

# Model Curriculum

## Food Regulatory Affairs Manager

**SECTOR: FOOD PROCESSING**

**SUB-SECTOR: FRUIT & VEGETABLE, FOOD GRAIN MILLING (INCLUDING OILSEEDS), DAIRY PRODUCTS, MEAT & POULTRY, FISH & SEAFOOD, BREAD & BAKERY, ALCOHOLIC BEVERAGES, AERATED WATER/ SOFT DRINKS, SOYA FOOD, PACKAGED FOOD**

**OCCUPATION: QUALITY ASSURANCE**

**REF ID: FIC/Q9002, V1.0**

**NSQF LEVEL: 6**



**Certificate**

**CURRICULUM COMPLIANCE TO  
QUALIFICATION PACK – NATIONAL OCCUPATIONAL  
STANDARDS**

is hereby issued by the

**FOOD INDUSTRY CAPACITY AND SKILL INITIATIVE (FICSI)**

for the

**MODEL CURRICULUM**

Complying to National Occupational Standards of  
Job Role/Qualification Pack: **'Food Regulatory Affairs Manager'**  
QP No. **'FIC/Og003, Version 1.0, NSQF Level 6'**

Date of Issuance: February 2, 2016

Valid up to: March 30, 2019

\* Valid up to the next review date of the Qualification Pack

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Authorised Signatory  
(Food Industry Capacity and Skill Initiative)

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# Food Regulatory Affairs Manager

## CURRICULUM / SYLLABUS

This program is aimed at training candidates for the job of a “Food Regulatory Affairs Manager”, in the “Food Processing” Sector/Industry and aims at building the following key competencies amongst the learner

<b>Program Name</b>	<b>Food Regulatory Affairs Manager</b>		
<b>Qualification Pack Name &amp; Reference ID. ID</b>	FIC/Q9002, v1.0		
<b>Version No.</b>	1.0	<b>Version Update Date</b>	31/03/2022
<b>Pre-requisites to Training</b>	Master’s degree in food science with 8-10 years’ experience in food processing unit or food regulatory matters		
<b>Training Outcomes</b>	<p><b>After completing this programme, participants will be able to:</b></p> <ul style="list-style-type: none"> <li>• Designing, developing, implementing and changing food regulatory systems in the organisation.</li> <li>• Act as a liaison between organisation and government regulatory agencies</li> <li>• Ensure that the products produced and distributed comply with regulatory standards.</li> </ul>		

This course encompasses 3 out of 3 National Occupational Standards (NOS) of “Food Regulatory Affairs Manager” Qualification Pack issued by “Food Industry Capacity and Skill Initiative”.

Sr. No.	Module	Key Learning Outcomes	Equipment Required
1	<b>Introduction to the training program</b>  <b>Theory Duration</b> (hh:mm) 01:30 <b>Practical Duration</b> (hh:mm) 00:00  <b>Corresponding NOS Code</b> Bridge Module	<ul style="list-style-type: none"> <li>Introduce each other and build rapport with fellow participants and the trainer.</li> </ul>	White board/Chart papers, marker
2	<b>Overview of the “Food Regulatory Affairs Manager” Role</b>  <b>Theory Duration</b> (hh:mm) 01:00 <b>Practical Duration</b> (hh:mm) 00:00  <b>Corresponding NOS Code</b>	<ul style="list-style-type: none"> <li>Understanding the roles and responsibilities of food regulatory affairs manager</li> <li>Awareness of the nature and availability of job opportunities</li> </ul>	Laptop/computer white board, marker, projector, chart papers
3	<b>Introduction to the Food Processing Industry</b>  <b>Theory Duration</b> (hh:mm) 01:00 <b>Practical Duration</b> (hh:mm) 00:00  <b>Corresponding NOS Code</b>	<ul style="list-style-type: none"> <li>Define food processing</li> <li>List the various sub-sectors of food processing industry</li> </ul>	Laptop, white/black board, marker, chart papers, projector, Trainer’s guide, Student manual
4	<b>Introduction to the food regulations and affairs</b>  <b>Theory Duration</b> (hh:mm) 05:00 <b>Practical Duration</b>	<ul style="list-style-type: none"> <li>List the terminology used in the food regulation process</li> <li>State various methods to ensure food regulation</li> <li>State the processes to oversee for ensuring that the food regulations are in compliance</li> </ul>	Laptop, white/black board, marker, chart papers, projector, trainer’s guide, student handbook

