Ensuring Food Safety with Quality Management Software

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https://www.youtube.com/watch?v=QWijlTDHLMQ (2:17)

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FSMA is a First Step Towards Risk-Based, Science-Based Integrated Food Safety & Quality Management

"In a food safety system, decisions about resource allocation need to be made consistently in order to maximize benefits and reduce risks while also considering costs.

Food safety risk managers must consider a wide variety of concerns in their decision making, including the needs and values of diverse stakeholders, the controllability of various risks, the size and vulnerabilities of the populations affected, and economic factors. Although the balancing of diverse risks, benefits and costs is challenging, the lack of a systematic, risk-based approach to facilitate decision making can cause problems ranging from a decrease in public trust to the occurrence of unintended consequences to society, the environment and the marketplace."

National Academy of Sciences. (2010). Enhancing Food Safety: the Role of the Food and Drug Administration. Committee on the Review of the Food and Drug Administration's Role in Ensuring Safe Food. Institute of Medicine and National Research Council. Washington, D.C., National Academy Press.

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Objectives

You will learn about:

1. Relationships between **standards and guidelines** ISO 22000:2015, FSSC 22000, ISO/TS 22002, PRPs, GMPs, and HACCP/HARPC

2. How to **QMS** can ensure consistent and effective processes across sites and processes, and help you make the most of your **CAPA** process

3. Why **internal and supplier communication is critical** for the effectiveness of the quality program

4. What **blockchain** is, and how IBM Food Trust is demonstrating its value and utility right now

5. How to **get started/increase maturity with QMS & FSMS software**

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1: Food Safety & Quality

core components, value propositions

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"Food **quality** is the extent to which all the established requirements relating to the characteristics of a food are met…

Food **safety** is the extent to which those requirements relating specifically to characteristics or properties that have the *potential to be* ***harmful to health*** *or to cause* ***illness*** *or* ***injury*** are met."

Alli, I. (2003). Food quality assurance: principles and practices. CRC Press.

"Classical quality control methods only emphasiz[ing] ***hygienic quality*** of final products are inadequate to control hazards occurring at early stages of the process.

Allata, S., Valero, A., & Benhadja, L. (2017). Implementation of traceability and food safety systems (HACCP) under the ISO 22000: 2005 standard in North Africa: The case study of an ice cream company in Algeria. Food control, 79, 239-253.

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Food Protection Risk Matrix

Spink, J., & Moyer, D. C. (2011). Defining the public health threat of food fraud. Journal of Food Science, 76(9), R157-R163.

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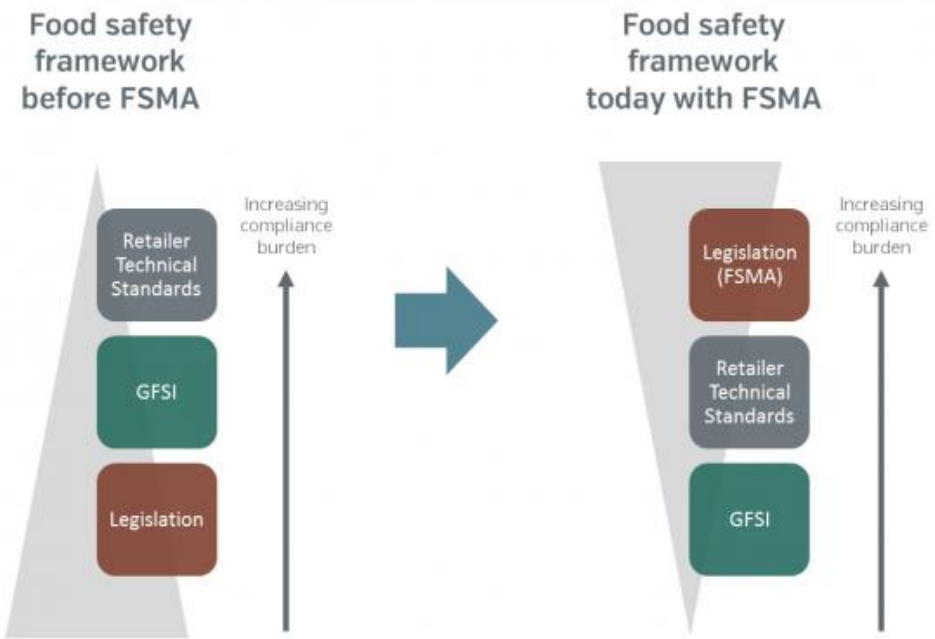
The Food Safety Modernization Act (FSMA) Preventive Controls for Human Food (PCHF) Rule **Adds Rigor** to GFSI Recognized Schemes



Howlett, G. (2016, May). The difference between HACCP and HARPC. A case of the Emperor's New Clothes? Safefood 360. Available from https://safefood360.com/2016/05/the-difference-between-haccp-and-harpc/

Things an FSMS can do:

- Establish and maintain a hygienic environment
- Manage preventive controls to reduce nonconformances
- Keep records that detail when activities dictated by those controls were enacted

Things a QMS can do:

- Prevent or reduce recalls
- Reduce defects and variation
- Reduce product loss
- Increase customer satisfaction
- Design and develop new products

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FSMA COMPLIANCE DATES

2015

SEP 17, 2015 (PCHF)
- Preventive Controls Human Food Final Rule

SEP 17, 2015 (PCAF)
- Preventive Controls Animal Food Final Rule

NOV 16, 2015 (PCHF)
- Preventive Controls Human Food Effective Date

NOV 16, 2015 (PCAF)
- Preventive Controls Animal Food Effective Date

NOV 27, 2015 (FSVP)
- Foreign Supplier Verification Program Final Rule

NOV 27, 2015 (PS)
- Produce Safety Final Rule

2016

JAN 01, 2016 (PCHF)
- Very Small Businesses retain records to support Qualified Facility status

JAN 01, 2016 (PCAF)
- Very Small Businesses retain records to support Qualified Facility Status

JAN 26, 2016 (FSVP)
- FSVP Effective Date

JAN 26, 2016 (PS)
- Produce Safety Effective Date

APR 06, 2016 (ST)
- Sanitary Transportation of Human and Animal Final Rule

MAY 27, 2016 (IA)
- Intentional Adulteration Final Rule

JUN 06, 2016 (ST)
- Sanitary Transportation Effective Date

JUL 26, 2016 (IA)
- Intentional Adulteration Effective Date

SEP 19, 2016 (PCHF)[1,2,3,4]
- Large Business

SEP 19, 2016 (PCAF)[2]
- Large Business CGMP compliance

2017

JAN 26, 2017 (PS)[1]
- Sprouts - Large

APR 06, 2017 (ST)
- Large Business

MAY 30, 2017 (FSVP)[1,6]
- Importer not subject to PC or produce rules

MAY 30, 2017 (FSVP)[1,6]
- Importer of human food whose Large Foreign Importers required to comply with PCHF

JUL 26, 2017 (FSVP)[1,6]
- Importer whose Large Foreign Supplier Required to comply with Produce Safety Rule

JUL 26, 2017 (FSVP)[1,6]
- Importer whose Large Foreign Supplier required to comply with sprout requirements of Produce Safety Rule

SEP 18, 2017 (PCHF)[1,2,3,4]
- Small Business compliance

SEP 18, 2017 (PCAF)[2,3]
- Small Business CGMP compliance

SEP 18, 2017 (PCAF)[1,2,3,5]
- Large Business PC compliance

2018

JAN 26, 2018 (PS)[1]
- Sprouts - Small

JAN 26, 2018 (PS)[1]
- Large Farms (except water)

MAR 19, 2018 (FSVP)[1,6]
- Importer of human food whose Small Foreign Supplier required to comply with PCHF

MAR 19, 2018 (FSVP)[1,6]
- Importer of animal food whose Large Foreign Supplier is subject to PCAF CGMP requirements

APR 26, 2018 (ST)
- Small Business

JUL 26, 2018 (FSVP)[1,6]
- Importer whose Small Foreign Supplier required to comply with sprout requirements of Produce Safety Rule

JUL 26, 2018 (FSVP)[1,6]
- Importer whose Small Foreign Supplier is a farm producing sprouts and eligible for a Qualified Exemption under the Produce Safety Rule

SEP 17, 2018 (PCHF)[2,3,4]
- Qualified Facilities (including Very Small Businesses) compliance

SEP 17, 2018 (PCHF)
- Business subject to Pasteurized Milk Ordinance (PMO)

SEP 17, 2018 (PCAF)[2,3]
- Qualified facilities (including Very Small Businesses) CGMP compliance

SEP 17, 2018 (PCAF)[1,2,3,5]
- Small Business PC compliance

2019

JAN 28, 2019 (PS)[1]
- Sprouts - Very Small

JAN 28, 2019 (PS)[1]
- Small Farms (except water)

MAR 18, 2019 (FSVP)[1,6]
- Importer of animal food whose Small Foreign Supplier is subject to PCAF CGMP requirements

MAR 18, 2019 (FSVP)[1,6]
- Foreign Importers subject to the PMO required to comply with PCHF

MAR 18, 2019 (FSVP)[1,6]
- Importer of human food whose Qualified Foreign Supplier (including Very Small Foreign Supplier) required to comply with PCHF

JUL 26, 2019 (FSVP)[1,6]
- Importer whose Very Small Foreign Supplier is a farm producing sprouts and eligible for a Qualified Exemption under the Produce Safety Rule

JUL 26, 2019 (IA)
- Large Business

JUL 27, 2019 (FSVP)[1,6]
- Importer whose Very Small Foreign Supplier required to comply with Produce Safety Rule

JUL 29, 2019 (FSVP)[1,6]
- Importer whose Small Foreign Supplier required to comply with Produce Safety Rule

JUL 29, 2019 (FSVP)[2,3,5]
- Importer whose Small Foreign Supplier subject to Produce Safety Rule and eligible for a Qualified Exemption

JUL 29, 2019 (FSVP)[1,6]
- Importer whose Very Small Foreign Supplier required to comply with Sprout Requirements of Produce Safety Rule

SEP 17, 2019 (PCAF)[2,3,5]
- Qualified Facilities (including Very Small Businesses) PC Compliance

2020

JAN 27, 2020 (PS)
- Large Farms (all provisions)

JAN 27, 2020 (PS)[1]
- Very Small Farms (except water)

MAR 17, 2020 (FSVP)[1,6]
- Importer of animal food whose Qualified Foreign Supplier (including Very Small Foreign Suppliers) is subject to PCAF CGMP requirements

JUL 26, 2020 (IA)
- Small Business

JUL 27, 2020 (FSVP)[1,6]
- Importer whose Very Small Foreign Supplier subject to Produce Safety Rule and eligible for a Qualified Exemption

2021

JAN 26, 2021 (PS)
- Small Farms (all provisions)

JUL 26, 2021 (IA)
- Very Small Business

2022

JAN 26, 2022 (PS)
- Very Small Farms (all provisions)

- Produce Safety Regulation (PS)
- Preventive Controls Human Food (PCHF)
- Preventive Controls Animal Food (PCAF)
- Foreign Supplier Verification Program (FSVP)
- Intentional Adulteration (IA)
- Sanitary Transportation of Food (ST)

CGMP = Current Good Manufacturing Practices
PC = Preventive Controls
PMO = Pasteurized Milk Ordinance

1. Except for certain provisions concerning written customer assurances. Additional two years to comply with these specific requirements.
2. Except for facilities that only pack and/or hold raw agricultural commodities that are produce and/or nut hulls and shells. Compliance date for these facilities extended approximately 16 months to match the compliance dates for businesses in the same size categories in the produce safety regulation.
3. Except for facilities that would qualify as a secondary activities farm except that they do not meet the ownership criterion. Compliance date for these facilities extended approximately 16 months to match the compliance dates for businesses in the same size categories in the produce safety regulation.
4. Except for facilities that color raw agricultural commodities. Compliance date for these facilities extended approximately 16 months to match the compliance dates for businesses in the same size categories in the produce safety regulation.
5. Except for facilities solely engaged in the ginning of cotton. Compliance date for these facilities extended approximately 16 months to match the other extension dates that relate to the "farm" definition.
6. Except for the importation of food contact substances. Additional two years to comply with the FSVP requirements.

+lsu +fsma compliance dates

From https://www.lsuagcenter.com/topics/food_health/food/safety/food%20safety%20modernization%20act

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"Quality assurance has become a **cornerstone of food safety policy** in the food industry [which has] started to implement integrated quality and food safety management systems."

Aung, M. M., & Chang, Y. S. (2014). Traceability in a food supply chain: Safety and quality perspectives. *Food Control*, 39, 172-184.

