

***Using risk management tools to manage  
the integrity of the cold chain***

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## Where we are today

- We have more than 14 years of market experience in a variety of industries, including automotive, medical technology, pharmaceuticals and Agri-Food Business
- We've sold more than 45,000 software licenses to more than 500 customers
- We've trained around 6,000 users directly
- We're committed to the highest standards of quality (FDA, ISO, GMP etc.)
- We hold annual PLATO user meetings for our customers to support the continued further development of our software products to best meet our customers' needs





## **Professional software solutions for Quality and Knowledge Management**

- **SCIO™ Risk Management**
- **ERGON™ Action Management**
- **XERI™ Document Management**
- **AUDIT Management**
- **PROTIS™ Complaints Management**



### *Using risk management tools to manage the integrity of the cold chain*

- Initial situation
- The steps of the enterprise risk management process
- Modules and Software Programmes
- Case study
- Concept of chain oriented application
- Conclusion



Food enterprises have to translate

- food safety requirements of new government regulations, recommendations, guidelines,
  - customer (retailer) requirements as well as
  - requirements of audit standards etc.
- into enterprise-internal specific product and process criteria.

➔ Risk managers (e. g. quality assurance managers, teams of experts: advisors, industrial or research institute experts) do risk assessment as part of **Hazard Analysis and Critical Control Point (HACCP) studies**.



- The **F**ailure **M**ode and **E**ffects **A**nalysis (**FMEA**) is a systematically and comprehensibly method for
  - risk assessment,
  - risk evaluation and
  - action management.

**Aim:** Develop strategies to avoid failures instead of correct failures.

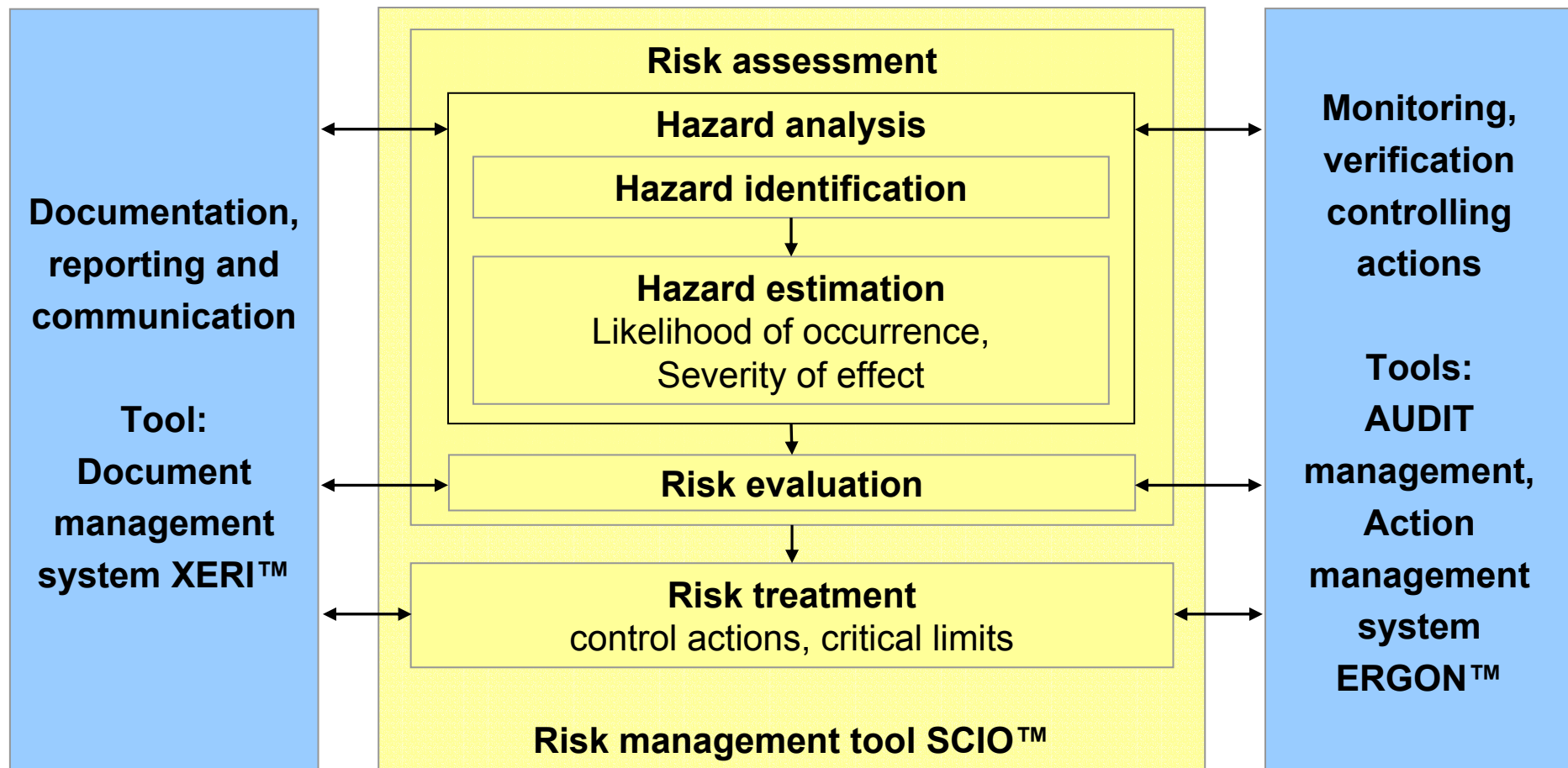
- It is useful to combine the **FMEA** with the **HACCP System**.