Sr. No.	Module	Key Learning Outcomes	Equipment Required
	(hh:mm) 30:00  <b>Corresponding NOS Code</b>	<ul style="list-style-type: none"> <li>Understand what are regulatory policies of an organization and follow them</li> </ul>	
5	<b>Design, develop and implement regulatory system</b>  <b>Theory Duration</b> (hh:mm) 13:00  <b>Practical Duration</b> (hh:mm) 21:00  <b>Corresponding NOS Code</b> FIC/N9011	<ul style="list-style-type: none"> <li>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</li> <li>Design regulatory system with focus on risk reduction, risk-based priorities, reflect integrated and economically feasible initiatives, and ensure high quality and transparency</li> <li>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</li> <li>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)</li> <li>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</li> <li>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</li> <li>Design food regulatory system involving GMP, GHP, and monitoring systems like HACCP</li> <li>Design regulatory system that improve efficiency and compliance, build consumer confidence in the safety and quality of food products</li> </ul>	Laptop, white/black board, marker, chart papers, projector, trainer's guide, student handbook, quality manual, quality policy

Sr. No.	Module	Key Learning Outcomes	Equipment Required
		<p>produced, processed, marketed, distributed and sold</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• Design regulatory system including provisions for the right of consumers to have access to accurate and sufficient information and make adequate choices</li> <li>• 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</li> <li>• 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</li> <li>• 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</li> <li>• 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</li> <li>• Evaluate labels of packed food products to ensure it meets national and international food regulatory standards and provide approval or recommend changes</li> <li>• Evaluate promotional and materials for regulatory impact and provide approval</li> <li>• Provide support for review of essential documents, development and review of consent forms for submission to regulatory authorities for clearance</li> </ul>	

Sr. No.	Module	Key Learning Outcomes	Equipment Required
		<ul style="list-style-type: none"> <li>• Initiate and contribute to process improvements which have an impact on regulatory affairs, quality assurance and other departments</li> <li>• Conduct audits on food processing unit for compliance with regulatory, safety and hygiene standards implemented and followed in the organisation</li> <li>• Conduct periodic audits to evaluate haccp plans and their implementation in the organisation and ensure it meets the regulatory standards</li> <li>• 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</li> <li>• Identify reason for consumer cases in court related to non-compliance of food products to regulatory standards, collect relevant information's and documents transmitting evidence to produce in court to assist prosecution</li> <li>• Monitor company progress toward fulfillment of regulatory commitments</li> <li>• 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</li> <li>• 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</li> <li>• Provide training on procedures for collecting evidence in case of problems/consumer complaints/consumer cases in court</li> </ul>	



Sr. No.	Module	Key Learning Outcomes	Equipment Required
		<p>and handling them with technical and scientific approach</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• Provide training on upgradation and changes in the food regulatory system and methods to implement, monitor and achieve them</li> </ul>	
6	<p><b>Manage change in food regulatory system</b></p> <p><b>Theory Duration</b> (hh:mm) 14:00</p> <p><b>Practical Duration</b> (hh:mm) 20:00</p> <p><b>Corresponding NOS Code</b> FIC/N9012</p>	<ul style="list-style-type: none"> <li>• Identify procedures, systems, structures that need to be changed for effective implementation of food regulatory system</li> <li>• Assess gaps in the current policies and procedures and analyze the future requirements</li> <li>• Identify and assess barriers to change in regulatory system, develop strategies and plans to overcome those barriers</li> <li>• Assess risks and benefits associated with the strategies and plans, and develop contingency arrangements design new work processes, procedures, systems, structures and roles to achieve planned changes in regulatory system</li> <li>• Ensure plan for change in regulatory system include short-term as well as longer-term deliverables</li> <li>• Develop system for monitoring and assessing regulatory system to assess progress in changes implemented</li> <li>• Develop reporting and communicating system to review the effectiveness of the changes in regulatory system and to obtain feedback</li> <li>• Provide training and support to implement changes planned in regulatory system</li> <li>• Communicate reasons, importance and benefits of implementing change in regulatory system, future that can be achieved through</li> </ul>	<p>Laptop, white/black board, marker, chart papers, projector, trainer's guide, student handbook, quality manual, quality policy, regulatory policies</p>