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2: Quality Management for Food Safety

how HACCP/HARPC, ISO 22000, ISO/TS 22002, FSSC 22000, PRPs, GMP & GFSI recognized schemes work together

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GFSI Recognized Schemes

	AI. Farming Of Animals	AII. Farming Of Fish	BI. Farming Of Plants	BII. Farming Of Grains And Pulses	C. Animal Conversion	D. Pre-Processing Handling of Plant Products	EI. Processing Of Animal Perishable Products	EII. Processing Of Plant Perishable Products	EIII. Processing Of Animal And Plant Perishable Products (Mixed Products)	EIV. Processing Of Ambient Stable Products	F. Production Of Feed	G. Food Service	H. Retail And Wholesale	J. Provision Of Storage And Distribution Services	L. Production Of (Bio) Chemicals	M. Production Of Food Packaging	N. Food Broker/ Agent
BRC					**Standard:** BRC Global Standard for Food Version 7 **Date of Recognition:** 05/03/2018 **Benchmark Leader:** Moreno Giordani									**Standard:** BRC Global Standard for Storage and Distribution Version 3 **Date of Recognition:** 05/03/2018 **Benchmark Leader:** Moreno Giordani	**Standard:** BRC Global Standard for Food Version 7 **Date of Recognition:** 05/03/2018 **Benchmark Leader:** Moreno Giordani	**Standard:** BRC Global Standard for Packaging and Packaging Materials and Distribution Version 5 **Date of Recognition:** 05/03/2018 **Benchmark Leader:** Moreno Giordani	**Standard:** BRC Global Standard for Agents and Brokers Version 2 **Date of Recognition:** 05/03/2018 **Benchmark Leader:** Moreno Giordani
CanadaGAP			**Standard:** CanadaGAP Version 7.1 (option B, C, D) **Date of Recognition:** 20/06/2018 **Benchmark Leader:** Susan Ranck			**Standard:** CanadaGAP Version 7.1 (option B, C, D) **Date of Recognition:** 20/06/2018 **Benchmark Leader:** Susan Ranck											
FSSC22000					**Standard:** ISO 22000:2005, Pre-requisite: ISO/TS 22002-1:2009, FSSC22000 additional requirements: Part II 2.1.4 **Date of Recognition:** 04/10/2018 **Benchmark Leader:** Katharine Smithers						**Standard:** ISO 22000:2005, Pre-requisite: NEN/NTA 8059:2016, FSSC22000 additional requirements: Part II 2.1.4 **Date of Recognition:** 04/10/2018			**Standard:** ISO 22000:2005, Pre-requisite: ISO/TS 22002-1:2009, FSSC22000 additional requirements: Part II 2.1.4 **Date of Recognition:** 04/10/2018	**Standard:** ISO 22000:2005, Pre-requisite: ISO/TS 22002-4:2013, FSSC22000 additional requirements: Part II 2.1.4 **Date of Recognition:** 04/10/2018	
GAA							**tion:** 16/05/2013 **Benchmark Leader:** Steven Homer										
GlobalGAP		**Standard:** IFA Aquaculture **Date of Recognition:** 21/01/2019 **Benchmark Leader:** Anne Farouk	**Standard:** IFA Fruits and Vegetables **Date of Recognition:** 21/01/2019 **Benchmark Leader:** Anne Farouk			**Standard:** IFA Fruits and Vegetables **Date of Recognition:** 21/01/2019 **Benchmark Leader:** Anne Farouk											
GRMS					**Standard:** GRMS Version 6 **Date of Recognition:** 06/12/2018 **Benchmark Leader:** Marc Gehlkopf		**Standard:** GRMS Version 6 **Date of Recognition:** 06/12/2018 **Benchmark Leader:** Marc Gehlkopf										
IFS					**Standard:** IFS Food Version 6.1 **Date of Recognition:** 30/07/2018 **Benchmark Leader:** Moreno Giordani									**Standard:** IFS Logistics Version 2.2 **Date of Recognition:** 30/07/2018 **Benchmark Leader:** Moreno Giordani	**Standard:** IFS Food Version 6.1 **Date of Recognition:** 30/07/2018 **Benchmark Leader:** Moreno Giordani	**Standard:** IFS PACSecure 1.1 **Date of Recognition:** 30/07/2018 **Benchmark Leader:** Moreno Giordani	
Primus			**Standard:** PrimusGFS Version 3 **Date of Recognition:** 20/06/2018 **Benchmark Leader:** Susan Ranck			**Standard:** PrimusGFS Version 3 **Date of Recognition:** 20/06/2018 **Benchmark Leader:** Susan Ranck		**Standard:** PrimusGFS Version 3 **Date of Recognition:** 20/06/2018 **Benchmark Leader:** Susan Ranck						**Standard:** PrimusGFS Version 3 **Date of Recognition:** 20/06/2018 **Benchmark Leader:** Susan Ranck			
SQF	**Standard:** SQF Food Safety Code for Primary Production Version 8 **Date of Recognition:** 13/09/2018 **Benchmark Leader:** Susan Ranck		**Standard:** SQF Food Safety Code for Primary Production Version 8 **Date of Recognition:** 13/09/2018 **Benchmark Leader:** Susan Ranck		**Standard:** SQF Food Safety Code for Manufacturing **Date of Recognition:** 13/09/2018 **Benchmark Leader:** Susan Ranck									**Standard:** SQF Food Safety Code for Storage and Distribution Version 8 **Date of Recognition:** 13/09/2018 **Benchmark Leader:** Susan Ranck	**Standard:** SQF Food Safety Code for Manufacturing **Date of Recognition:** 13/09/2018 **Benchmark Leader:** Susan Ranck	**Standard:** SQF Food Safety Code for Manufacturing **Date of Recognition:** 13/09/2018 **Benchmark Leader:** Susan Ranck	

https://www.mygfsi.com/files/CPO_printable-version_2.pdf

- FSSC 22000
- SQF Code Ed. 8
- BRC Global Standard for Food Safety
- BRC-IOP Global Standard for Packaging and Packaging Materials
- IFS Version 6
- CanadaGAP
- Global Red Meat Standard (GRMS)
- PrimusGFS Standard
- IFS PACsecure Version 1
- IFS Logistics Version 2.1
- JFSM
- AsiaGAP

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ELEMENTS OF ALL GFSI RECOGNISED SCHEMES

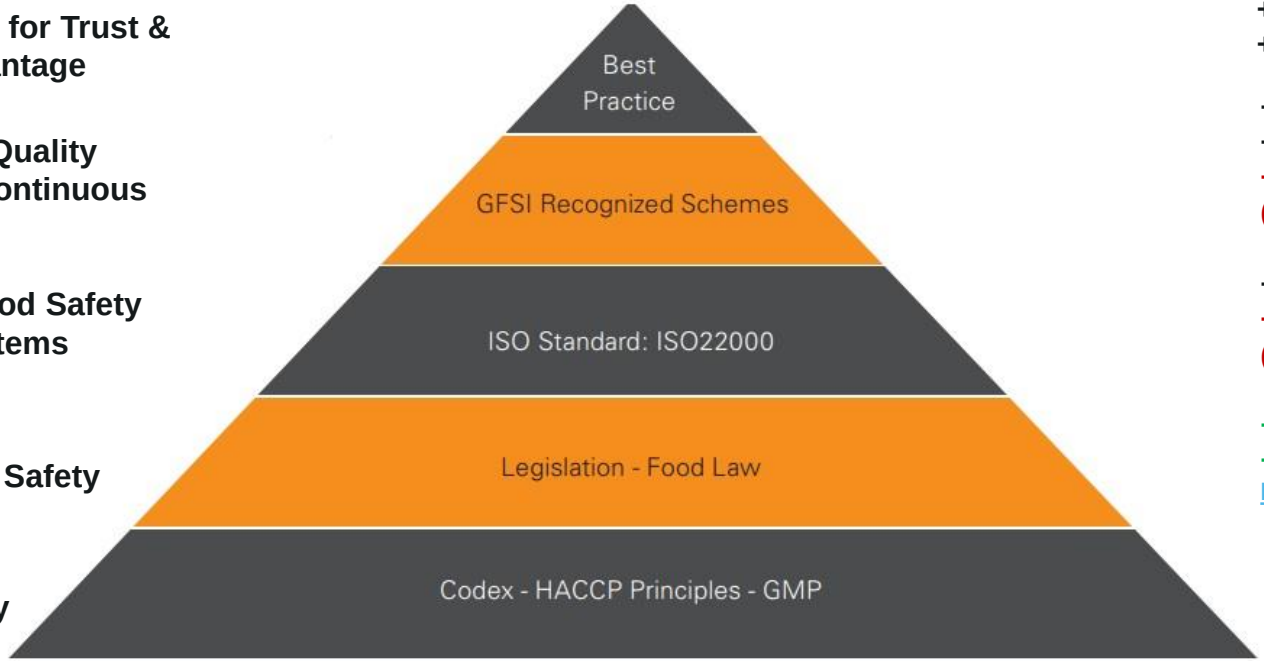
New Mechanisms for Trust & Competitive Advantage

Incorporation of Quality Management & Continuous Improvement

Guidelines for Food Safety Management Systems

Legally Mandated Requirements for Safety

Antecedents of Safety and Quality



+ New Science
+ Traceability/Blockchain

+ IFS (QMS+ENV+SR)
+ BRC (FSMS+QMS)
+ SQF Level 3 (HACCP+FSMS+QMS)

+ FSSC 22000 (FSMS)
+ SQF Level 2 (HACCP+FSMS)

+ FDCA (1938)
+ FSMA (2011)
http://www.ecfr.gov

+ PRPs (e.g. ISO 22002)
+ GMPs (e.g. 21 CFR 110)
+ HARPC (21 CFR 117)
+ SQF Level 1

Source: GFSI: Enhancing Food Safety Through Third Party Certifcation

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Relationship Between EHS, Quality, & Food Safety

EHS role works to keep **WORKERS & THE ENVIRONMENT** safe, without negatively impacting production speed or product quality.

Quality role works to keep **THE PRODUCT** safe, while managing systematic, repeatable processes that satisfy operations goals (e.g. yield) and product quality requirements (e.g. taste, value).

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TQM	ISO 9000:2000-QMS	HACCP	ISO 22000-FSMS
• Focus on customer • Leadership • Let everybody be committed • Approaching of process • Focus on system management • Continuous development • Reality approaching • Cooperation with suppliers	• Customer focus • Leadership • Involvement of people • Process approach • System approach to management • Continual improvement • Factual approach to decision making • Mutually beneficial supplier relationships	• Hazard analysis • Critical control points (CCPs) • Critical limits • Monitoring procedures • Corrective actions • Verification procedures • Documentation procedures	• Customer focus • Leadership and team work • Involvement of people • Process approach and food safety • System approach to management • Continual improvement • Factual approach to decision making • Mutually beneficial supplier relationships • Legislation, regulations • Science and experience • Interactive communication

Table 1. The Principles of TQM, ISO 9000:2000-QMS, ISO 22000-FSMS and HACCP

Quality

Food Safety

	Strategic	Operational	Support
ISO 9000:2000-QMS	QP.1 Market Research and Customer Relation QP.2 Internal Communications QP.3 Document and record Control QP.4 Planning QP.5 Resources Management	QP.6 Product Design QP.7 Food Manufacturing	QP.8 Purchasing QP.9 Internal Audit QP.10 Data Analysis QP.11 Maintenance of measurement's and process equipments QP.12 Calibration of measurement's equipment
ISO 22000:2005-FSMS	PR.1 Construction and lay-out of buildings and associated utilities PR.2 Lay-out of premises, including workspace and employee facilities PR.3 The suitability of equipment and its accessibility for cleaning, maintenance and preventative maintenance	PR.4 Supplies of air, water, energy and other utilities PR.5 Supporting services, including waste and sewage disposal PR.6 Cleaning and sanitizing PR.7 Pest control PR.8 Personnel hygiene PR.9 Measures for the prevention of cross contamination	PR.10 Management of purchased materials (e.g. raw materials, ingredients, chemicals and packaging), and supplies

Q

F S

QP: Quality Process, PR: Pre-requisite

Table 2. Some quality processes and prerequisite programs

Dalgiç, A. C., Vardin, H., & Belibagli, K. B. (2011). Improvement of Food Safety and Quality by Statistical Process Control (SPC) in Food Processing Systems: A Case Study of Traditional Sucuk (Sausage) Processing. In *Quality Control of Herbal Medicines and Related Areas*. IntechOpen.

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FSMA & ISO 9001:2015 Incorporate Risk-Based Thinking

Risk-based thinking is introduced to make **better decisions** in uncertain environments:

- Reduce frequency of losses
- Reduce likelihood of losses
- Reduce costs of losses
- Improve response time
- Reduce stress
- Increase communication
- Enhance learning
- Capture opportunities for improvement

From Willumsen, P., Oehmen, J., Rossi, M., & Welo, T. (2017). Applying lean thinking to risk management in product development. In Proc. 21st Intl. Conf. on Engr. Design (ICED 17), Vancouver, 269-278.

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FSMA Cornerstone is Food Safety Plan (FSP)

Walsh, C., & Leva, M. C. (2018). A review of human factors and food safety in Ireland. *Safety Science.*

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HACCP is an internationally recognized standard for hazard analysis to:

- Ensure sanitary conditions for manufacturing, processing, packaging and storage
- Prevent post-process contamination
- Deliver safe, wholesome food with no visible deterioration in quality

HARPC is a FSMA-driven update to HACCP that:

- Adds risk-based thinking and risk management
- Emphasizes the need to continuously monitor and improve GMPs and PRPs

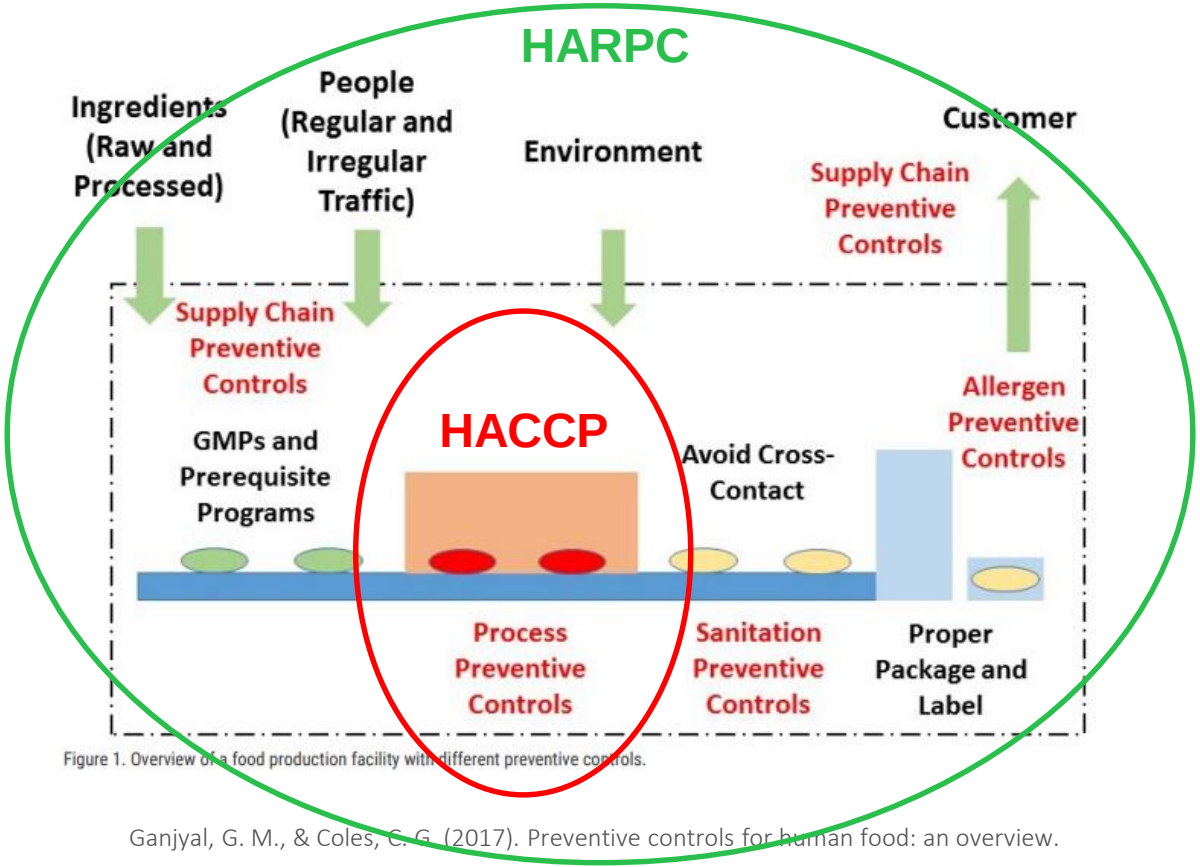

Figure 1. Overview of a food production facility with different preventive controls.

