI)2. Total Quality Management3. Occupational Health & Safety Advisory Services4. Environmental Management System
Minimum Job Entry Age	30 Years
Last Reviewed On	03/08/2021
Next Review Date	31/03/2022
Deactivation Date	31/03/2022
NSQC Approval Date	03/08/2018
Version	1.0
Reference code on NQR	2018/FI/FICSI/02465
NQR Version	1.0

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FIC/N9011: Design, develop and implement regulatory system

Description

This OS unit is about designing, developing and implementing regulatory systems in food processing units to ensure product compliance to national and international food regulatory system.

Scope

This unit/task covers the following:

Elements and Performance Criteria

Design and develop regulatory system for the organisation (for food products produced)

To be competent, the user/individual on the job must be able to:

- PC1.** understand food safety regulations and develop regulatory policies for the organisation with clear definitions to increase consistency, legal security and to provide high level of food safety
- PC2.** design regulatory system with focus on risk reduction, risk-based priorities, reflect integrated and economically feasible initiatives, and ensure high quality and transparency
- PC3.** design and develop regulatory system with intuitive approach to food safety such that problem are recognized, understood, dealt, and checked to ensure problem has been dealt efficiently and effectively
- PC4.** design regulatory system with contingency planning like product traceability and product recall in case of problems, procedures for handling containment, with clear attribution of roles like lines of authority and co-ordination mechanism across food chain (from procuring raw materials, production until product reaching consumers)
- PC5.** design regulatory system with improved communication on food safety information in marketing materials, product labels etc, providing science based information to clear up the unjustified fear among consumers
- PC6.** set food safety system involving food producers, processors, distributors, retailers and consumers to recognize their primary responsibility and to share a common goal of ensuring food safety at all stages
- PC7.** design food regulatory system involving GMP, GHP, and monitoring systems like HACCP
- PC8.** design regulatory system that improve efficiency and compliance, build consumer confidence in the safety and quality of food products produced, processed, marketed, distributed and sold
- PC9.** design and develop regulatory system ensuring food and health standards are followed in each stage of production and produce food products that meet national and international regulatory standards and protect the health of consumers
- PC10.** design regulatory system including provisions for the right of consumers to have access to accurate and sufficient information and make adequate choices
- PC11.** provide strategic advice and cost effective strategies on regulatory aspects/requirements to senior management and project managing teams throughout the development of a new product

Develop, monitor and audit regulatory system in the organisation (for food products produced)

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To be competent, the user/individual on the job must be able to:

- PC12.** interpret regulatory standards and develop organisation standards meeting national and international food safety regulations like fssai, fda, eu food safety regulations, codex alimentarius etc for products produced, exported and imported, and labels of products packed by the organisation
- PC13.** develop and review standard operating procedures (sops) and ensure that they are in compliance with current regulatory requirements and provide regulatory support for corporate quality assurance efforts
- PC14.** develop organisation standards for labels of food products produced and packed, promotional marketing materials, products imported and exported by the organisation to meet national and international food regulatory
- PC15.** evaluate labels of packed food products to ensure it meets national and international food regulatory standards and provide approval or recommend changes
- PC16.** evaluate promotional and materials for regulatory impact and provide approval
- PC17.** provide support for review of essential documents, development and review of consent forms for submission to regulatory authorities for clearance
- PC18.** initiate and contribute to process improvements which have an impact on regulatory affairs, quality assurance and other departments
- PC19.** conduct audits on food processing unit for compliance with regulatory, safety and hygiene standards implemented and followed in the organisation
- PC20.** conduct periodic audits to evaluate haccp plans and their implementation in the organisation and ensure it meets the regulatory standards
- PC21.** review internal and external audit reports to check the effectiveness of the present regulatory system and recommend necessary changes in the policies and procedures to reduce failures in the future
- PC22.** identify reason for consumer cases in court related to non-compliance of food products to regulatory standards, collect relevant informations and documents transmitting evidence to produce in court to assist prosecution
- PC23.** monitor company progress toward fulfillment of regulatory commitments

Provide training on regulatory system (for food products produced)

To be competent, the user/individual on the job must be able to:

- PC24.** provide training to department managers on organisation policies on food and safety regulations, national and international food laws and regulations, methods and procedures for implementing regulations for procuring raw materials, producing food products, marketing and selling quality products to the consumers
- PC25.** provide training to all department managers on the importance of food regulatory standards and need for its compliance, statutory and regulatory requirements for the products produced, labels of packed products and promotional materials, and the consequences for not following the regulatory requirements
- PC26.** provide training on procedures for collecting evidence in case of problems/consumer complaints/consumer cases in court and handling them with technical and scientific approach
- PC27.** provide training to all department managers on methods to implement and monitor regulatory system in their area of function, writing reports with relevant information and data to present to local food regulatory authorities for any concerns raised / clarification required, methods to approach and maintain relationship with food regulatory authorities