Sr. No.	Module	Key Learning Outcomes	Equipment Required
		<p>implementing and following the change, to management and concerned employees</p> <ul style="list-style-type: none"> <li>• Make the management and employees welcome change in regulatory system as an opportunity to deliver products of national and international quality</li> <li>• 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</li> <li>• Implement the strategies and plans for change in regulatory system with available resources</li> <li>• 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</li> <li>• Set and prioritize objectives for the change in regulatory system, identify and deal with obstacles to change, and support employees through the change process</li> <li>• Communicate progress achieved thorough change in regulatory system to everyone involved, and make them understand and enjoy achievement</li> <li>• Review reports on total quality management system to evaluate effectiveness of changes implemented in regulatory system of the organisation</li> <li>• Organize internal and external audit on total quality management system to evaluate effectiveness of the changes implemented in regulatory system</li> <li>• Monitor changes implemented in regulatory system , document and communicate the outcome of implemented change to the management</li> <li>• Recognize and reward employees and teams for implementing regulatory system and achieving results thorough new policies and procedures</li> </ul>	

Sr. No.	Module	Key Learning Outcomes	Equipment Required
		<ul style="list-style-type: none"> <li>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</li> </ul>	
7	<p><b>Prepare representations to regulatory authorities and for new product registrations</b></p> <p><b>Theory Duration</b> (hh:mm) 09:00</p> <p><b>Practical Duration</b> (hh:mm) 14:00</p> <p><b>Corresponding NOS Code</b> FIC/N9013</p>	<ul style="list-style-type: none"> <li>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</li> <li>Review regulatory guidance and requirements pertaining to products produced in the organisation and prepare documents providing thoughtful and accurate comments</li> <li>Prepare regulatory documents to authorities that translate regulatory requirements into practical, workable plans with timelines for development and implementation</li> <li>Coordinate with food regulatory authorities to review disputed matters, negotiation and finalization on products and projects, and for comments and formal approvals</li> <li>Prepare documents that include check lists created and maintained to implement regulatory requirements, technical data, and declarations of conformity</li> <li>Interface with consultants, research organizations, partners, co-manufacturers etc. for preparation, review, compilation, finalization and submission of documents for regulatory approvals</li> <li>Prepare responses to communications and other requests from government food regulatory authorities</li> <li>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</li> <li>Identify reasons related to non-compliance of food products to regulatory standards, collect relevant information's and data,</li> </ul>	<p>Laptop, white/black board, marker, chart papers, projector, trainer's guide, student handbook, quality manual, quality policy, audit documents, regulatory policies</p>

Sr. No.	Module	Key Learning Outcomes	Equipment Required
		<p>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</p> <ul style="list-style-type: none"> <li>• Interact with various regulatory authorities during concept, development and industrialization stages of projects for clarification and approvals</li> <li>• Interact with the notified bodies and competent authorities for developing and reviewing regulatory standards</li> <li>• Coordinate with regulatory authorities for reporting, to comment on proposed regulations, and to represent company's interest in the development of standards and guidelines</li> <li>• 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</li> <li>• 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</li> <li>• Participate in seminar, workshops, conferences and meetings organised by FSSAI and other industry association, representing the organisation to maintain, strengthen and expand contacts</li> <li>• 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</li> </ul>	

Sr. No.	Module	Key Learning Outcomes	Equipment Required
		organisation and to manage them proactively <ul style="list-style-type: none"> <li>• Develop and write clear arguments and explanations for new product license</li> <li>• Prepare and present registration documents to regulatory authorities and notified bodies for new product approvals</li> <li>• Present written representation for new products and carry out negotiations with regulatory authorities to obtain necessary approvals for new product production and marketing</li> <li>• Evaluate, prepare and submit new product registration applications and follow through the application during the evaluation phase to achieve favorable outcome</li> <li>• Prepare responses to letter/e-mail communications and other requests from government food regulatory bodies on new product approval</li> <li>• Provide regulatory and product compliance report in the area of advertising and label claims for new products</li> </ul>	
8	<b>Field Visits</b>  <b>Theory Duration</b> (hh:mm) 04:00  <b>Practical Duration</b> (hh:mm) 20:00  <b>Corresponding NOS Code</b>	<ul style="list-style-type: none"> <li>• Observe the location, layout and safety aspects of food processing</li> <li>• Observe the storage facilities for raw materials and finished products</li> <li>• Observe the various machineries used in process</li> <li>• Observe the various machineries used in process</li> <li>• Observe the cleaning methods and processes followed to maintain the process machineries and tools</li> <li>• Observe the raw materials used and their storage procedures</li> <li>• Observe the packaging and storage processes of raw material and finished product</li> <li>• Observe the post-production cleaning and maintenance process followed in the industry</li> </ul>	All the tools and equipment listed above must be available at the site of field visit
9	<b>Revision</b>  <b>Theory Duration</b> (hh:mm) 01:00	<ul style="list-style-type: none"> <li>• Revised the knowledge gained so far</li> </ul>	All the tools and equipment listed above must be available at the time of revision