Ganjyal, G. M., & Coles, C. G. (2017). Preventive controls for human food: an overview.

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international standard

HACCP

prescribed by FSMA (21 CFR Part 117)

HARPC

Assumes PRPs in place

- Process Controls
  - Cooking, refrigeration
  - Controls during storage or transport
- Biological, Chemical, & Physical Hazards

+

Assumes no PRPs in place

- Supply Chain Controls
- Allergen Controls
  - Cross-contact & labeling
- Sanitation Controls
- Radiological (e.g. contaminated soil)
- Economically Motivated (e.g. fillers)

- GMPs are regulated and PRPs are not; 21 CFR Part 117 specifies required GMPs
- Food fraud, under FDA, only addresses hazards that would impact food safety; intentional sabotage by an insider must also be considered
- You can refer to all Preventive Controls in your FSP as Critical Control Points
- Food Safety Plan Parameters/Values can be categorical (Pass/Fail) – unlike CCPs

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Table 4
Hazard analysis of ice cream conducted in the MAZAFROID.

Process steps	Hazards	Types	Causes (5 M's)[a]	P[b]	S[c]	P × S	Decision tree[d]					Preventive measures	Record
							Q[e]1	Q.2	Q.3	Q.4	Q.5		
Reception	Physical: foreign bodies (wood, hair, etc.)	C[f]	Material (raw material/ packaging material)	5	1	5	Yes	Yes	No	Yes	Yes	Visual inspection	PRP
Pasteurization	Biological: pathogenic microorganisms	P	Method	1	5	5	Yes	Yes	Yes			Monitoring of time and temperature of pasteurization (80°C/25s)	CCP 03
Cooling	Biological: pathogenic microorganisms	M	Method	1	5	5	Yes	Yes	Yes			Monitoring of temperature and time profile of cooling post-pasteurization (4 °C within 1.5 h)	CCP 04
Flavour and colorant addition	Physical: foreign bodies (hair …)	C	Man power	1	1	1	No					Staff hygiene control.	PRP
	Biological: pathogenic microorganisms	C	Raw material/ Man power/ Machine	1	5	5	Yes	Yes	No	Yes	No	Control of expiry date before use. Staff hygiene control. Respect cleaning and disinfection programme	PRP
Aging	Biological: pathogenic microorganisms	M	Method	1	5	5	Yes	Yes	No	Yes	No	Monitoring of time and temperature of aging (4 °C/24 h)	oPRP 01
Freezing with air incorporation	Chemical: air compressor oil	C	Machine	1	1	1	No					calibration of centrifugal machine and change of de-oiling filter of air compressor periodically	PRP
	Biological: pathogenic microorganisms	C	Raw material (air)	2	1	2	No					Filtration and sterilization of air incorporated	PRP
Packaging/ labelling	Chemical: packaging materials substances	C	Material	1	1	1	No					Specifications of packaging materials.	PRP
	Biological: pathogenic microorganisms	C	Material (packaging material)/Man power	1	5	5	Yes	Yes	No	Yes	No	Implementation of GHP. Staff hygiene control. Specifications of packaging materials. Storage in controlled area	PRP
	Allergens: milk proteins, lactose	C	Method	1	2	2	No					Mention of allergen on label. Staff training and label inspection.	PRP
Hardening	Biological: pathogenic microorganisms	C	Machine	1	5	5	Yes	Yes	No	No		Regular cleaning and disinfection	PRP
Storage of ice cream	Biological: pathogenic microorganisms	M	Method (process)	1	5	5	Yes	Yes	Yes			Monitoring of refrigerator temperature (≤−18 °C)	CCP 05
Transport	Biological: pathogenic microorganisms	M	Method (process)	1	5	5	Yes	Yes	Yes			Monitoring of ice cream transport truck temperature (≤-18 °C)	CCP 06

[a] 5 M's, Material (raw), Machine (technology), Mother Nature (environment), Man power (physical work), Method (process).
[b] P, probability.
[c] S, severity.
[d] The five questions can be found in Fig. 2.
[e] Q, Question.
[f] C, Contamination.
[g] M, Multiplication.
[h] P, Persistance.

Allata, S., Valero, A., & Benhadja, L. (2017). Implementation of traceability and food safety systems (HACCP) under the ISO 22000: 2005 standard in North Africa: The case study of an ice cream company in Algeria. Food control, 79, 239-253.

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Is it a CCP, PRP, or oPRP?

A Decision Tree

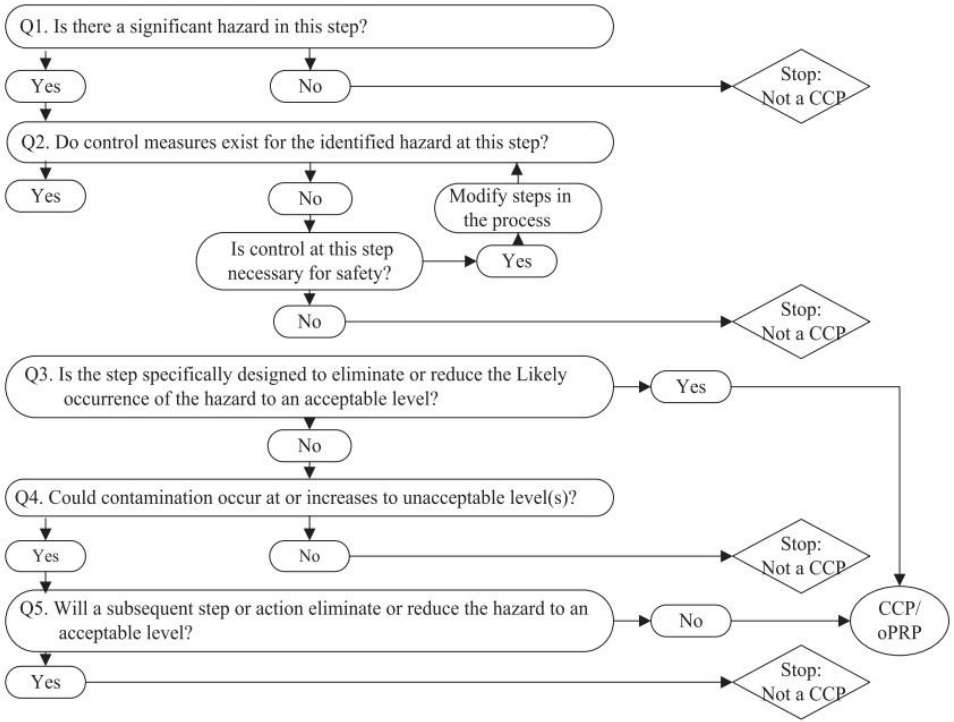
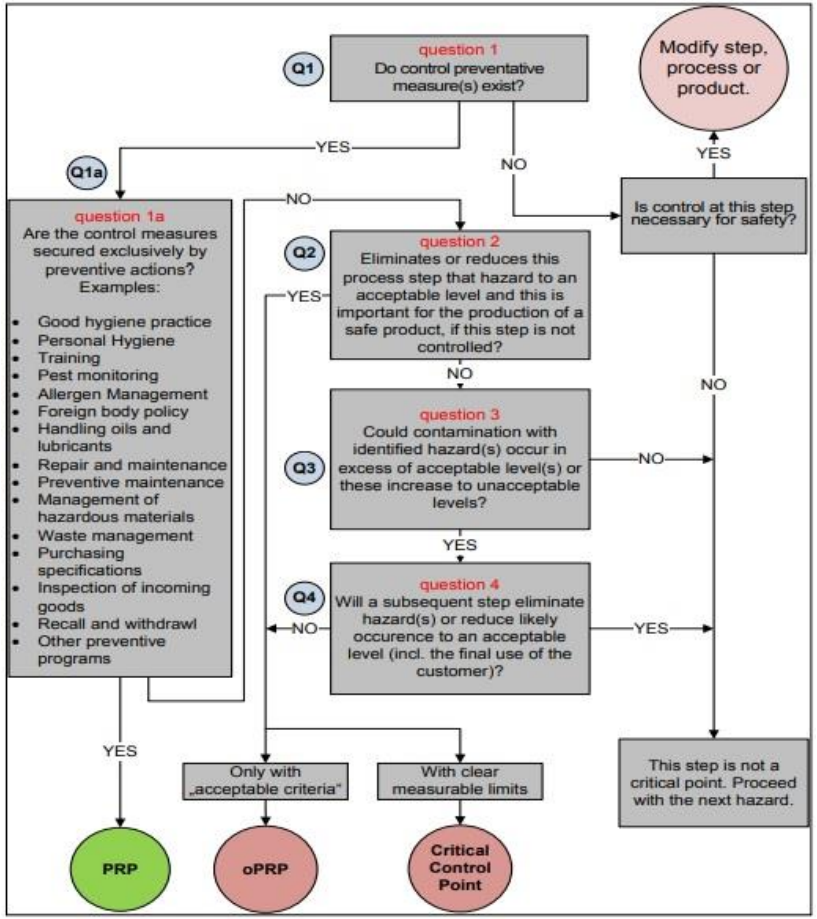


Fig. 2. Decision tree for HACCP implementation adopted from Horchner et al. (2006).



From https://www.safefood-online.de/en/download.php?id=15

Allata, S., Valero, A., & Benhadja, L. (2017). Implementation of traceability and food safety systems (HACCP) under the ISO 22000: 2005 standard in North Africa: The case study of an ice cream company in Algeria. Food control, 79, 239-253.

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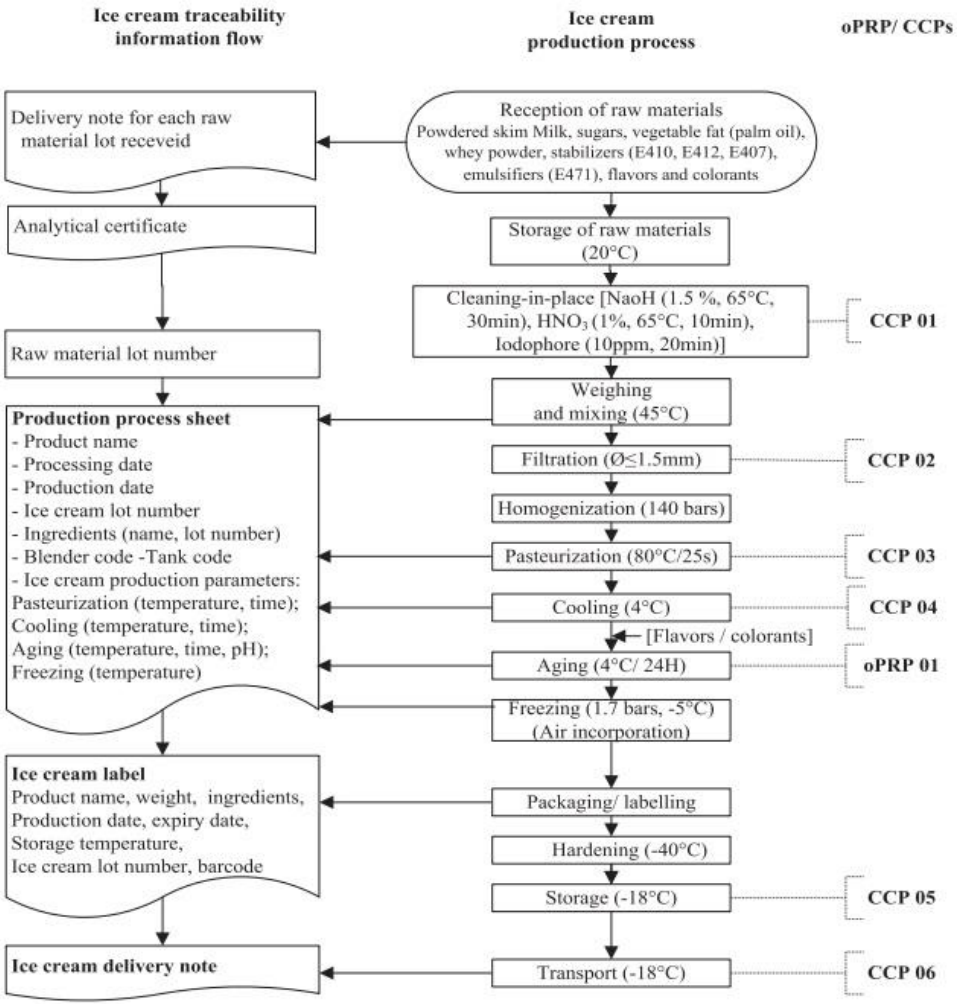

Fig. 1. The elaboration process of ice cream and the traceability information flow. CCP: Critical Control Point; oPRP: Operational Prerequisite Program.