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- PC28.** provide training on upgradation and changes in the food regulatory system and methods to implement, monitor and achieve them

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** principles and processes of organization
- KU2.** organisaiton goals and policies
- KU3.** business processes of the organisation
- KU4.** food regualtory system related to the process and products produced in the organisation
- KU5.** policies and proecdures for designing regulatory system for the organisaiton
- KU6.** training system in the organisation for implenting food regulatory system
- KU7.** research and project management techniques
- KU8.** code of business conduct
- KU9.** risk and information management
- KU10.** national and international legal and regulatory systems like FSSAI, FDA, CODEX alimentarius, EU food safety regulations etc, and GMP, GHP, HACCP, OHSAS etc
- KU11.** policies and procedures to be followed to meet the national and international regulatory requirements like GMP, GHP, HACCP etc
- KU12.** relevant legal requirements related to the products produced in the organisation
- KU13.** food microbiology and its standards and regulations for products produced in the organisation
- KU14.** current and emerging regulatory concerns and expectations on the organisation
- KU15.** methods to deal with current and emerging social concerns and expectations
- KU16.** processes for maintaining relevant policies and procedures and methods to ensure sustainability and effectiveness
- KU17.** methods to meet the consequence due to failure in policies and procedures and methods to review and take corrective action on people and policies
- KU18.** reporting and reviewing system to understand the effectiveness of the regulatory system implemented

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** note the information communicated
- GS2.** note the raw materials used for production and the finished products produced
- GS3.** note the readings of the process parameters and provide necessary information to fill the process chart
- GS4.** note down observations (if any) related to the process
- GS5.** write information documents to internal departments/ internal teams
- GS6.** note down the data for online ERP or as per applicability in the organization

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- GS7.** read and interpret the process required for producing various types of products
- GS8.** read and interpret and process flowchart for all products produced
- GS9.** read equipment manuals and process documents to understand the equipments operation and process requirement
- GS10.** read internal information documents sent by internal teams
- GS11.** discuss task lists, schedules and activities
- GS12.** effectively communicate with team members
- GS13.** question in order to understand the nature of the problem and to clarify queries
- GS14.** attentively listen and comprehend the information given by the speaker
- GS15.** communicate clearly on the issues being faced
- GS16.** analyse critical points in day to day tasks through experience and observation and identify control measures to solve the issue
- GS17.** handle issues in case the manager is not available (as per the authority matrix defined by the organization)
- GS18.** plan and organize the work order and jobs received
- GS19.** organize raw materials and packaging materials required for all products
- GS20.** plan and prioritize the work based on the instructions received
- GS21.** plan to utilise time and equipment's effectively
- GS22.** organize all process/ equipment manuals so as to access information easily
- GS23.** support the manager in scheduling tasks for helper(s)
- GS24.** understand customer requirements and their priority and respond as per their needs
- GS25.** support manager in solving problems by detailing out problems
- GS26.** discuss the possible solutions with the manager for problem solving
- GS27.** apply domain information about maintenance processes and technical knowledge about tools and equipment
- GS28.** use common sense and make judgments on day to day basis
- GS29.** use reasoning skills to identify and resolve basic problems
- GS30.** use intuition to detect any potential problems which could arise during operations
- GS31.** use acquired knowledge of the process for identifying and handling issues