Sr. No.	Module	Key Learning Outcomes	Equipment Required
	<b>Practical Duration</b> (hh:mm) 01:00  <b>Corresponding NOS Code</b>		
10	<b>Evaluation</b>  <b>Theory Duration</b> (hh:mm) 06:00  <b>Practical Duration</b> (hh:mm) 28:00  <b>Corresponding NOS Code</b>	<ul style="list-style-type: none"> <li>Assess the knowledge and skills acquired by the participants</li> </ul>	All the tools and equipment listed above must be available for evaluation
11	<b>On-the-job Training</b>  <b>Theory Duration</b> (hh:mm) 08:00  <b>Practical Duration</b> (hh:mm) 24:00  <b>Corresponding NOS Code</b>	<ul style="list-style-type: none"> <li>Apply the skills and knowledge acquired in the training program in the field</li> </ul>	All the tools and equipment listed above must be available on the site at the time of OJT
	<b>Total Duration</b> <b>240:00</b>  <b>Theory Duration</b> <b>79:00</b>  <b>Practical Duration</b> <b>161:00</b>	<b>Unique Equipment Required:</b> Laptop, white/black board, marker, chart papers, projector, trainer's guide, student handbook, quality manual, quality policy, audit documents, regulatory policies	

Grand Total Course Duration: **240 Hours, 0 Minutes**

(This syllabus/ curriculum has been approved by SSC: Food Industry Capacity and Skill Initiative)

## Trainer Prerequisites for Job role: “Food Regulatory Affairs Manager” mapped to Qualification Pack: “FIC/Q9002, v1.0”

Sr. No.	Area	Details
1	<b>Description</b>	To deliver accredited training service, mapping to the curriculum detailed above, in accordance with the Qualification Pack “FIC/Q9002”, Version 1.0
2	<b>Personal Attributes</b>	An aptitude for conducting training, and pre/ post work to ensure competent, employable candidates at the end of the training, and pre/post work to ensure competent, employable candidates at the end of the training. Strong communication skills, ability to work as part of a team; a passion for quality and for developing others; well-organized and focused, eager to learn and keep oneself updated with the latest in the mentioned fields.
3	<b>Minimum Educational Qualifications</b>	<ul style="list-style-type: none"> <li>B.Sc/B.Tech/BE in Food Process Engineering/ Food Safety and Quality Management in Food Process Engineering with 5-6 years of hand on experience in QA/regulations of a food Processing Industry or</li> <li>M.Sc/M.Tech/ME or in Food Process Engineering/ Food Safety and Quality Management in Food Safety/Food Process Engineering with 3-4- years of hand on experience in QA/regulations of a food Processing Industry</li> </ul>
4a	<b>Domain Certification</b>	Certified for Job Role: “ <u>Food regulatory affairs Manager</u> ” mapped to QP: “ <u>FIC/Q9002, v1.0</u> ”. Minimum accepted score is 80%
4b	<b>Platform Certification</b>	Recommended that the Trainer is certified for the Job Role: “Trainer”, mapped to the Qualification Pack: “SSC/Q1402”. Minimum accepted SCORE IS 80 % as per FICSI guidelines.
5	<b>Experience</b>	<ul style="list-style-type: none"> <li>B.Sc/B.Tech/BE in Food Process Engineering/ Food Safety and Quality Management in Food Process Engineering with 5-6 years of hand on experience in QA/regulations of a food Processing Industry or</li> <li>M.Sc/M.Tech/ME or in Food Process Engineering/ Food Safety and Quality Management in Food Safety/Food Process Engineering with 3-4- years of hand on experience in QA/regulations of a food Processing Industry</li> </ul>