The Process is the Centerpiece

Preventive Controls form the basis of the control plan, from which individual records regarding monitoring requirements are identified

Traceability can be assured by examining all steps of the process and devising a recordkeeping process that incorporates all factors from PCs

(Traceability does not span full supply chain)

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FMEA Can Be Used to Identify PCs

Table 4
Abstract of HACCP plan with integrated FMEA preventive actions

Phase	Hazard	FMEA preventive actions	HACCP control
Wafer cooling	Anomalous aspect (colour, shape, etc.)	Operative instructions about cooling parameters and controls	Visual inspection by group lead
Primary packaging	Incorrect propriety of stamped data (shelf-life, special information)	Definition of stamp life and periodical substitution	Visual inspection by group lead
Primary packaging	Inadequate package shape and integrity	Preventive control of integrity and position of wrapping paper reel Operative instructions of wrapping paper calibration	Visual inspection by group lead

Scipioni, A., Saccarola, G., Centazzo, A., & Arena, F. (2002). FMEA methodology design, implementation and integration with HACCP system in a food company. *Food Control*, 13(8), 495-501.

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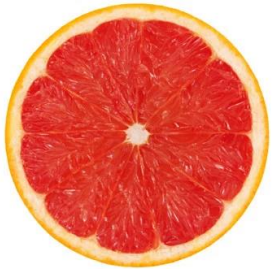
“HACCP areas posing the greatest risk to food safety were verification, recordkeeping and correction action. Nonconformities were found in HACCP systems which worked for several years. This raises the question whether food producers who implemented HACCP system really guarantee complete food safety… **incorporation of FMEA within the verification procedure of HACCP system** may be a convenient tool for better food safety assurance.”

Trafialek, J., & Kolanowski, W. (2014). Application of Failure Mode and Effect Analysis (FMEA) for audit of HACCP system. *Food Control*, 44, 35-44.



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3: Importance of Communication

maintaining transparency and visibility across organizational boundaries in the supply chain can prevent errors & disasters

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"An on-site audit [requires gathering up-to-date **information**,] **communication of results** and [sharing] observations among team members and with the auditee."

"QMS can reduce the appearance of defective products… **improve internal communication**, increase customer's satisfaction, and therefore [market share, increasing] opportunities for expansion in new markets."

Kotsanopoulos, K. V., & Arvanitoyannis, I. S. (2017). The role of auditing, food safety, and food quality standards in the food industry: A review. *Comprehensive Reviews in Food Science and Food Safety*, 16(5), 760-775.

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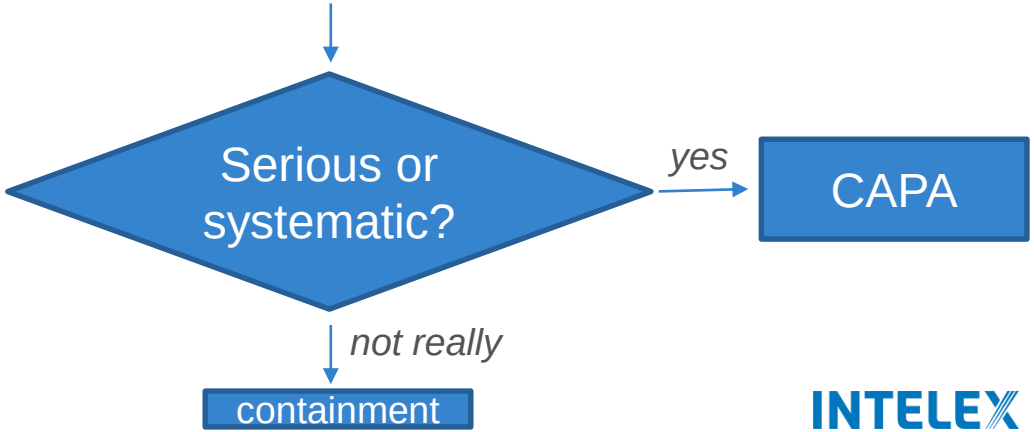
Quality Events

indicate that quality & food safety goals are not being met and action is needed

- Nonconforming product
- Incidents/near misses
- Customer complaints
- Recalls/warranty calls
- Deviations (from SOP)
- Out-of-control Action Plans
- Industry-specific events (e.g. recalls)



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Quality Controls

to prevent or correct unwanted or unexpected change → stability and consistency

- Calibrations
- Maintenance
- Inspections
- Allergen & sanitation controls
- Supply chain controls
- Process validation
- Mistake-proofing
- In-situ process monitoring
- Environment monitoring
- Professional testing/competency assessment
- Training programs and reminders
- Corrective actions taken
- Information security/network security

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Corrective Actions are the Core

Many different kinds of corrective actions are required to maintain food safety and quality, while continuously improving:

- Supplier CAR
- Customer CAR
- CAR for nonconforming product
- CAR for deviation(s) from process
- CAR for inadequate PRP
- CAR for allergen or sanitation issue
- CAR for supply chain controls
- CAR for inadequate/ineffective CCP/PC
- Internal Audit CAR
- Supplier Audit CAR

IFS. (2017, November). IFS Food: Standard for auditing quality and food safety of food products. Version 6.1.

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Table 4.8 Activities through which top management shall ensure the improvement of the system and examples of those activities

Activities	Examples
Communication	Ensure that there is sufficient external information available to update the FSMS. Guarantee that issues that have an impact on food safety are communicated with personnel.
Management review	The output of the FSMS performance evaluation should include decisions for its improvement. New food safety objectives and updated food safety policy.
Internal audits	Results from internal audits shall be discussed in the management review or even force the management to take immediate action (corrections or corrective actions) related to the identification of nonconformities.
Evaluation of individual verification results	Review of the training plan or PRP(s) found necessary after results of the verification activities.
Analysis of results of verification activities	Take action after identifying a trend that can generate potentially unsafe products.
Validation of the combinations of control measures	Change control measures or define new combinations when validation fails to prove its effectiveness.
Corrective actions	Take actions to eliminate the cause of a nonconformity and guarantee that the problem is not repeated in the future.

Soares, N., Martins, C., & Vicente, A. A. (2016). Food safety management system EN ISO 22000: 2005. Available from https://repositorium.sdum.uminho.pt/bitstream/1822/56460/1/document_29693_1.pdf

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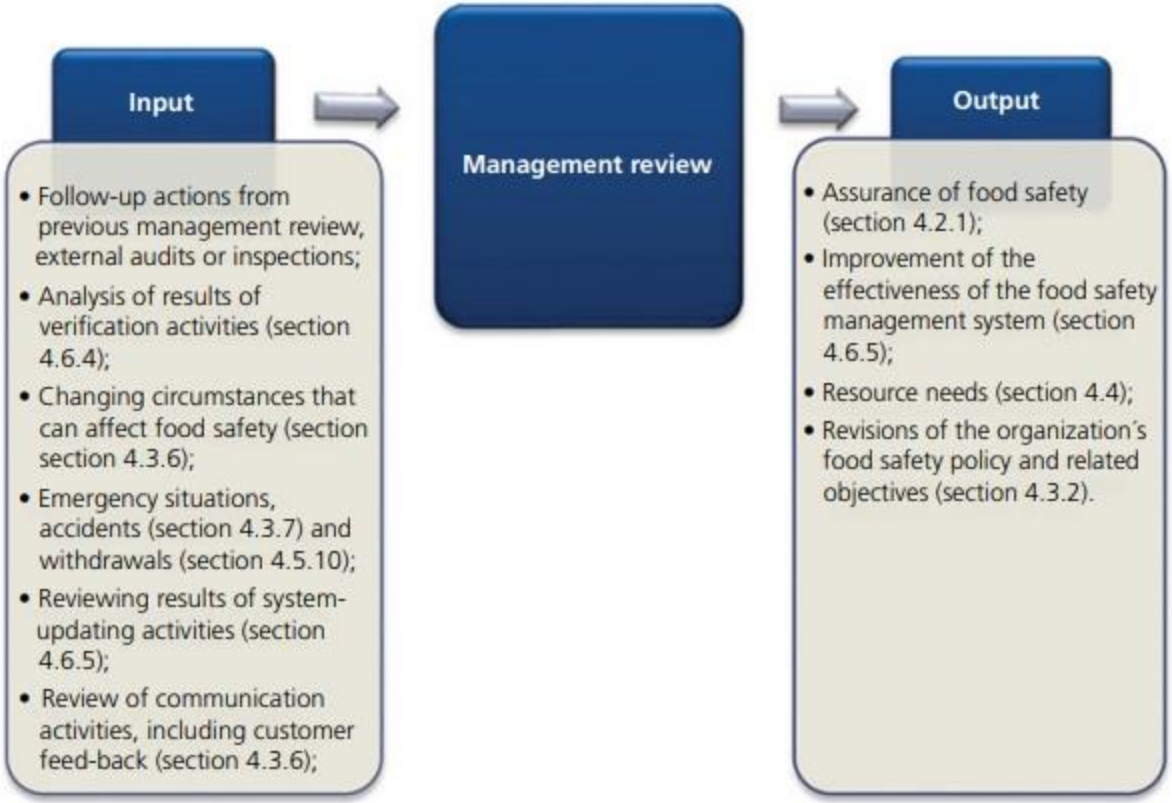

Figure 4.8 Management review input information and output decisions.

Soares, N., Martins, C., & Vicente, A. A. (2016). Food safety management system EN ISO 22000: 2005. Available from https://repositorium.sdum.uminho.pt/bitstream/1822/56460/1/document_29693_1.pdf

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"An **accurate and complete transmission of information** between the food chain and external stakeholders will ensure, in a more efficient way, the identification and control of all relevant risks to food safety."

- Share information about food safety throughout the food chain and inside the organization
- Inform the Food Safety Team (FST) of any change that may compromise food safety
- Provide faster update(s) and distribution of new documentation, [provides automatic] evidence of [changes]…

Soares, N., Martins, C., & Vicente, A. A. (2016). Food safety management system EN ISO 22000: 2005. Available from https://repositorium.sdum.uminho.pt/bitstream/1822/56460/1/document_29693_1.pdf

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4: Emerging Technologies for Traceability

how IBM Food Trust has demonstrated that
Hyperledger blockchain can add value in this industry

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Traceability

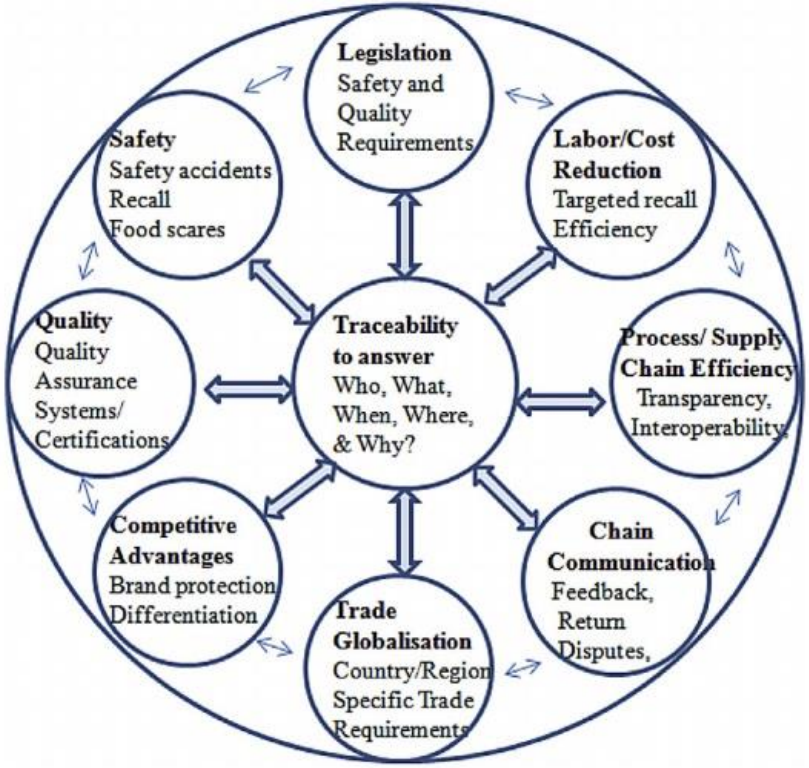

Fig. 1. Drivers for traceability of food supply chain.

Aung, M. M., & Chang, Y. S. (2014). Traceability in a food supply chain: Safety and quality perspectives. *Food Control*, 39, 172-184.