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Design and develop regulatory system for the organisation (for food products produced)</i>	16.5	27.5	-	-
PC1. understand food safety regulations and develop regulatory policies for the organisation with clear definitions to increase consistency, legal security and to provide high level of food safety	1.5	2.5	-	-
PC2. design regulatory system with focus on risk reduction, risk-based priorities, reflect integrated and economically feasible initiatives, and ensure high quality and transparency	1.5	2.5	-	-
PC3. design and develop regulatory system with intuitive approach to food safety such that problem are recognized, understood, dealt, and checked to ensure problem has been dealt efficiently and effectively	1.5	2.5	-	-
PC4. design regulatory system with contingency planning like product traceability and product recall in case of problems, procedures for handling containment, with clear attribution of roles like lines of authority and co-ordination mechanism across food chain (from procuring raw materials, production until product reaching consumers)	1.5	2.5	-	-
PC5. design regulatory system with improved communication on food safety information in marketing materials, product labels etc, providing science based information to clear up the unjustified fear among consumers	1.5	2.5	-	-
PC6. set food safety system involving food producers, processors, distributors, retailers and consumers to recognize their primary responsibility and to share a common goal of ensuring food safety at all stages	1.5	2.5	-	-
PC7. design food regulatory system involving GMP, GHP, and monitoring systems like HACCP	1.5	2.5	-	-
PC8. design regulatory system that improve efficiency and compliance, build consumer confidence in the safety and quality of food products produced, processed, marketed, distributed and sold	1.5	2.5	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC9. design and develop regulatory system ensuring food and health standards are followed in each stage of production and produce food products that meet national and international regulatory standards and protect the health of consumers	1.5	2.5	-	-
PC10. design regulatory system including provisions for the right of consumers to have access to accurate and sufficient information and make adequate choices	1.5	2.5	-	-
PC11. provide strategic advice and cost effective strategies on regulatory aspects/requirements to senior management and project managing teams throughout the development of a new product	1.5	2.5	-	-
<i>Develop, monitor and audit regulatory system in the organisation (for food products produced)</i>	13.5	27.5	-	-
PC12. interpret regulatory standards and develop organisation standards meeting national and international food safety regulations like fssai, fda, eu food safety regulations, codex alimentarius etc for products produced, exported and imported, and labels of products packed by the organisation	1.5	2.5	-	-
PC13. develop and review standard operating procedures (sops) and ensure that they are in compliance with current regulatory requirements and provide regulatory support for corporate quality assurance efforts	1.5	2.5	-	-
PC14. develop organisation standards for labels of food products produced and packed, promotional marketing materials, products imported and exported by the organisation to meet national and international food regulatory	1.5	2.5	-	-
PC15. evaluate labels of packed food products to ensure it meets national and international food regulatory standards and provide approval or recommend changes	1	3	-	-
PC16. evaluate promotional and materials for regulatory impact and provide approval	1	3	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC17. provide support for review of essential documents, development and review of consent forms for submission to regulatory authorities for clearance	1	2	-	-
PC18. initiate and contribute to process improvements which have an impact on regulatory affairs, quality assurance and other departments	1	2	-	-
PC19. conduct audits on food processing unit for compliance with regulatory, safety and hygiene standards implemented and followed in the organisation	1	2	-	-
PC20. conduct periodic audits to evaluate haccp plans and their implementation in the organisation and ensure it meets the regulatory standards	1	2	-	-
PC21. review internal and external audit reports to check the effectiveness of the present regulatory system and recommend necessary changes in the policies and procedures to reduce failures in the future	1	2	-	-
PC22. identify reason for consumer cases in court related to non-compliance of food products to regulatory standards, collect relevant informations and documents transmitting evidence to produce in court to assist prosecution	1	2	-	-
PC23. monitor company progress toward fulfillment of regulatory commitments	1	2	-	-
<i>Provide training on regulatory system (for food products produced)</i>	5	10	-	-
PC24. provide training to department managers on organisation policies on food and safety regulations, national and international food laws and regulations, methods and procedures for implementing regulations for procuring raw materials, producing food products, marketing and selling quality products to the consumers	1	2	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC25. provide training to all department managers on the importance of food regulatory standards and need for its compliance, statutory and regulatory requirements for the products produced, labels of packed products and promotional materials, and the consequences for not following the regulatory requirements	1	2	-	-
PC26. provide training on procedures for collecting evidence in case of problems/consumer complaints/consumer cases in court and handling them with technical and scientific approach	1	2	-	-
PC27. provide training to all department managers on methods to implement and monitor regulatory system in their area of function, writing reports with relevant information and data to present to local food regulatory authorities for any concerns raised / clarification required, methods to approach and maintain relationship with food regulatory authorities	1	2	-	-
PC28. provide training on upgradation and changes in the food regulatory system and methods to implement, monitor and achieve them	1	2	-	-
NOS Total	35	65	-	-

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National Occupational Standards (NOS) Parameters

NOS Code	FIC/N9011
NOS Name	Design, develop and implement regulatory system
Sector	Food Processing
Sub-Sector	Fruits and Vegetables, Food Grain Milling, Dairy Products, Meat and Poultry, Fish and Sea Food, Bread and Bakery, Alcoholic Beverages, Aerated Water/Soft Drinks, Soya Food, Packaged Foods
Occupation	Quality Assurance
NSQF Level	6
Credits	TBD
Version	1.0
Last Reviewed Date	03/08/2021
Next Review Date	31/03/2022
Deactivation Date	31/03/2022
NSQC Clearance Date	03/08/2018

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FIC/N9012: Manage change in food regulatory system

Description

This OS unit is about managing change in regulatory system in food processing unit to ensure product compliance to national and international food regulatory system.