(Codex Alimentarius, 1997: RECOMMENDED INTERNATIONAL CODE OF PRACTICE  
GENERAL PRINCIPLES OF FOOD HYGIENE; Regulation (EC) No 853/2004 on the hygiene of  
foodstuffs)





## The steps of the risk management process







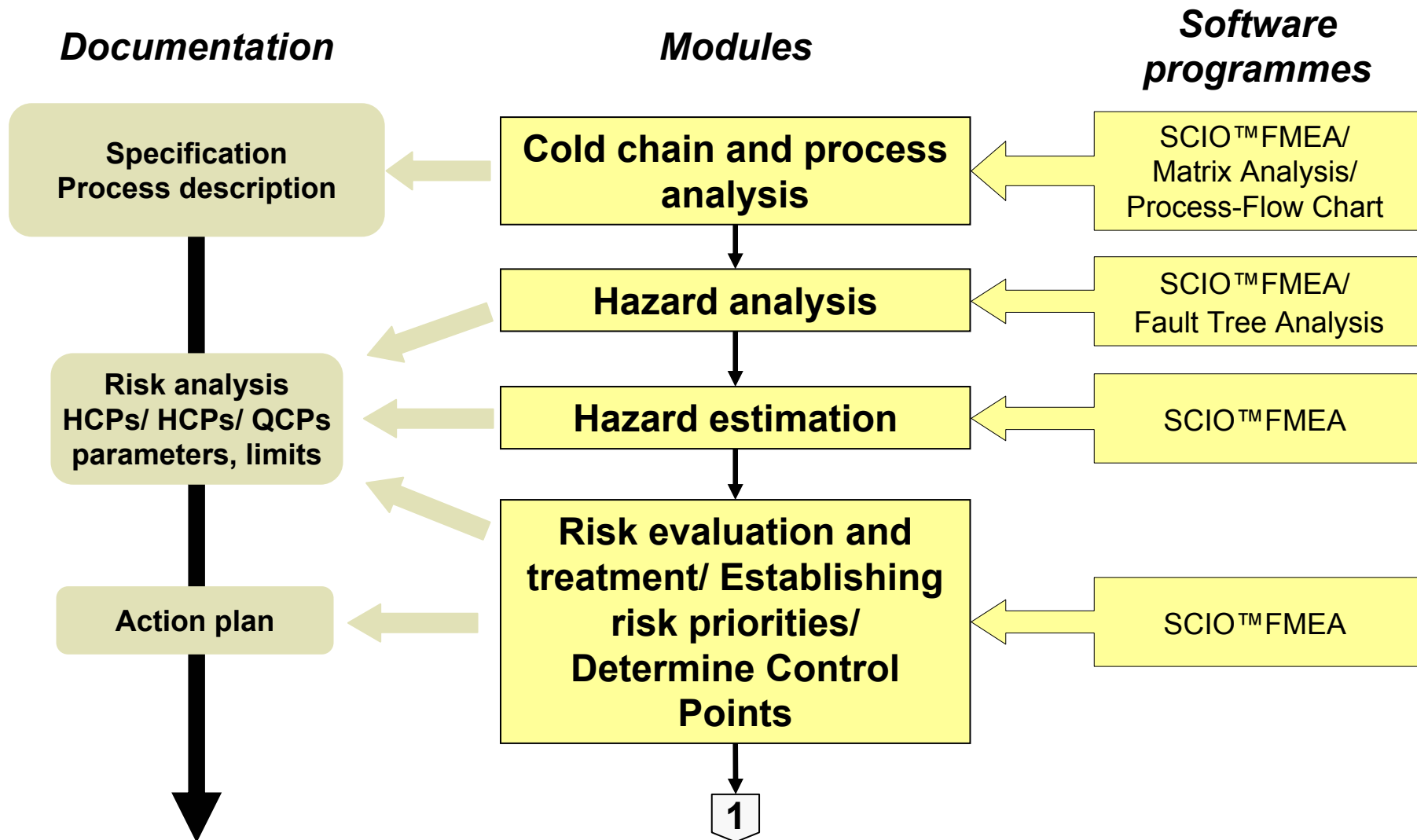
The use of risk management tools provide risk managers to define

