



Marco Scialpi – TUV Rheinland FCM Global Business Development Head

Working experience

25 years experience in Food Safety, Quality Management, Product Risk Management and IT.

TUV International GmbH as FCM Global Business Development Head and FCM Technical Senior expert.

Develop, innovate and enhance FCM as regulatory, compliance, testing and digitalized services

Nestlé as R&D, Cereal Partner Worldwide, Deloitte & Touche MS, Cap Gemini, Ernest & Young and Det Norske Veritas

A project I like working on _

TUVR 360° Digital compliance platform: to support value chain in handling in one place all product compliance requirements to safely distribute globally their own product and to develop the Product Digital Identity to enhance product consumer selection based on consumer values instead of only price or customer preferences.



What I like at free time

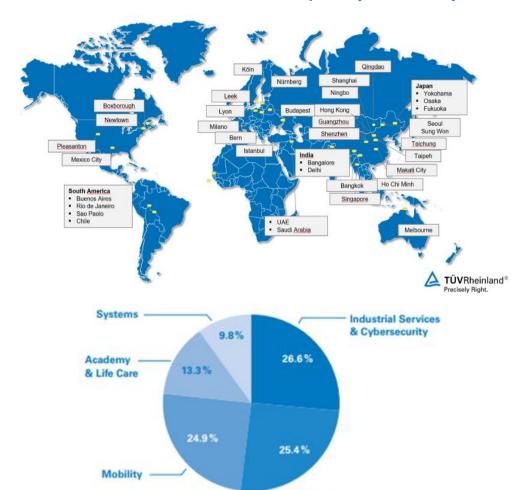
Freediving apnea: to continue keeping the head under the water as well after work ©

Cooking: Food is essential for an Italian to survive abroad and basic principle to understand other cultures



TÜV Rheinland: at home on all continents

Since 1872 ensure Product quality & safety to Industry and Consumers



Products

HQ in Cologne Germany

21.441

Employees worldwide 2019 57% outside of Germany

€ 4

2,085 mio € revenue 2019

46% generated out of Germany





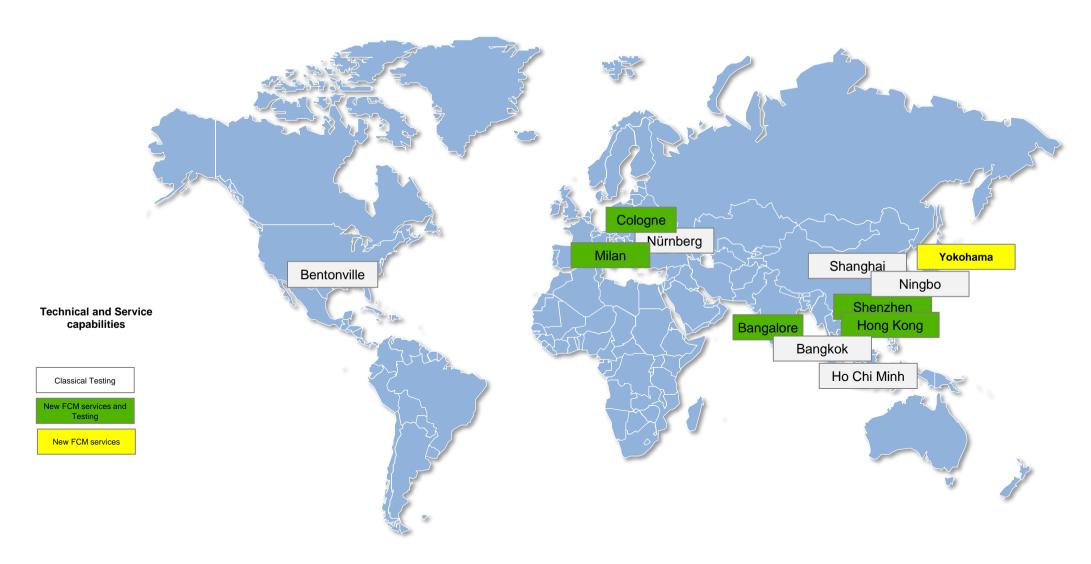
24 Business Fields

Technical and Service

5 Business Streams



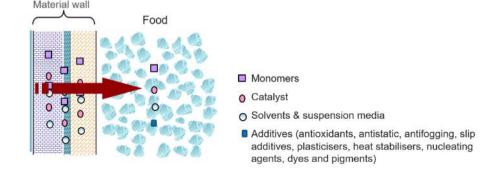
Global FCM Labs and FCM Services Capabilities





What is FCM migration into food?

Migration is the transfer of chemical substances via FCMs into food.