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Blockchain Depends on Hashing

- Convert an object to a sequence of letters and numbers *from which you can't recover the original object*
- Lots of hashing algorithms:
  - MD5, SHA1, CRC32, **SHA256**, SHA512, XXHASH32, MURMUR32
- Goal is to "minimize collisions"

```
> phrase <- "Here is my password"
> digest(phrase, "crc32")
[1] "61835063"
> digest(phrase, "murmur32")
[1] "611907fc"
> digest(phrase, "md5")
[1] "6303034c25d4e1763f2dd30341ddb0d5"
```

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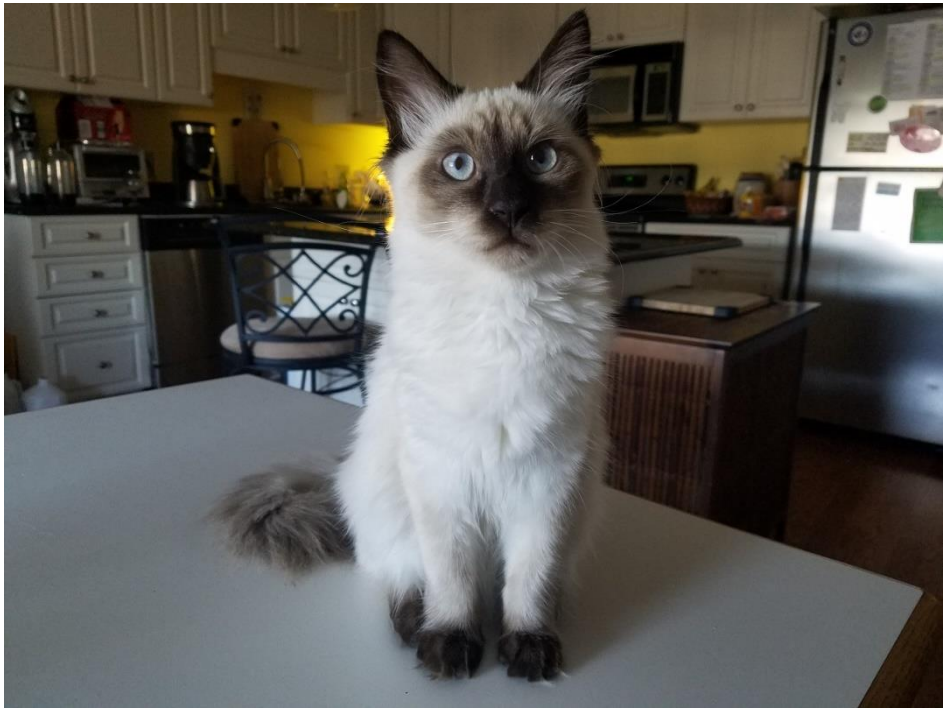
Hash My Cat

```
> kitty <- readJPEG("kitty.jpg")
> digest(kitty, "sha256")
[1]
"dcd239ba6a09080eb61b7310a5428753
f63d05ae2b282bf81dc0182f7552f60d"
```



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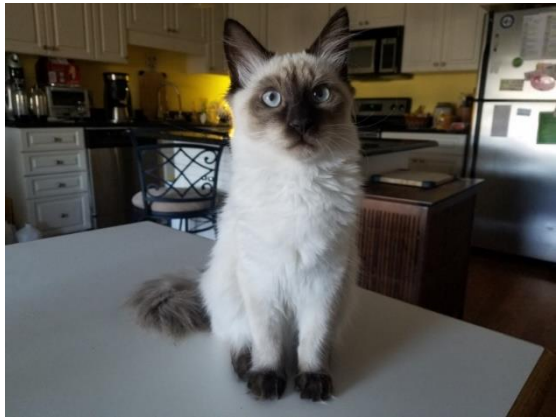
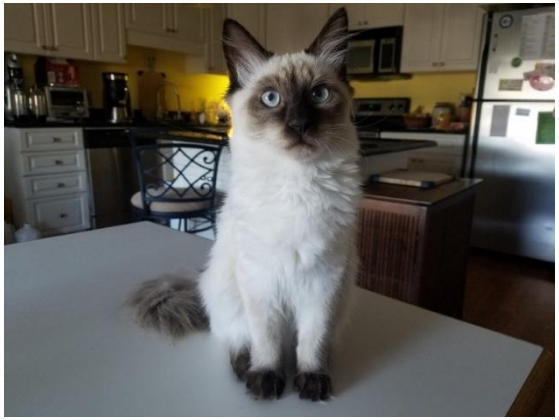
Hash My Cat

1





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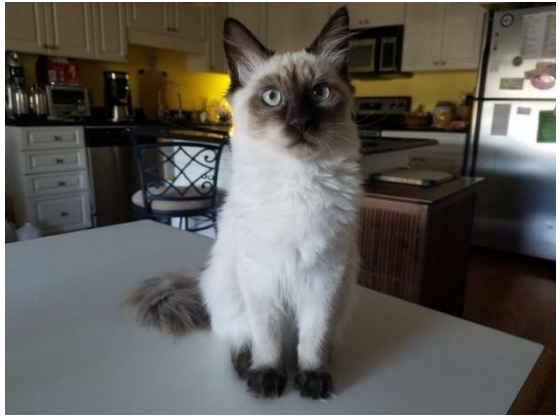

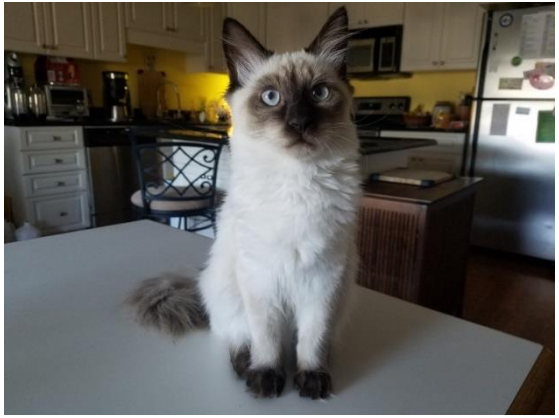

4

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Small changes in an object →

Large change in a hash →

“Break” a blockchain

```
> digest(kitty, "sha256")
[1]
"dcd239ba6a09080eb61b7310a5428753f63d
05ae2b282bf81dc0182f7552f60d"

> digest(kitty2, "sha256")
[1]
"dcd239ba6a09080eb61b7310a5428753f63d
05ae2b282bf81dc0182f7552f60d"

> digest(kitty3, "sha256")
[1]
"fe5791ee490693d7d7b25379278b2374c3af
da25c76aec5f3aa17e7e8b184362"

> digest(kitty4, "sha256")
[1]
"dcd239ba6a09080eb61b7310a5428753f63d
05ae2b282bf81dc0182f7552f60d"
```

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Blockchain Data Structure

From https://www.slideshare.net/IBMDevOpsforEnterpriseSystems/making-blockchain-real-for-business-at-the-z-systems-agile-enterprise-development-conference-2016

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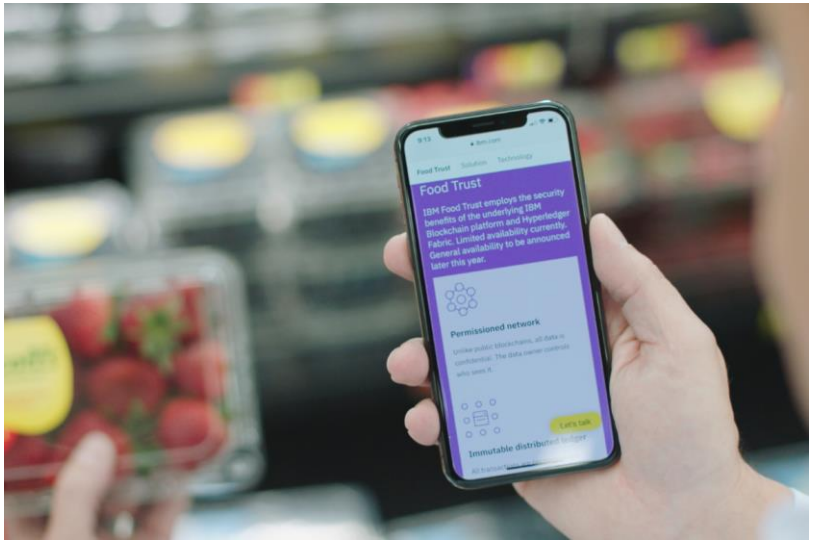
Blockchain Value Propositions

- Immutable record of peer-to-peer transactions
- Relief from a central authority
- Transparent recordkeeping
- Private channels to protect data privacy
- *Immediately auditable*

HYPERLEDGER



- Requires modeling:
  - Participants
  - Assets
  - Transactions
  - Conditions for Transactions ("Smart Contracts")

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"… in the end it is all about how organizational insights and knowledge are turned into strategic insights and **advantage**."

-- Harry Hertz, Director Emeritus Baldrige Performance Excellence Program

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5: Advancing Your EHSQ Maturity with Software

moving to the next level

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FSMA Preparedness Risk Index

Information Management Tools	No Food Safety Management System	Ad Hoc System Partial Structure	SQF Level 1 & 2 HACCP-based Methodology	SQF Level 3 or equivalent
Streamlined, Centralized, Web-Based Management System	Somewhat Prepared (adopt a FSMS)	Somewhat Prepared (adopt a FSMS)	Very Well-Prepared	Extremely Well-Prepared
Word Processor, Spreadsheets, Sharepoint (or equivalent)	Unprepared	Unprepared	Somewhat Prepared	Meets Minimum Standard
Paper	Very Unprepared	Unprepared	Somewhat Prepared	Somewhat Prepared
Little to No Documentation (no defined system)	Extremely Unprepared	Very Unprepared	N/A	N/A
	Food Safety Management System (FSMS)			

Leavoy, P. (2013). The Essential Guide to the Food Safety Modernization Act (FSMA): Everything You Need to Know About America's Coming Food Safety Revolution. *Intelex Insight Report.*

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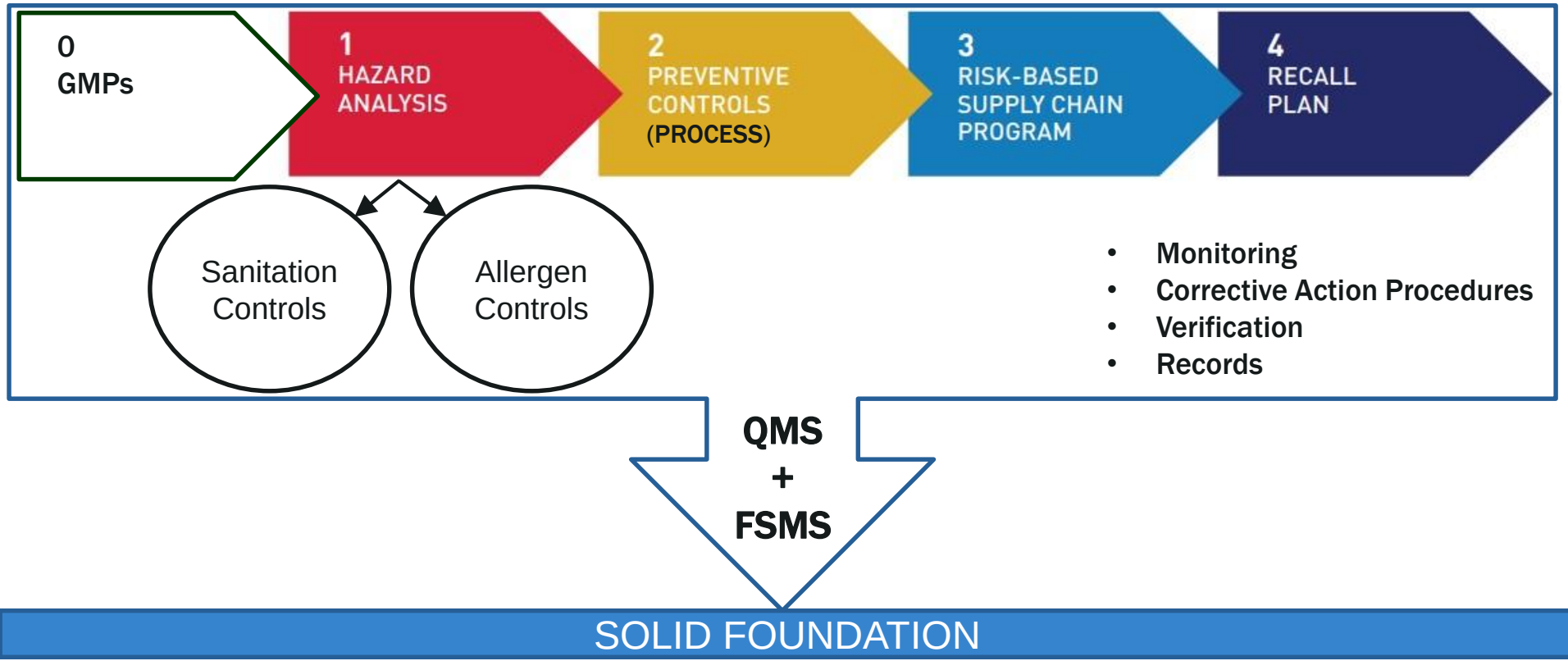

Adapted from FDA. (2016). Key Facts about Preventive Controls for Human Food (PCHF). Available from https://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm584807.pdf

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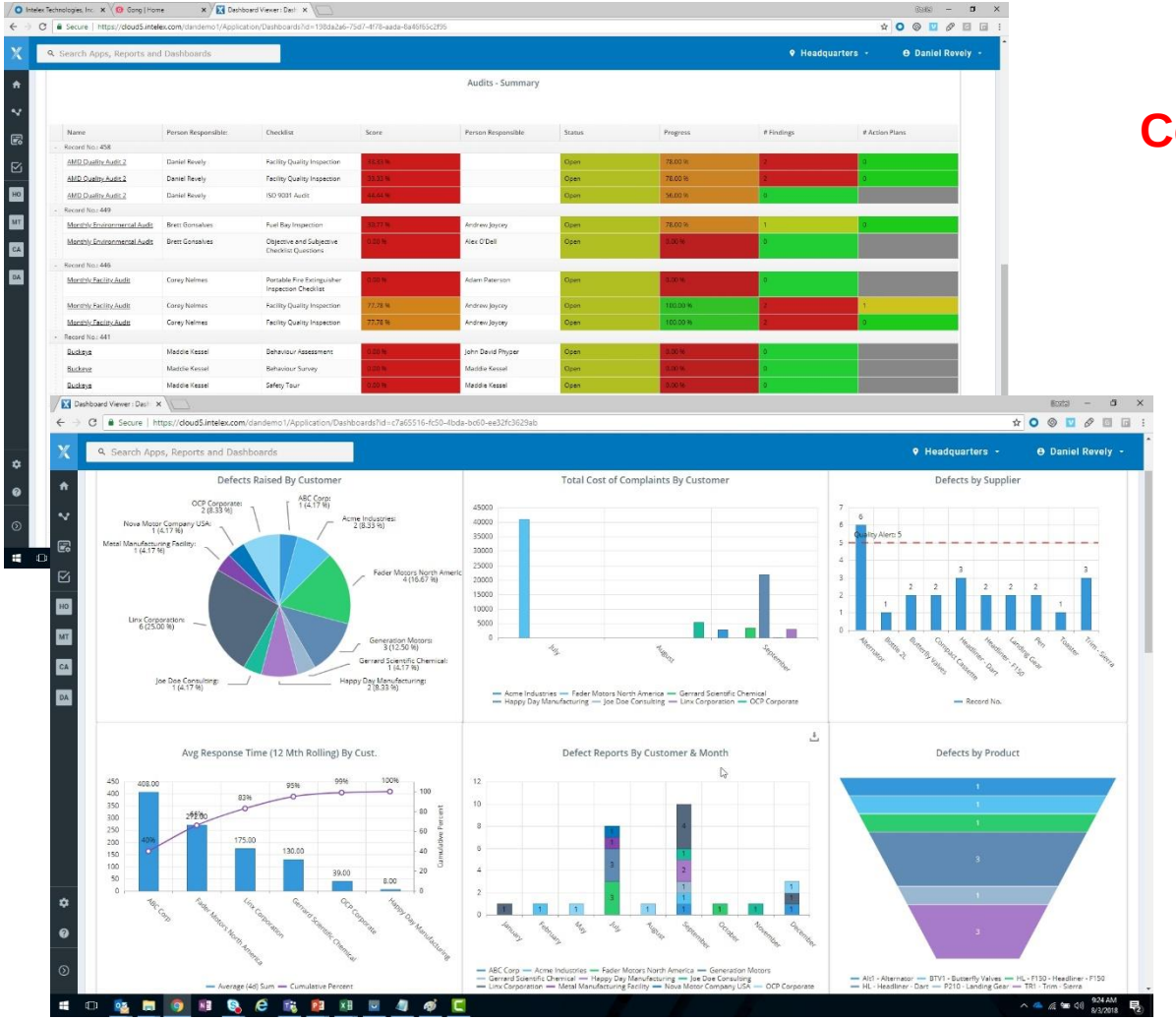
Software Support for Food Safety & Quality