Scope

This unit/task covers the following:

- Plan change in regulatory system (for food products produced)
- Lead to implement changes in regulatory system (for food products produced)
- Monitor changes implemented in regulatory system (for food products produced)

Elements and Performance Criteria

Plan change in regulatory system (for food products produced)

To be competent, the user/individual on the job must be able to:

- PC1.** identify procedures, systems, structures that need to be changed for effective implementation of food regulatory system
- PC2.** assess gaps in the current policies and procedures and analyze the future requirements
- PC3.** identify and assess barriers to change in regulatory system, develop strategies and plans to overcome those barriers
- PC4.** assess risks and benefits associated with the strategies and plans, and develop contingency arrangements
- PC5.** design new work processes, procedures, systems, structures and roles to achieve planned changes in regulatory system
- PC6.** ensure plan for change in regulatory system include short-term as well as longer-term deliverables
- PC7.** develop system for monitoring and assessing regulatory system to assess progress in changes implemented
- PC8.** develop reporting and communicating system to review the effectiveness of the changes in regulatory system and to obtain feedback
- PC9.** provide training and support to implement changes planned in regulatory system

Lead to implement changes in regulatory system (for food products produced)

To be competent, the user/individual on the job must be able to:

- PC10.** communicate reasons, importance and benefits of implementing change in regulatory system, future that can be achieved through implementing and following the change, to management and concerned employees
- PC11.** make the management and employees welcome change in regulatory system as an opportunity to deliver products of national and international quality
- PC12.** make the management and employees understand the need and importance for change in regulatory system, result expected out of change and its effect on the organisation
- PC13.** implement the strategies and plans for change in regulatory system with available resources

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- PC14.** make the managers responsible for implementing change in regulatory system understand their responsibilities and commitment, and use their influence and power over employees to implement change
- PC15.** set and prioritize objectives for the change in regulatory system, identify and deal with obstacles to change, and support employees through the change process
- PC16.** communicate progress achieved through change in regulatory system to everyone involved, and make them understand and enjoy achievement

Monitor changes implemented in regulatory system (for food products produced)

To be competent, the user/individual on the job must be able to:

- PC17.** review reports on total quality management system to evaluate effectiveness of changes implemented in regulatory system of the organisation
- PC18.** organize internal and external audit on total quality management system to evaluate effectiveness of the changes implemented in regulatory system
- PC19.** monitor changes implemented in regulatory system, document and communicate the outcome of implemented change to the management
- PC20.** recognize and reward employees and teams for implementing regulatory system and achieving results through new policies and procedures
- PC21.** monitor and ensure changes implemented in regulatory system are effective and meet the requirements of the organisation and regulatory system laid by national and international regulatory bodies

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** organisation goals and policies
- KU2.** organisation vision for future
- KU3.** food regulatory system related to the process and products produced in the organisation
- KU4.** critical activities related to food regulatory system of the organisation
- KU5.** strategy, policies, procedures and standards that need to be changed
- KU6.** national and international legal and regulatory requirements related to the products produced in the organisation like FSSAI, FDA, CODEX alimentarius, EU food safety regulations etc
- KU7.** current and emerging political, economic, social, technological,
- KU8.** current and emerging political, economic, social, technological, environmental and legal developments and their effect on the food regulatory system
- KU9.** methods to analyze strengths and weaknesses of the system for planning changes
- KU10.** methods for making and managing change effectively
- KU11.** analyzing strategy, procedures, policies and structure that need to be changed
- KU12.** reason for implementing changes, risks and benefits expected out of changes planned and implemented
- KU13.** methods to assess the benefits and risks associated with strategies and plans
- KU14.** methods to influence change process in the management
- KU15.** analyzing employees knowledge, skill and attitude to implement change

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KU16. culture of the organization and its implication to change process

KU17. methods and procedures to monitor change

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. note the information communicated

GS2. note the raw materials used for production and the finished products produced

GS3. note the readings of the process parameters and provide necessary information to fill the process chart

GS4. note down observations (if any) related to the process

GS5. write information documents to internal departments/ internal teams

GS6. note down the data for online ERP or as per applicability in the organization

GS7. read and interpret the process required for producing various types of products

GS8. read and interpret and process flowchart for all products produced

GS9. read equipment manuals and process documents to understand the equipments operation and process requirement

GS10. read internal information documents sent by internal teams

GS11. discuss task lists, schedules and activities

GS12. effectively communicate with team members

GS13. question in order to understand the nature of the problem and to clarify queries

GS14. attentively listen and comprehend the information given by the speaker

GS15. communicate clearly on the issues being faced

GS16. analyse critical points in day to day tasks through experience and observation and identify control measures to solve the issue

GS17. handle issues in case the manager is not available (as per the authority matrix defined by the organization)

GS18. plan and organize the work order and jobs received

GS19. organize raw materials and packaging materials required for all products

GS20. plan and prioritize the work based on the instructions received

GS21. plan to utilise time and equipment's effectively

GS22. organize all process/ equipment manuals so as to access information easily

GS23. support the manager in scheduling tasks for helper(s)