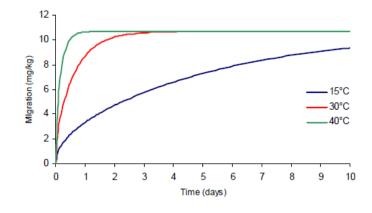


Factors affecting rate of migration from FCM into food

- Nature and composition of FCM (size, structure and type of molecules)
- Type of food
- Intended usage of FCM (e.g. food contact temperature, contact time & FCM surface area to food volume ratio)

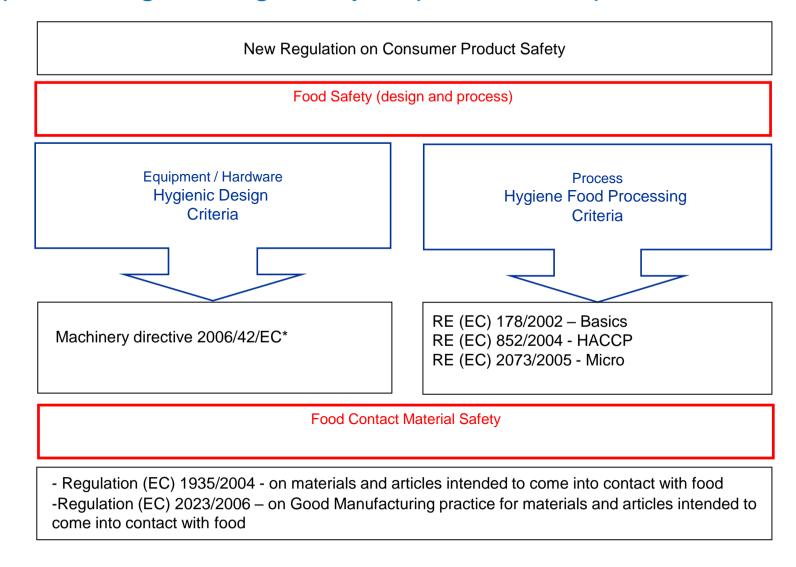








FCM for food processing line regulatory request in Europe





Machine Directive 2006/42 aligned with FCM regulation



ANNEX I

Essential health and safety requirements relating to the the design and construction of machinery

GENERAL PRINCIPLES

 SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

2,1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS

2.1.1. General

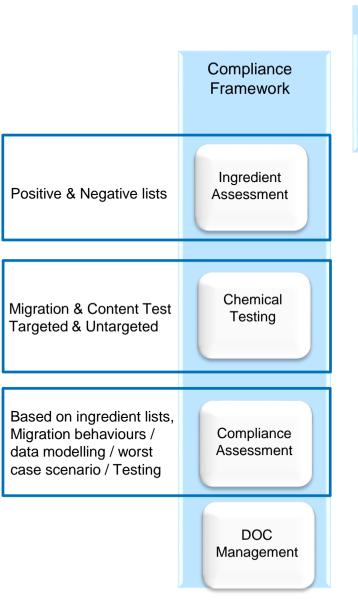
Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

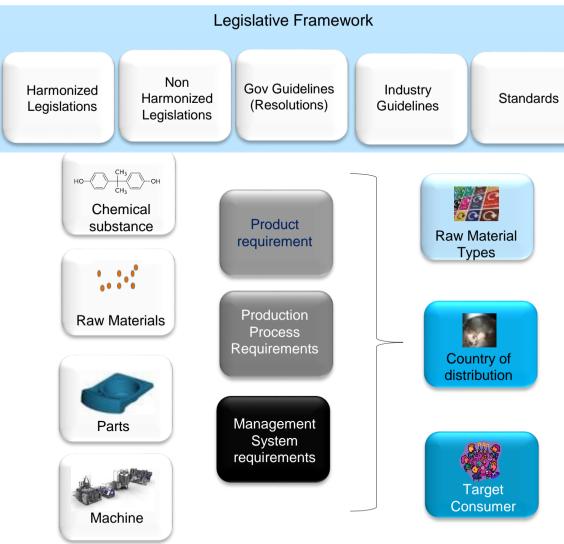
The following requirements must be observed:

(a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used;