Requirement	Application Type	Tasks
Document Control & Training Management	Document Control & Training Management	Always know which SOPs and work instructions are current, manage review and approval paths, make sure your PCQI(s) have up-to-date qualifications (21 CFR 117.8), see which staff need to be updated
Internal Audits	Audit & Inspection Management	Maintain checklists for ensuring PRPs/GMPs are met, manage and monitor inspections, monitor allergens, monitor process controls (e.g. cooking), keep track of receiving and loading
Maintain HACCP/HARPC Controls & Records	Process Hazard Analysis; Control Plan; Monitoring & Measurement	Identify process steps, hazards, and control plans; record calibration, maintenance, inspection, and preventive controls tasks
Manage Nonconformances & Complaints	Nonconformance Reporting (NCR); Customer Complaints	Track customer, internal, and supplier corrective nonconformances & complaints; automatically escalate according to rules & remind people when tasks and actions are upcoming or overdue
Manage Corrective Actions & Corrections	Corrective and Preventive Action (CAPA)	Track customer, internal, and supplier corrective actions and identify trends and patterns; keep track of minor (non-event) Corrections
Supplier Preventive Controls	Supplier Relationship Mgmt, Supplier CAPA	See which suppliers have failed audits, expired documents, or corrective actions that need attention; provide supplier portals
Change Management	Management of Change (MoC)	Keep track of improvements and adjustments to processes and preventive controls; validation, verification, continuous improvement



Step 1:
Computerization & Connectivity

Step 2:
Visibility & Transparency

Step 3:
Predictive Capability

Step 4:
Adaptability & Self-Learning

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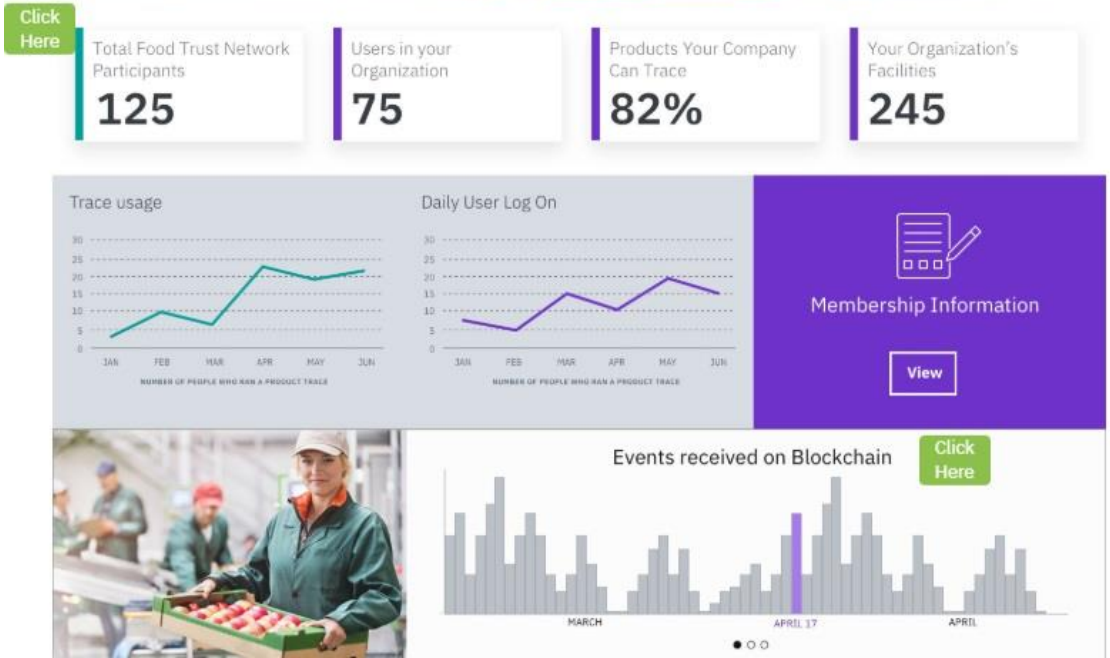

Step 1:
Computerization & Connectivity

Step 2:
Visibility & Transparency

Step 3:
Predictive Capability

Step 4:
Adaptability & Self-Learning

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Sonduren Fanarredha
Sr. Product Marketing Manager, Quality & Supplier
Moderator

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Challenges Now & in the Future

1. **Siloed data is insufficient** to identify trends and make informed decisions using real time insights within the organization and its supplier ecosystem

2. Ensuring all operations are in **Compliance** with ever changing standards, industry requirements and regulations

3. **Reduced Productivity** due to disparate systems and lack of integration between processes in the organization and through suppliers

4. Difficult to build a **Culture of Quality** without the right tools and partners

*Source: Intelex Quality Survey December 2016

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Intelex is the leader in EHSQ software

Most organizations begin their EHSQ journey with the objective of compliance in mind. Intelex helps you achieve more than compliance and cost avoidance by accelerating your EHSQ maturity progression, leading to business transformation.

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The Intelex Platform

The most powerful EHSQ platform on the market, it provides a robust and secure backbone to the Intelex system and the core management functionality upon which all Intelex solutions are built.

The Intelex Platform comes complete with the following components standard with every implementation:

- Mobile & Offline Capability
- Business Intelligence & Analytics
- Translation Workbench
- Document Control
- EHSQ Community
- API Access
- Root Cause Analysis
- Communications Management
- Meetings Management
- Audit Trail
- Electronic Signatures
- Single Sign On (SSO)
- Data Import Tool
- Navigator
- Image Mapping
- Support & Learning Portal

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Intelex QMS & Platform

Modernize and simplify your QMS

Alliance

Leverage the power of Engagement and Collaboration to unlock the full potential of your QMS

Integrated QMS

Integrated EHSQ solution to connect applications across our platform for a fully automated and tailored experience

Rich Reporting

Use preformatted and custom reports, graphs and scorecards for at-a-glance insights on all aspects of your business.

Mobile

Streamlined and simple user interface on mobile to put Intelex into the hands of people that matter most

Power of Cloud

Our cloud based EHSQ solution provides quick implementation time and cost savings

Intelex is the **only EHSQ** software with **a truly integrated quality management system** to help you manage the breadth of your business

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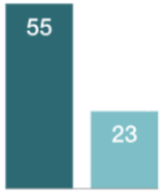
Transform to Survive

What leading companies do differently from the rest

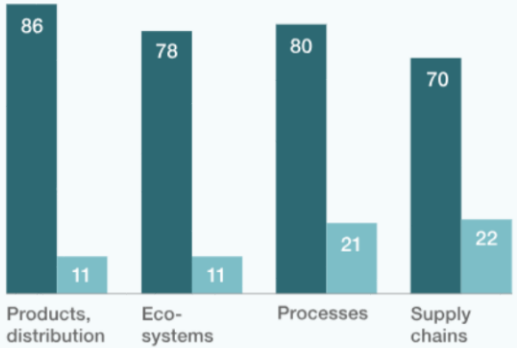
% of respondents[1]
(n = 2,135)

Winners Others

Ensure digital strategy is aligned with corporate strategy



Exercise high level of strategic response to digital change in:

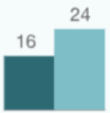


Avoid pitfalls in organization and culture

Have siloed mind-sets and behavior

Lack a common culture across business units

Lack a common view of their customers across the organization



McKinsey&Company

INTELEX

Angelica Lauriano - Panelist
Senior Account Executive – Food & Beverage
Intelex Technologies
Angelica.Lauriano@Intelex.com
LinkedIn: Angelica Lauriano
760-500-8066

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Food Safety & Quality Management Software

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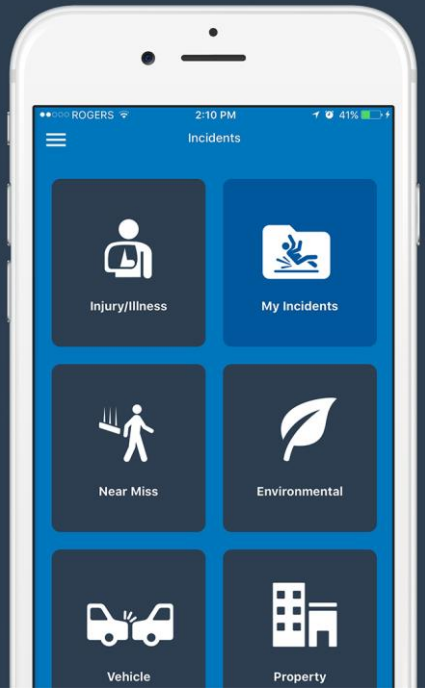
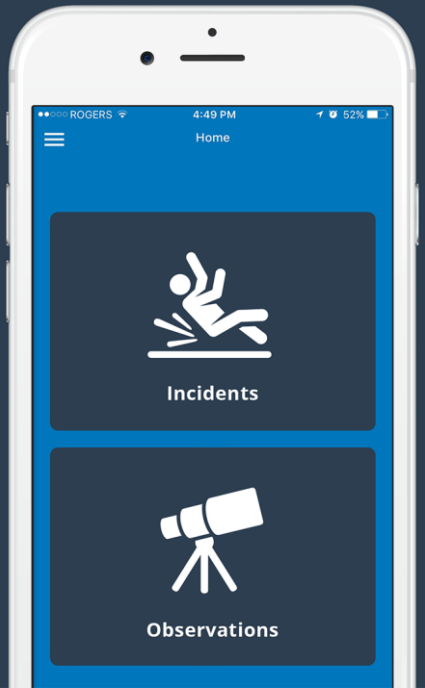
Easy Data Entry Mobile App