### Annexure: Assessment Criteria

<b>Assessment Criteria</b>	
<b>Job Role</b>	<b>Food regulatory affairs manager</b>
<b>Qualification Pack</b>	<b>FIC/Q9002 v1.0</b>
<b>Sector Skill Council</b>	<b>Food Processing</b>

<b>Sr. No.</b>	<b>Guidelines for Assessment</b>
1	Criteria for assessment for each Qualification Pack will be created by the Sector Skill Council. Each 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 PC.
2	The assessment for the theory part will be based on knowledge bank of questions created by the SSC.
3	Individual assessment agencies will create unique question papers for theory part for each candidate at each examination/training centre (as per assessment criteria below)
4	Individual assessment agencies will create unique evaluations for skill practical for every student at each examination/training center based on this criteria
5	To pass the Qualification Pack, every trainee should score a minimum of 70% (overall) in every QP
6	The marks are allocated PC wise; however, every NOS will carry a weight age in the total marks allocated to the specific QP



Assessable Outcome	Assessment Criteria	Total Mark (600)	Out Of	Marks Allocation	
				Theory	Skills Practical
<b>1. FIC/N9011: Design, develop and implement regulatory system</b>	PC.1 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	<b>100</b>	4	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		4	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		4	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		4	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		4	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		4	1.5	2.5
	PC7. design food regulatory system involving gmp, ghp, and monitoring systems like haccp		4	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		4	1.5	2.5
	PC9. design and develop regulatory system ensuring food and health standards are followed in each stage of production and		4	1.5	2.5

Assessable Outcome	Assessment Criteria	Total Mark (600)	Out Of	Marks Allocation	
				Theory	Skills Practical
	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		4	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		4	1.5	2.5
	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		4	1.5	2.5
	PC13. develop and review standard operating procedures (sops) and ensure sops are in compliance with current regulatory requirements and provide regulatory support for corporate quality assurance efforts		4	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		4	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		4	1	3
	PC16. evaluate promotional and materials for regulatory impact and provide approval		4	1	3
	PC17. provide support for review of essential documents, development and review of consent forms for submission to regulatory authorities for clearance		3	1	2
	PC18. initiate and contribute to process improvements which have an impact on		3	1	2

Assessable Outcome	Assessment Criteria	Total Mark (600)	Out Of	Marks Allocation	
				Theory	Skills Practical
	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		3	1	2
	PC20. conduct periodic audits to evaluate haccp plans and their implementation in the organisation and ensure it meets the regulatory standards		3	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		3	1	2
	PC22. identify reason for consumer cases in court related to non-compliance of food products to regulatory standards, collect relevant information's and documents transmitting evidence to produce in court to assist prosecution		3	1	2
	PC23. monitor company progress toward fulfillment of regulatory commitments		3	1	2
	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		3	1	2
	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		3	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		3	1	2

Assessable Outcome	Assessment Criteria	Total Mark (600)	Out Of	Marks Allocation	
				Theory	Skills Practical
	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		3	1	2
	PC28. provide training on upgradation and changes in the food regulatory system and methods to implement, monitor and achieve them		3	1	2
			<b>100</b>	<b>35</b>	<b>65</b>
<b>2. FIC/N9012: Manage change in food regulatory system</b>	PC1. identify procedures, systems, structures that need to be changed for effective implementation of food regulatory system	<b>100</b>	5	1	4
	PC2. assess gaps in the current policies and procedures and analyze the future requirements		5	1	4
	PC3. identify and assess barriers to change in regulatory system, develop strategies and plans to overcome those barriers		5	1	4
	PC4. assess risks and benefits associated with the strategies and plans, and develop contingency arrangements		5	1	4
	PC5. design new work processes, procedures, systems, structures and roles to achieve planned changes in regulatory system		5	1	4
	PC6. ensure plan for change in regulatory system include shortterm as well as longer-term deliverables.		4	1.5	2.5
	PC7. develop system for monitoring and assessing regulatory system to assess progress in changes implemented		5	2	3
	PC8. develop reporting and communicating system to review the effectiveness of the changes in regulatory system and to obtain feedback		5	2	3
	PC9. provide training and support to implement changes planned in regulatory system		4	2	2
	PC10. communicate reasons, importance and benefits of implementing change in regulatory system, future that can be achieved through implementing and		5	2	3