GS24. understand customer requirements and their priority and respond as per their needs

GS25. support manager in solving problems by detailing out problems

GS26. discuss the possible solutions with the manager for problem solving

GS27. apply domain information about maintenance processes and technical knowledge about tools and equipment

GS28. use common sense and make judgments on day to day basis

GS29. use reasoning skills to identify and resolve basic problems

GS30. use intuition to detect any potential problems which could arise during operations



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GS31. use acquired knowledge of the process for identifying and handling issues

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Plan change in regulatory system (for food products produced)</i>	12.5	30.5	-	-
PC1. identify procedures, systems, structures that need to be changed for effective implementation of food regulatory system	1	4	-	-
PC2. assess gaps in the current policies and procedures and analyze the future requirements	1	4	-	-
PC3. identify and assess barriers to change in regulatory system, develop strategies and plans to overcome those barriers	1	4	-	-
PC4. assess risks and benefits associated with the strategies and plans, and develop contingency arrangements	1	4	-	-
PC5. design new work processes, procedures, systems, structures and roles to achieve planned changes in regulatory system	1	4	-	-
PC6. ensure plan for change in regulatory system include short-term as well as longer-term deliverables	1.5	2.5	-	-
PC7. develop system for monitoring and assessing regulatory system to assess progress in changes implemented	2	3	-	-
PC8. develop reporting and communicating system to review the effectiveness of the changes in regulatory system and to obtain feedback	2	3	-	-
PC9. provide training and support to implement changes planned in regulatory system	2	2	-	-
<i>Lead to implement changes in regulatory system (for food products produced)</i>	13	20	-	-
PC10. communicate reasons, importance and benefits of implementing change in regulatory system, future that can be achieved through implementing and following the change, to management and concerned employees	2	3	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. make the management and employees welcome change in regulatory system as an opportunity to deliver products of national and international quality	1.5	2.5	-	-
PC12. make the management and employees understand the need and importance for change in regulatory system, result expected out of change and its effect on the organisation	2	3	-	-
PC13. implement the strategies and plans for change in regulatory system with available resources	2	3	-	-
PC14. make the managers responsible for implementing change in regulatory system understand their responsibilities and commitment, and use their influence and power over employees to implement change	2	3	-	-
PC15. set and prioritize objectives for the change in regulatory system, identify and deal with obstacles to change, and support employees through the change process	2	3	-	-
PC16. communicate progress achieved through change in regulatory system to everyone involved, and make them understand and enjoy achievement	1.5	2.5	-	-
<i>Monitor changes implemented in regulatory system (for food products produced)</i>	9.5	14.5	-	-
PC17. review reports on total quality management system to evaluate effectiveness of changes implemented in regulatory system of the organisation	2	3	-	-
PC18. organize internal and external audit on total quality management system to evaluate effectiveness of the changes implemented in regulatory system	2	3	-	-
PC19. monitor changes implemented in regulatory system, document and communicate the outcome of implemented change to the management	2	3	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC20. recognize and reward employees and teams for implementing regulatory system and achieving results through new policies and procedures	1.5	2.5	-	-
PC21. monitor and ensure changes implemented in regulatory system are effective and meet the requirements of the organisation and regulatory system laid by national and international regulatory bodies	2	3	-	-
NOS Total	35	65	-	-

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National Occupational Standards (NOS) Parameters

NOS Code	FIC/N9012
NOS Name	Manage change in food regulatory system
Sector	Food Processing
Sub-Sector	Fruits and Vegetables, Food Grain Milling, Dairy Products, Meat and Poultry, Fish and Sea Food, Bread and Bakery, Alcoholic Beverages, Aerated Water/Soft Drinks, Soya Food, Packaged Foods
Occupation	Quality Assurance
NSQF Level	6
Credits	TBD
Version	1.0
Last Reviewed Date	03/08/2021
Next Review Date	31/03/2022
Deactivation Date	31/03/2022
NSQC Clearance Date	03/08/2018

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FIC/N9013: Prepare representations to regulatory authorities and for new product registrations

Description

This OS unit is about preparing representations to regulatory authorities on existing food products and for new product registrations, liaison with food regulatory authorities, industrial and trade associations

Scope

This unit/task covers the following:

Elements and Performance Criteria

Prepare representation documents to regulatory authorities (for food products produced)

To be competent, the user/individual on the job must be able to:

- PC1.** prepare simple and complex regulatory documents in accordance with applicable FSSAI regulations by collecting, collating and evaluating scientific data that has been well researched on relevant aspects
- PC2.** review regulatory guidance and requirements pertaining to products produced in the organisation and prepare documents providing thoughtful and accurate comments
- PC3.** prepare regulatory documents to authorities that translate regulatory requirements into practical, workable plans with timelines for development and implementation
- PC4.** coordinate with food regulatory authorities to review disputed matters, negotiation and finalization on products and projects, and for comments and formal approvals
- PC5.** prepare documents that include check lists created and maintained to implement regulatory requirements, technical data, and declarations of conformity
- PC6.** interface with consultants, research organizations, partners, comanufacturers etc for preparation, review, compilation, finalization and submission of documents for regulatory approvals
- PC7.** prepare responses to communications and other requests from government food regulatory authorities
- PC8.** prepare safety reports and documents on raw materials, ingredients, additives, flavours etc used in the products produced and marketed by the organisation, for regulatory submissions and clearance
- PC9.** identify reasons related to non-compliance of food products to regulatory standards, collect relevant informations and data, prepare technical documents with scientific facts and supporting evidence, and submit to relevant authorities, respond to communications from government authorities, and follow up regularly to revoke product ban

Liaise with regulatory authorities (for food products produced)

To be competent, the user/individual on the job must be able to:

- PC10.** interact with various regulatory authorities during concept, development and industrialization stages of projects for clarification and approvals
- PC11.** interact with the notified bodies and competent authorities for developing and reviewing regulatory standards

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- PC12.** coordinate with regulatory authorities for reporting, to comment on proposed regulations, and to represent company's interest in the development of standards and guidelines
- PC13.** discuss on the differences that exist in the regulations laid down by different governments and their interpretation by the regulatory agencies and ensure that efficient and economical regulatory standards are planned
- PC14.** identify possible threats or opportunities from upcoming regulations under fssai, consumer affairs, other government food policies and regulations and liaise with industry associations to tackle/manage them effectively
- PC15.** participate in seminar, workshops, conferences and meetings organised by fssai and other industry association, representing the organisation to maintain, strengthen and expand contacts
- PC16.** work closely with regulatory and trade associations like cii (confederation of indian industries), ficci (federation of indian chambers of commerce and industries), cifti (confederation of indian food trade and industry), aifpa (all india food processors association), assocham (the associated chambers of commerce of india) etc on national and international regulatory changes and challenges that have impact on food products produced in the organisation and to manage them proactively

New product registrations (for food products produced)

To be competent, the user/individual on the job must be able to:

- PC17.** develop and write clear arguments and explanations for new product license
- PC18.** prepare and present registration documents to regulatory authorities and notified bodies for new product approvals
- PC19.** present written representation for new products and carry out negotiations with regulatory authorities to obtain necessary approvals for new product production and marketing
- PC20.** evaluate, prepare and submit new product registration applications and follow through the application during the evaluation phase to achieve favorable outcome
- PC21.** prepare responses to letter/e-mail communications and other requests from government food regulatory bodies on new product approval
- PC22.** provide regulatory and product compliance report in the area of advertising and label claims for new products

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** food regulatory system related to the process and products produced in the organisation
- KU2.** government food regulatory authorities and other regulatory bodies
- KU3.** national and international relationship maintenance strategy with food regulatory authorities
- KU4.** formal procedures for handling legal and food regulatory requirements of the organisation
- KU5.** Government food regulatory authorities and other regulatory bodies
- KU6.** policies and procedures to be followed to meet the national and international regulatory requirements like GMP, GHP, HACCP, OHSAS etc
- KU7.** relevant legal requirements related to the products produced in the organisation
- KU8.** food microbiology and its standards and regulations for products produced in the organisation

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- KU9.** methods and procedures to prepare regulatory documents
- KU10.** various government regulatory authorities and other relevant bodies handling food safety regulations
- KU11.** various trade associations and procedures to obtain membership
- KU12.** formal procedures to approach and liaise with government regulatory authorities and other relevant bodies
- KU13.** methods to evaluate and collect types and source of information required for resolving food regulatory issues
- KU14.** legal communications and methods and procedures to respond to them
- KU15.** procedures that apply for participating in meetings organized by regulatory authorities and trade associations

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** note the information communicated
- GS2.** note the raw materials used for production and the finished products produced
- GS3.** note the readings of the process parameters and provide necessary information to fill the process chart
- GS4.** note down observations (if any) related to the process
- GS5.** write information documents to internal departments/ internal teams
- GS6.** note down the data for online ERP or as per applicability in the organization
- GS7.** read and interpret the process required for producing various types of products
- GS8.** read and interpret and process flowchart for all products produced
- GS9.** read equipment manuals and process documents to understand the equipments operation and process requirement
- GS10.** read internal information documents sent by internal teams
- GS11.** discuss task lists, schedules and activities
- GS12.** effectively communicate with team members
- GS13.** question in order to understand the nature of the problem and to clarify queries
- GS14.** attentively listen and comprehend the information given by the speaker
- GS15.** communicate clearly on the issues being faced
- GS16.** analyse critical points in day to day tasks through experience and observation and identify control measures to solve the issue
- GS17.** handle issues in case the manager is not available (as per the authority matrix defined by the organization)
- GS18.** plan and organize the work order and jobs received
- GS19.** organize raw materials and packaging materials required for all products
- GS20.** plan and prioritize the work based on the instructions received
- GS21.** plan to utilise time and equipment's effectively
- GS22.** organize all process/ equipment manuals so as to access information easily