Access Intelex, any time, any place

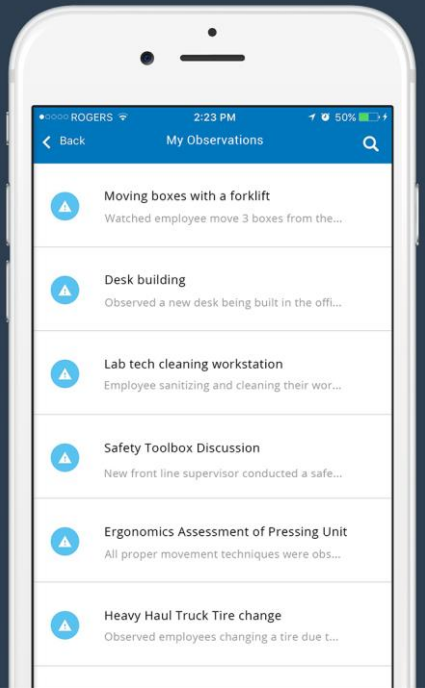
All the power of Intelex in your pocket

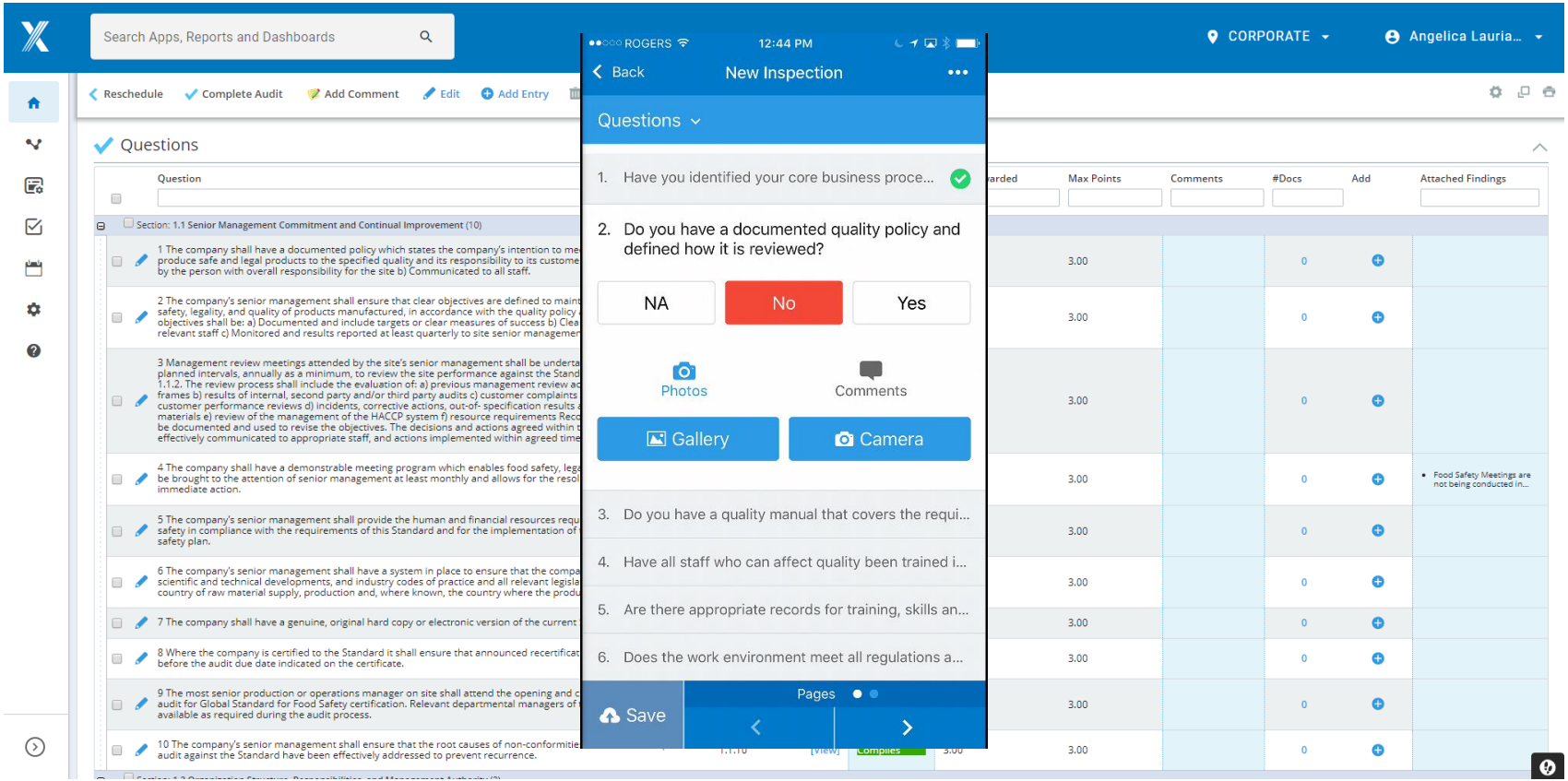


Capture EHSQ data in the moment



Personalized tasks and insights

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CORPORATE
Angelica Lauria...
Reschedule
Complete Audit
Add Comment
Edit
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Question
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Comments
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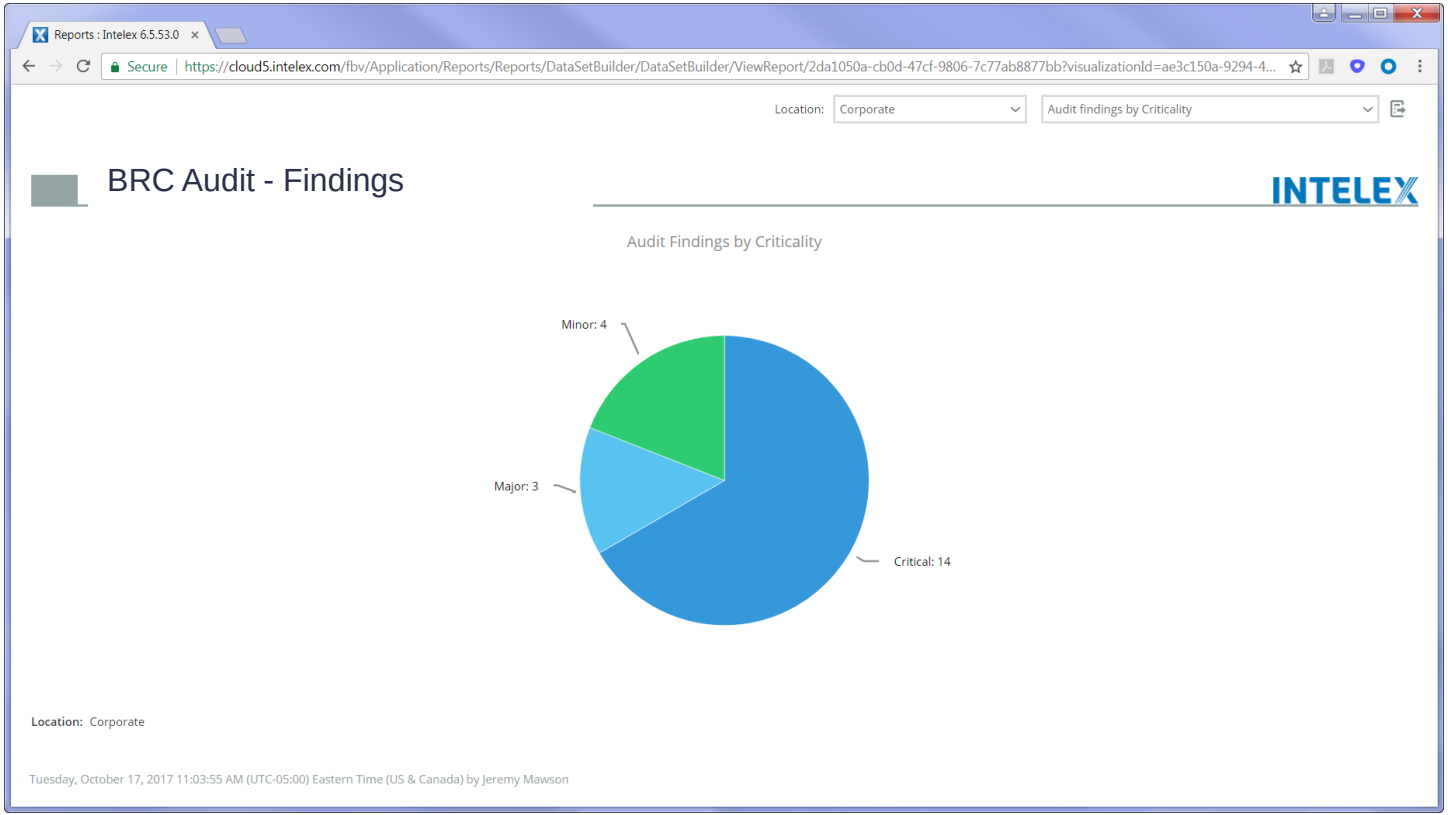
Add
Attached Findings
ROGERS
12:44 PM
Back
New Inspection
Questions
1. Have you identified your core business proce...
2. Do you have a documented quality policy and defined how it is reviewed?
NA
No
Yes
Photos
Comments
Gallery
Camera
3. Do you have a quality manual that covers the requi...
4. Have all staff who can affect quality been trained i...
5. Are there appropriate records for training, skills an...
6. Does the work environment meet all regulations a...
Save
Pages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Location: Corporate
Audit findings by Criticality
BRC Audit - Findings
INTELEX
Audit Findings by Criticality
Minor: 4
Major: 3
Critical: 14
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Tuesday, October 17, 2017 11:03:55 AM (UTC-05:00) Eastern Time (US & Canada) by Jeremy Mawson

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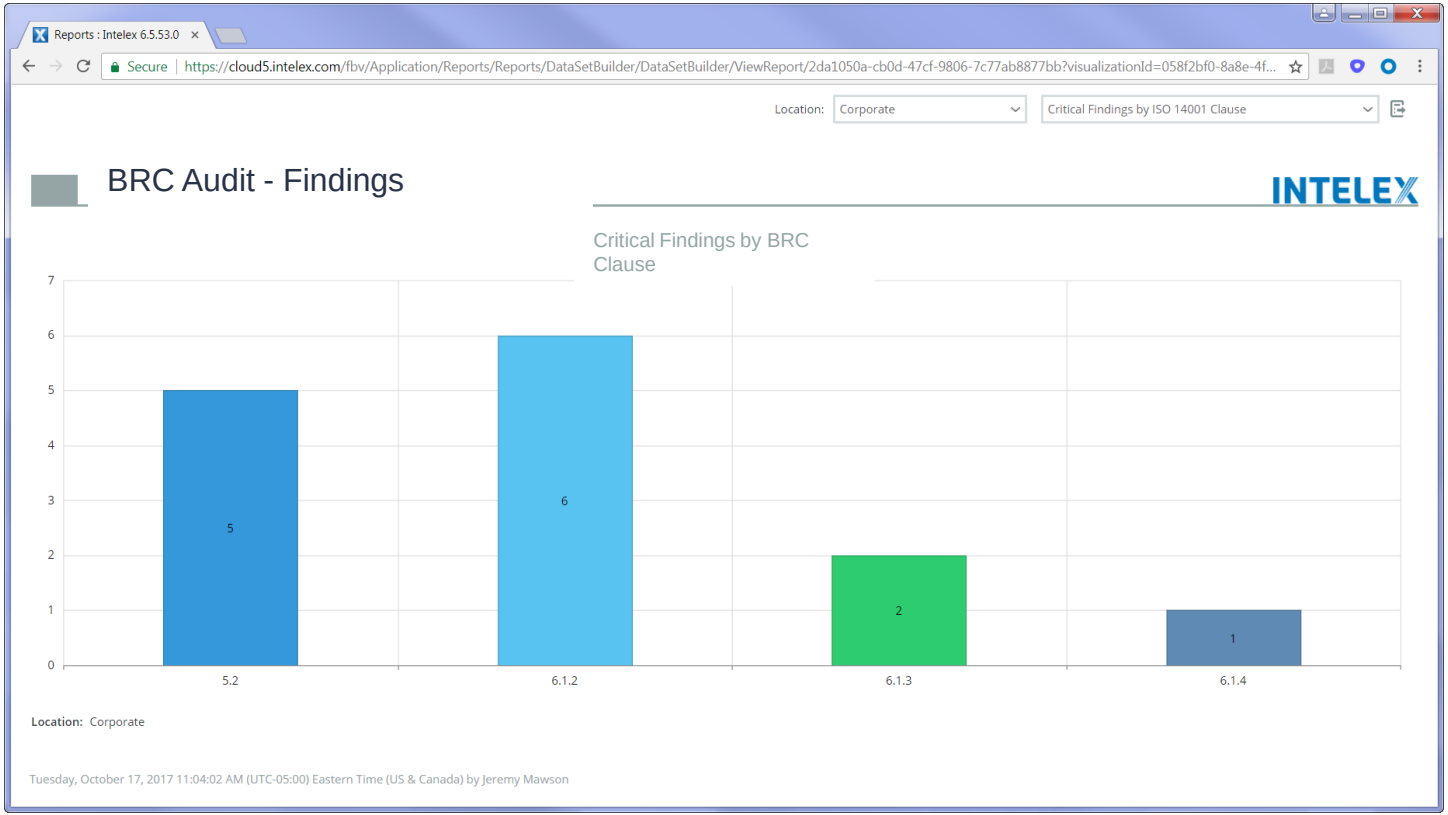
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Location: Corporate
Critical Findings by ISO 14001 Clause
BRC Audit - Findings
INTELEX
Critical Findings by BRC Clause
7
6
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6.1.3
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Location: Corporate
Tuesday, October 17, 2017 11:04:02 AM (UTC-05:00) Eastern Time (US & Canada) by Jeremy Mawson