Complex Compliance Framework Logic and stronger renewal of the last 25years

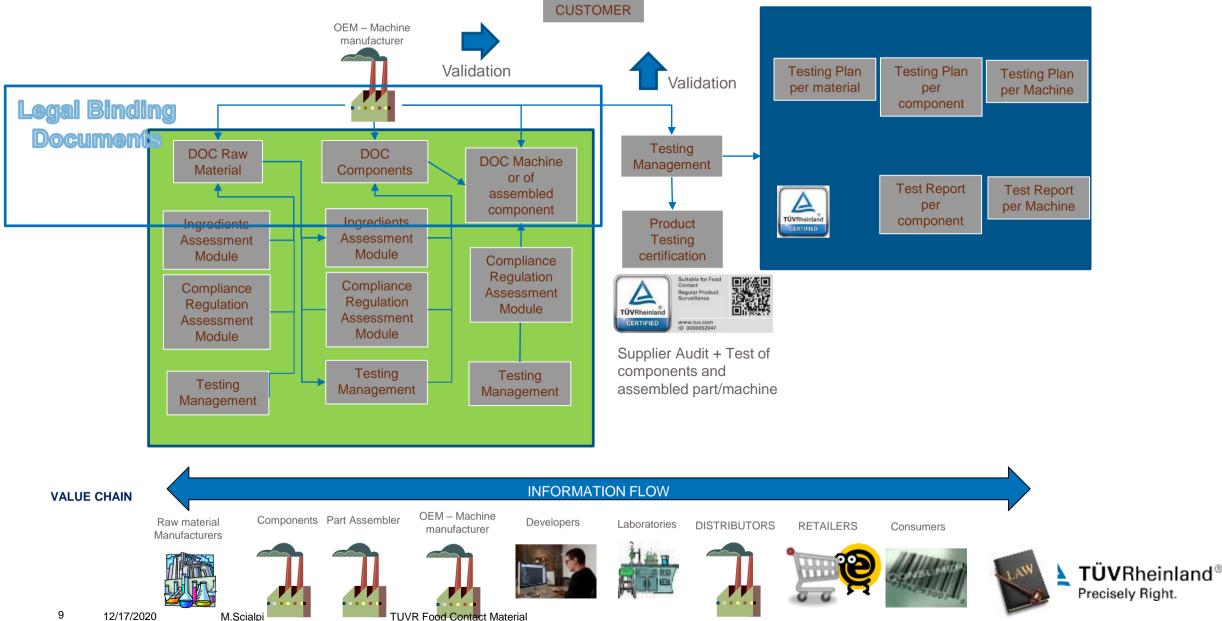








FCM DOC Compliance process for FOOD SYSTEM



M.Scialpi

TUVR FCM Compliance Services to support you

Regulatory & Compliance Knowledge services Compliance by Design services International standards Design/Process HACCP **BRCGS Packaging, ISO** GMP Visual standards 22000. GMP+ Microbiological challenge test GMP audit services Hygienic Product certification Pre-assessment audit services **HACCP Audit** DOC **Testing Mngmt** Program testing management Assessment/Management of: Testing plan definition •FCM Assembled Article/Machine Packaging DOC Chemical testing / NIAS Article/Component/ Packaging Chemical Water-Food Passport DOC Sensory Test Raw materials DOC **Continuous Supplier Training**





Regular Produc





www.tuv.com ID 0000052047



Hygienic Properties

www.buv.com







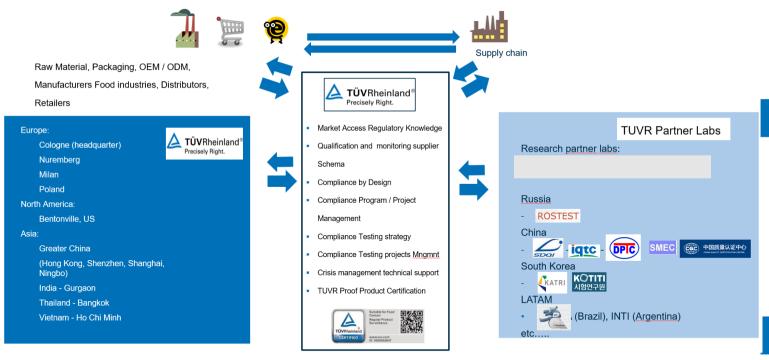
TUVR is the CQC Certification Recognized lab for testing and Initial factory audits for European Manufacturer sites, on both China GB standards and EU regulations.



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Our FCM Testing capability in global coverage

Internal and external partnership lab Networks

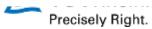


Testing standards capability

| Europe | | Asia - Pacific | North & South America |
|-------------|----------------|----------------|--------------------------|
| General EU* | Finland | Japan | Argentina |
| Germany | Poland | Korea | Brazil |
| Italy | Czech Republic | China | Colombia |
| France | Sweden | Taiwan | Mercosur |
| Switzerland | Austria | Singapore | United States (FDA) |
| Netherlands | Cyprus | Malaysia | |
| Belgium | Croatia | Thailand | Middle East |
| Norway | Portugal | Indonesia | Saudi Arabia |
| Luxembourg | Slovenia | India | |
| Denmark | Greece | Turkey | |
| Spain | Russia | Vietnam | |
| Hungary | Slovakia | | |

Customized Risk Base Profile testing plan

| | ourig plan | |
|-----------------------------|---|---|
| Level 1 | Level 2 | Level 3 |
| Test every single component | Composite test for component made of homogenous material - Composite testing of 3 components in single test group | Test only one component out of all homogenous materials - Select only one representative sample for testing |
| High | | Low |
| Low | | High |
| | Level 1 Test every single component High | Test every single component Composite test for component made of homogenous material Composite testing of 3 components in single test group High |



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How can we help?





Questions?

Please type your questions in the related chat or to send them to us by email! For lack of time we may not be able to answer all of them immediately, but we will get in touch with you through dedicated communication.





Thank you for your attention

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https://www.tuv.com/landingpage/en/food-contact-materials/index-2.html

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