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- GS23.** support the manager in scheduling tasks for helper(s)
- GS24.** understand customer requirements and their priority and respond as per their needs
- GS25.** support manager in solving problems by detailing out problems
- GS26.** discuss the possible solutions with the manager for problem solving
- GS27.** apply domain information about maintenance processes and technical knowledge about tools and equipment
- GS28.** use common sense and make judgments on day to day basis
- GS29.** use reasoning skills to identify and resolve basic problems
- GS30.** use intuition to detect any potential problems which could arise during operations
- GS31.** use acquired knowledge of the process for identifying and handling issues

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Prepare representation documents to regulatory authorities (for food products produced)</i>	11.5	28.5	-	-
PC1. prepare simple and complex regulatory documents in accordance with applicable FSSAI regulations by collecting, collating and evaluating scientific data that has been well researched on relevant aspects	1	4	-	-
PC2. review regulatory guidance and requirements pertaining to products produced in the organisation and prepare documents providing thoughtful and accurate comments	1	4	-	-
PC3. prepare regulatory documents to authorities that translate regulatory requirements into practical, workable plans with timelines for development and implementation	1	4	-	-
PC4. coordinate with food regulatory authorities to review disputed matters, negotiation and finalization on products and projects, and for comments and formal approvals	1	4	-	-
PC5. prepare documents that include check lists created and maintained to implement regulatory requirements, technical data, and declarations of conformity	1.5	2.5	-	-
PC6. interface with consultants, research organizations, partners, comanufacturers etc for preparation, review, compilation, finalization and submission of documents for regulatory approvals	1.5	2.5	-	-
PC7. prepare responses to communications and other requests from government food regulatory authorities	1.5	2.5	-	-
PC8. prepare safety reports and documents on raw materials, ingredients, additives, flavours etc used in the products produced and marketed by the organisation, for regulatory submissions and clearance	1.5	2.5	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC9. identify reasons related to non-compliance of food products to regulatory standards, collect relevant informations and data, prepare technical documents with scientific facts and supporting evidence, and submit to relevant authorities, respond to communications from government authorities, and follow up regularly to revoke product ban	1.5	2.5	-	-
<i>Liaise with regulatory authorities (for food products produced)</i>	13	20	-	-
PC10. interact with various regulatory authorities during concept, development and industrialization stages of projects for clarification and approvals	2	3	-	-
PC11. interact with the notified bodies and competent authorities for developing and reviewing regulatory standards	2	3	-	-
PC12. coordinate with regulatory authorities for reporting, to comment on proposed regulations, and to represent companys interest in the development of standards and guidelines	2	3	-	-
PC13. discuss on the differences that exist in the regulations laid down by different governments and their interpretation by the regulatory agencies and ensure that efficient and economical regulatory standards are planned	2	3	-	-
PC14. identify possible threats or opportunities from upcoming regulations under fssai, consumer affairs, other government food policies and regulations and liaise with industry associations to tackle/manage them effectively	1.5	2.5	-	-
PC15. participate in seminar, workshops, conferences and meetings organised by fssai and other industry association, representing the organisation to maintain, strengthen and expand contacts	1.5	2.5	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC16. work closely with regulatory and trade associations like cii (confederation of indian industries), ficci (federation of indian chambers of commerce and industries), cifti (confederation of indian food trade and industry), aifpa (all india food processors association), assocham(the associated chambers of commerce of india) etc on national and international regulatory changes and challenges that have impact on food products produced in the organisation and to manage them proactively	2	3	-	-
<i>New product registrations (for food products produced)</i>	10.5	16.5	-	-
PC17. develop and write clear arguments and explanations for new product license	2	3	-	-
PC18. prepare and present registration documents to regulatory authorities and notified bodies for new product approvals	2	3	-	-
PC19. present written representation for new products and carry out negotiations with regulatory authorities to obtain necessary approvals for new product production and marketing	2	3	-	-
PC20. evaluate, prepare and submit new product registration applications and follow through the application during the evaluation phase to achieve favorable outcome	1.5	2.5	-	-
PC21. prepare responses to letter/e-mail communications and other requests from government food regulatory bodies on new product approval	1.5	2.5	-	-
PC22. provide regulatory and product compliance report in the area of advertising and label claims for new products	1.5	2.5	-	-
NOS Total	35	65	-	-