Assessable Outcome	Assessment Criteria	Total Mark (600)	Out Of	Marks Allocation	
				Theory	Skills Practical
	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		4	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		5	2	3
	PC13. implement the strategies and plans for change in regulatory system with available resources		5	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		5	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		5	2	3
	PC16. communicate progress achieved through change in regulatory system to everyone involved, and make them understand and enjoy achievement		4	1.5	2.5
	PC17. review reports on total quality management system to evaluate effectiveness of changes implemented in regulatory system of the organisation		5	2	3
	PC18. organize internal and external audit on total quality management system to evaluate effectiveness of the changes implemented in regulatory system		5	2	3
	PC19. monitor changes implemented in regulatory system, document and communicate the outcome of implemented change to the management		5	2	3
	PC20. recognize and reward employees and teams for implementing regulatory system and achieving results through new policies and procedures		4	1.5	2.5
	PC21. monitor and ensure changes implemented in regulatory system are		5	2	3

Assessable Outcome	Assessment Criteria	Total Mark (600)	Out Of	Marks Allocation	
				Theory	Skills Practical
	effective and meet the requirements of the organisation and regulatory system laid by national and international regulatory bodies				
			<b>100</b>	<b>35</b>	<b>65</b>
<b>3. FIC/N9013: Prepare representations to regulatory authorities and for new product registrations</b>	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	<b>100</b>	5	1	4
	PC2. review regulatory guidance and requirements pertaining to products produced in the organisation and prepare documents providing thoughtful and accurate comments		5	1	4
	PC3. prepare regulatory documents to authorities that translate regulatory requirements into practical, workable plans with timelines for development and implementation		5	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		5	1	4
	PC5. prepare documents that include check lists created and maintained to implement regulatory requirements, technical data, and declarations of conformity		4	1.5	2.5
	PC6. interface with consultants, research organizations, partners, co-manufacturers etc for preparation, review, compilation, finalization and submission of documents for regulatory approvals		4	1.5	2.5
	PC7. prepare responses to communications and other requests from government food regulatory authorities		4	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		4	1.5	2.5

Assessable Outcome	Assessment Criteria	Total Mark (600)	Out Of	Marks Allocation	
				Theory	Skills Practical
	PC9. Identify reasons related to noncompliance of food products to regulatory standards, collect relevant information's 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		4	1.5	2.5
	PC10. 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		5	2	3
	PC11. review regulatory guidance and requirements pertaining to products produced in the organisation and prepare documents providing thoughtful and accurate comments		5	2	3
	PC12. prepare regulatory documents to authorities that translate regulatory requirements into practical, workable plans with timelines for development and implementation		5	2	3
	PC13. coordinate with food regulatory authorities to review disputed matters, negotiation and finalization on products and projects, and for comments and formal approvals		5	2	3
	PC14. prepare documents that include check lists created and maintained to implement regulatory requirements, technical data, and declarations of conformity		4	1.5	2.5
	PC15. interface with consultants, research organizations, partners, co-manufacturers etc for preparation, review, compilation, finalization and submission of documents for regulatory approvals		4	1.5	2.5
	PC16. prepare responses to communications and other requests from government food regulatory authorities		5	2	3
	PC17. develop and write clear arguments and explanations for new product license		5	2	3



Assessable Outcome	Assessment Criteria	Total Mark (600)	Out Of	Marks Allocation	
				Theory	Skills Practical
	PC18. prepare and present registration documents to regulatory authorities and notified bodies for new product approvals		5	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		5	2	3
	PC20. evaluate, prepare and submit new product registration applications and follow through the application during the evaluation phase to achieve favorable outcome		4	1.5	2.5
	PC21. prepare responses to letter/e-mail communications and other requests from government food regulatory bodies on new product approval		4	1.5	2.5
	PC22. Provide regulatory and product compliance report in the area of advertising and label claims for new products		4	1.5	2.5
	<b>Total</b>		<b>100</b>	<b>35</b>	<b>65</b>
	<b>Grand Total</b>	<b>300</b>	<b>300</b>	<b>200</b>	<b>100</b>
	<b>Percentage Weightage</b>		<b>100</b>	<b>60%</b>	<b>40%</b>
	<b>Minimum Pass% to qualify (aggregate):</b>			<b>70%</b>	