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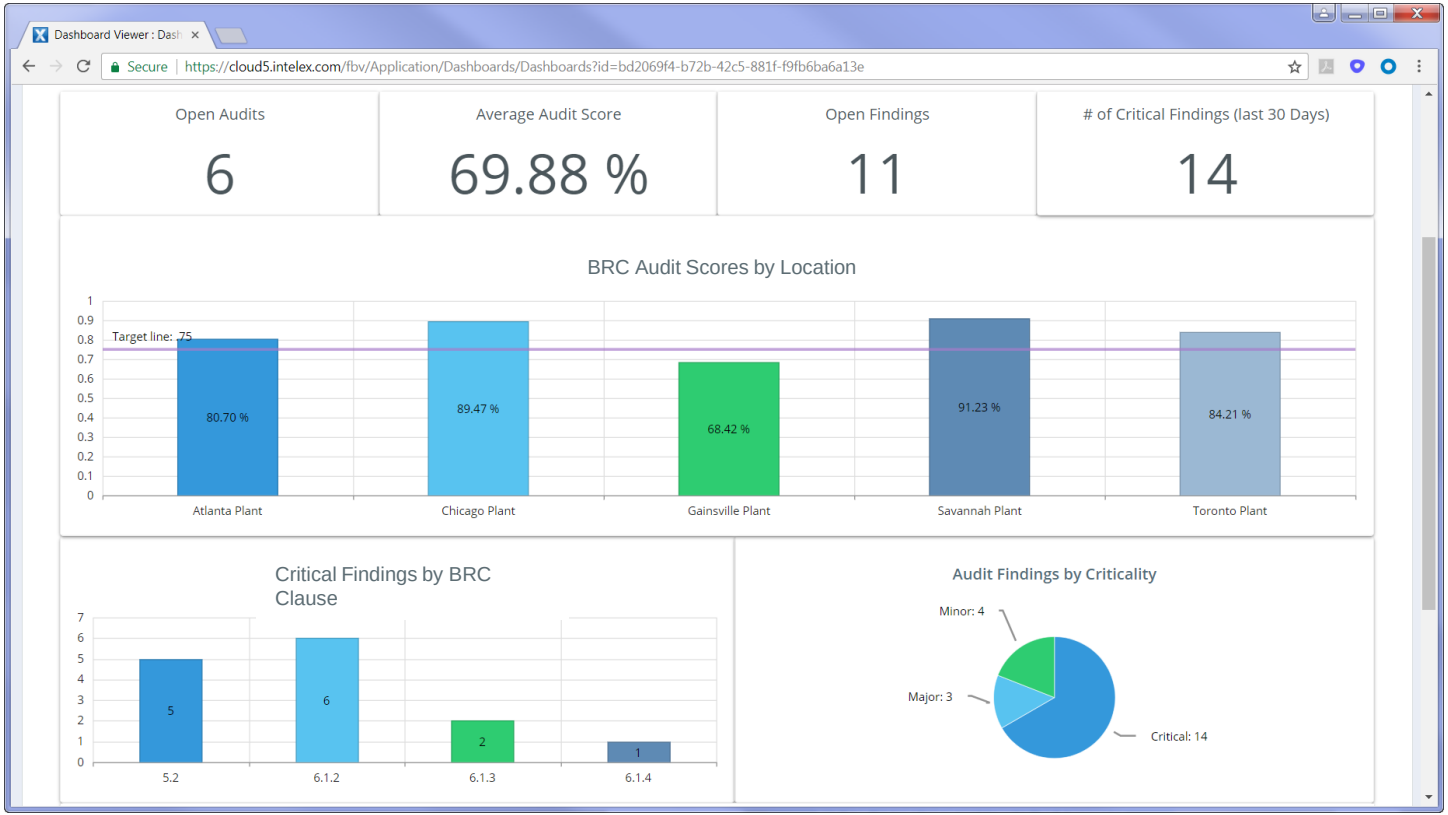
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Secure | https://cloud5.intelex.com/fbv/Application/Dashboards/Dashboards?id=bd2069f4-b72b-42c5-881f-f9fb6ba6a13e
Open Audits
6
Average Audit Score
69.88 %
Open Findings
11
# of Critical Findings (last 30 Days)
14
BRC Audit Scores by Location
Target line: .75
80.70 %
89.47 %
68.42 %
91.23 %
84.21 %
Atlanta Plant
Chicago Plant
Gainsville Plant
Savannah Plant
Toronto Plant
Critical Findings by BRC Clause
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6.1.4
Audit Findings by Criticality
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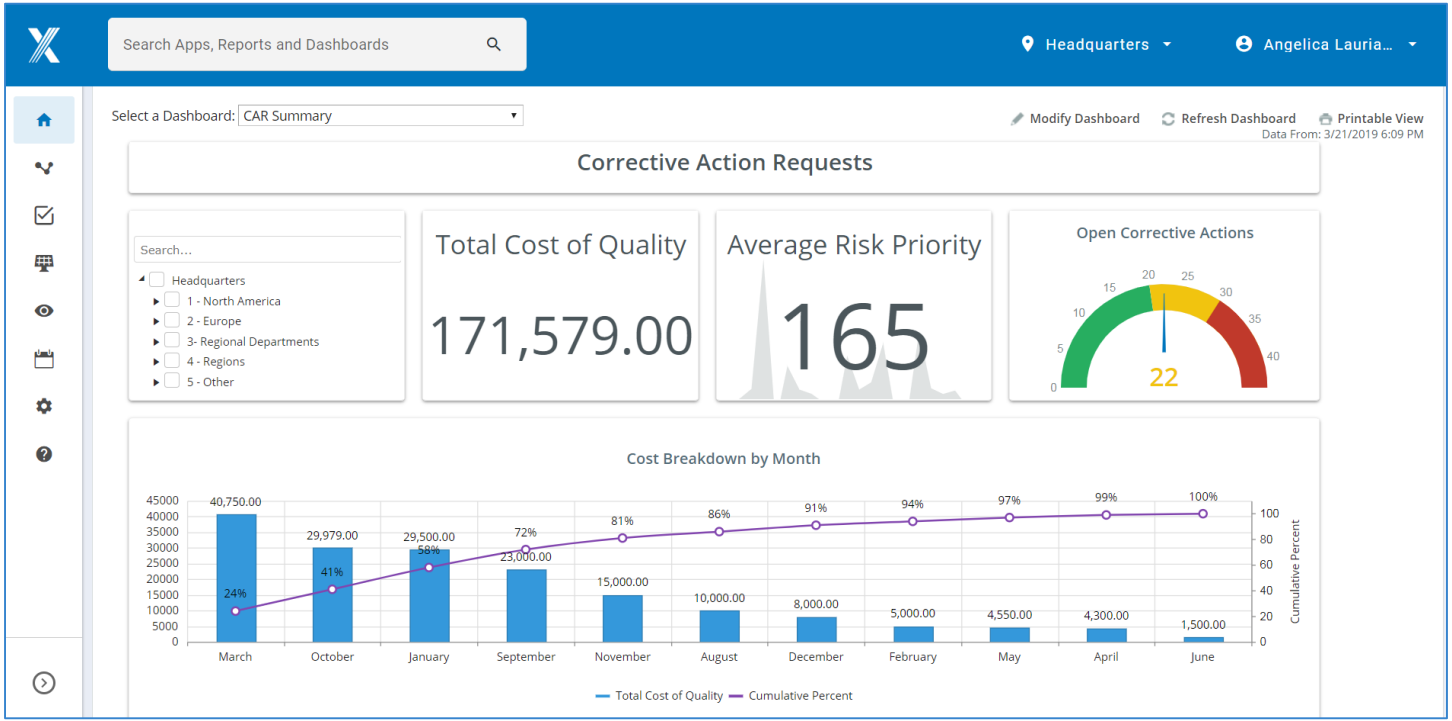
Major: 3
Critical: 14


Search Apps, Reports and Dashboards
Headquarters
Angelica Lauria...
Select a Dashboard: CAR Summary
Modify Dashboard
Refresh Dashboard
Printable View
Data From: 3/21/2019 6:09 PM
Corrective Action Requests
Search...
Headquarters
1 - North America
2 - Europe
3- Regional Departments
4 - Regions
5 - Other
Total Cost of Quality
171,579.00
Average Risk Priority
165
Open Corrective Actions
0
5
10
15
20
25
30
35
40
22
Cost Breakdown by Month
45000
40000
35000
30000
25000
20000
15000
10000
5000
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40,750.00
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29,500.00
23,000.00
15,000.00
10,000.00
8,000.00
5,000.00
4,550.00
4,300.00
1,500.00
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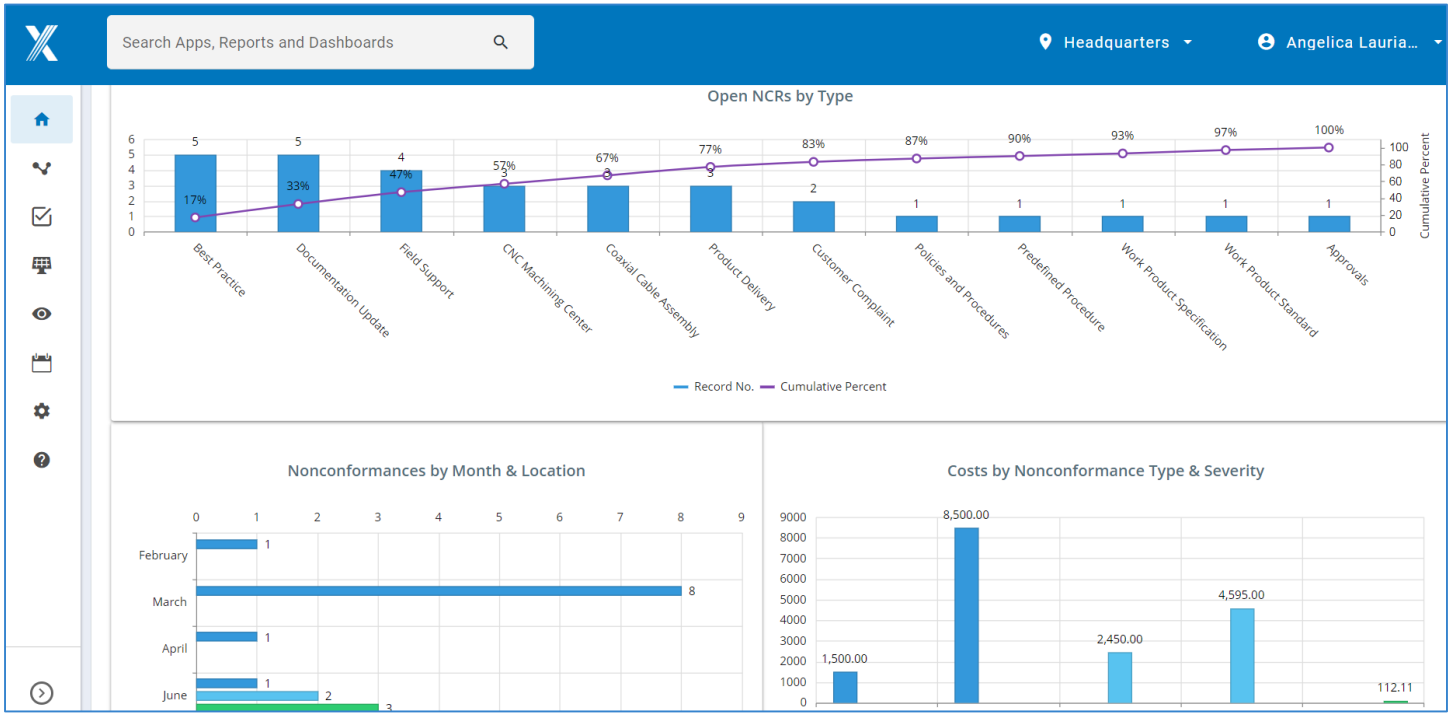
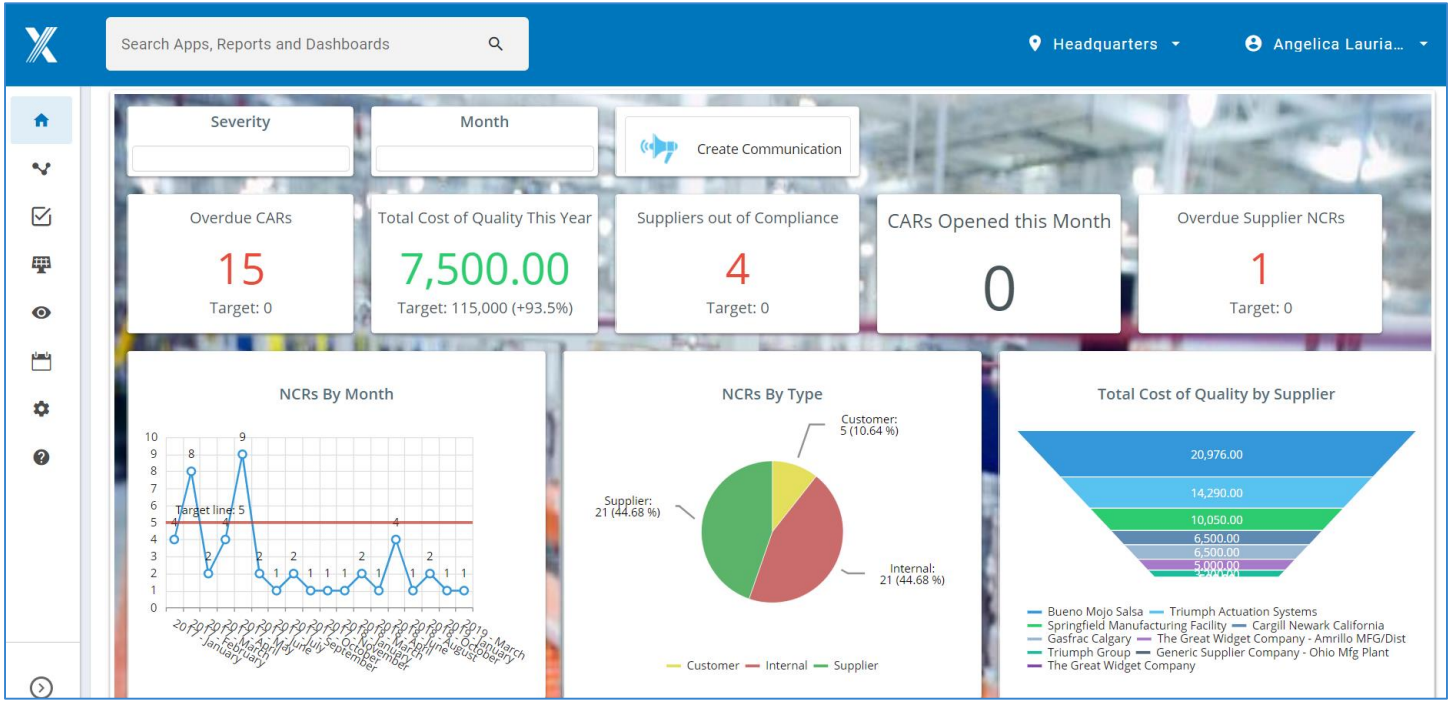
20
0
Cumulative Percent
Total Cost of Quality
Cumulative Percent


Search Apps, Reports and Dashboards
Headquarters
Angelica Lauria...
Open NCRs by Type
Best Practice
Documentation Update
Field Support
CNC Machining Center
Coaxial Cable Assembly
Product Delivery
Customer Complaint
Policies and Procedures
Predefined Procedure
Work Product Specification
Work Product Standard
Approvals
Cumulative Percent
Record No.
Cumulative Percent
Nonconformances by Month & Location
February
March
April
June
Costs by Nonconformance Type & Severity
1,500.00
8,500.00
2,450.00
4,595.00
112.11


Search Apps, Reports and Dashboards
Headquarters
Angelica Lauria...
Severity
Month
Create Communication
Overdue CARs
15
Target: 0
Total Cost of Quality This Year
7,500.00
Target: 115,000 (+93.5%)
Suppliers out of Compliance
4
Target: 0
CARs Opened this Month
0
Overdue Supplier NCRs
1
Target: 0
NCRs By Month
Target line: 5
NCRs By Type
Customer: 5 (10.64 %)
Supplier: 21 (44.68 %)
Internal: 21 (44.68 %)
Customer
Internal
Supplier
Total Cost of Quality by Supplier
20,976.00
14,290.00
10,050.00
6,500.00
6,500.00
5,000.00
Bueno Mojo Salsa
Triumph Actuation Systems
Springfield Manufacturing Facility
Cargill Newark California
Gasfrac Calgary
The Great Widget Company - Amrillo MFG/Dist
Triumph Group
Generic Supplier Company - Ohio Mfg Plant
The Great Widget Company

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Awards & Recognition

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