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National Occupational Standards (NOS) Parameters

NOS Code	FIC/N9013
NOS Name	Prepare representations to regulatory authorities and for new product registrations
Sector	Food Processing
Sub-Sector	Fruits and Vegetables, Food Grain Milling, Dairy Products, Meat and Poultry, Fish and Sea Food, Bread and Bakery, Alcoholic Beverages, Aerated Water/Soft Drinks, Soya Food, Packaged Foods
Occupation	Quality Assurance
NSQF Level	6
Credits	TBD
Version	1.0
Last Reviewed Date	03/08/2021
Next Review Date	31/03/2022
Deactivation Date	31/03/2022
NSQC Clearance Date	03/08/2018

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by the Sector Skill Council. Each Element/ Performance Criteria (PC) will be assigned marks proportional to its importance in NOS. SSC will also lay down proportion of marks for Theory and Skills Practical for each Element/ PC.
2. The assessment for the theory part will be based on knowledge bank of questions created by the SSC.
3. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.
4. Individual assessment agencies will create unique question papers for theory part for each candidate at each examination/training center (as per assessment criteria below).
5. Individual assessment agencies will create unique evaluations for skill practical for every student at each examination/ training center based on these criteria.

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6. To pass the Qualification Pack assessment, every trainee should score the Recommended Pass % aggregate for the QP.

7. In case of unsuccessful completion, the trainee may seek reassessment on the Qualification Pack.

Minimum Aggregate Passing % at QP Level : 70

(Please note: Every Trainee should score a minimum aggregate passing percentage as specified above, to successfully clear the Qualification Pack assessment.)

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
FIC/N9011.Design, develop and implement regulatory system	35	65	-	-	100	35
FIC/N9012.Manage change in food regulatory system	35	65	-	-	100	35
FIC/N9013.Prepare representations to regulatory authorities and for new product registrations	35	65	-	-	100	30
Total	105	195	-	-	300	100

Qualification Pack

Acronyms

NOS	National Occupational Standard(s)
NSQF	National Skills Qualifications Framework
QP	Qualifications Pack
TVET	Technical and Vocational Education and Training
CIP	Clean In Place
COP	Clean Out Of Place
ERP	Enterprise Resource Planning
FIFO	First In First Out
FEFO	First Expiry First Out
FSSAI	Food Safety and Standards Authority of India
GMP	Good Manufacturing Practices
GHP	Good Hygiene Practices
HACCP	Hazard Analysis and Critical Control Point

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Glossary

Sector	Sector is a conglomeration of different business operations having similar business and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests.
Sub-sector	Sub-sector is derived from a further breakdown based on the characteristics and interests of its components.
Occupation	Occupation is a set of job roles, which perform similar/ related set of functions in an industry.
Job role	Job role defines a unique set of functions that together form a unique employment opportunity in an organisation.
Occupational Standards (OS)	OS specify the standards of performance an individual must achieve when carrying out a function in the workplace, together with the Knowledge and Understanding (KU) they need to meet that standard consistently. Occupational Standards are applicable both in the Indian and global contexts.
Performance Criteria (PC)	Performance Criteria (PC) are statements that together specify the standard of performance required when carrying out a task.
National Occupational Standards (NOS)	NOS are occupational standards which apply uniquely in the Indian context.
Qualifications Pack (QP)	QP comprises the set of OS, together with the educational, training and other criteria required to perform a job role. A QP is assigned a unique qualifications pack code.
Unit Code	Unit code is a unique identifier for an Occupational Standard, which is denoted by an 'N'
Unit Title	Unit title gives a clear overall statement about what the incumbent should be able to do.
Description	Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate OS they are looking for.
Scope	Scope is a set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on quality of performance required.

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Knowledge and Understanding (KU)	<p>Knowledge and Understanding (KU) are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.</p>
Organisational Context	<p>Organisational context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.</p>
Technical Knowledge	<p>Technical knowledge is the specific knowledge needed to accomplish specific designated responsibilities.</p>
Core Skills/ Generic Skills (GS)	<p>Core skills or Generic Skills (GS) are a group of skills that are the key to learning and working in today's world. These skills are typically needed in any work environment in today's world. These skills are typically needed in any work environment. In the context of the OS, these include communication related skills that are applicable to most job roles.</p>
Electives	<p>Electives are NOS/set of NOS that are identified by the sector as contributive to specialization in a job role. There may be multiple electives within a QP for each specialized job role. Trainees must select at least one elective for the successful completion of a QP with Electives.</p>
Options	<p>Options are NOS/set of NOS that are identified by the sector as additional skills. There may be multiple options within a QP. It is not mandatory to select any of the options to complete a QP with Options.</p>