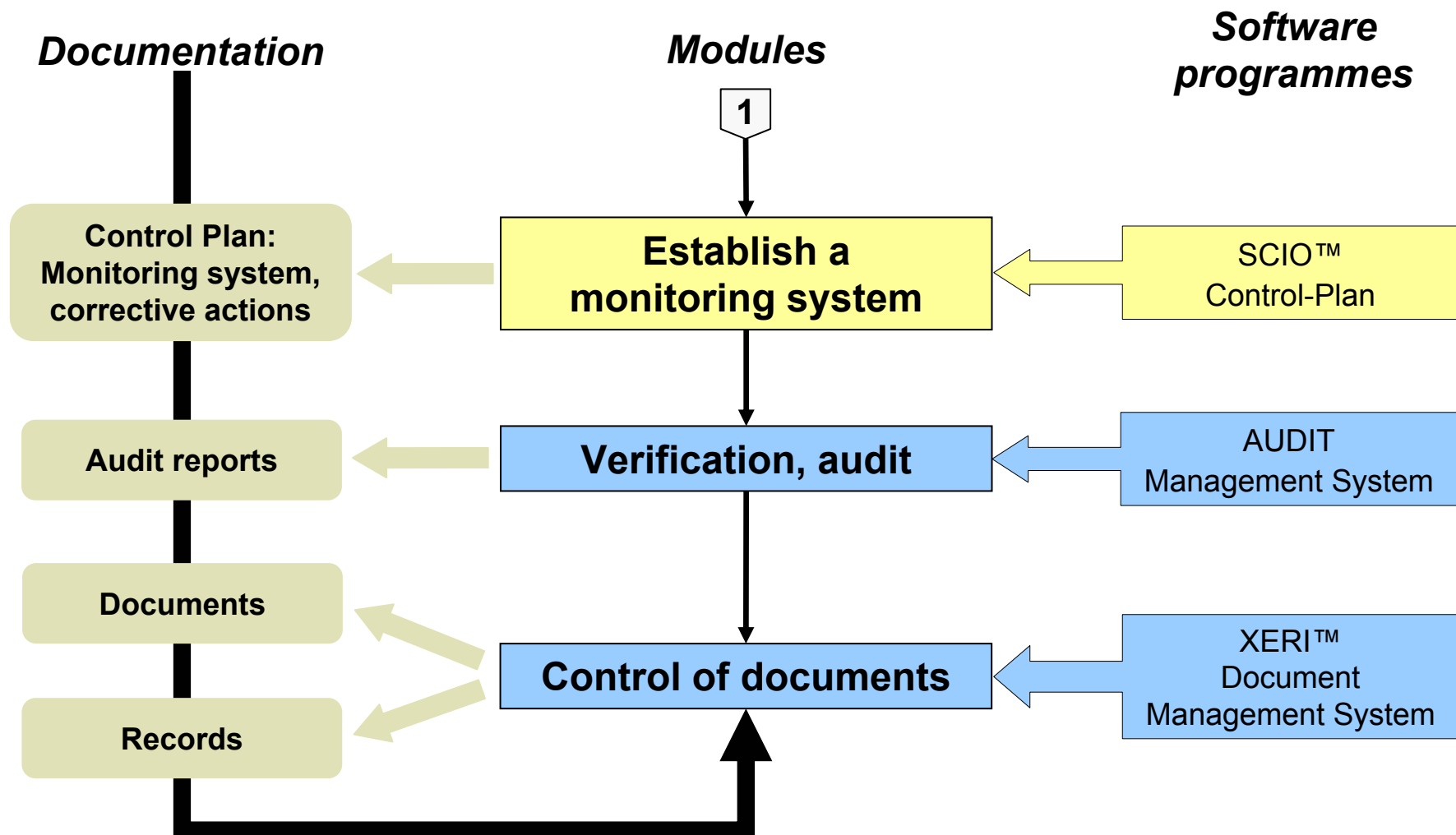
- Criteria for process performance (control parameters)
- Criteria for product composition and
- Criteria for storage conditions

According to the cold chain, there are two primary areas  
having effects on the integrity of the cold chain

- Temperature control (temperature and time)
- Process flow and contamination control (segregation between contaminated and clean areas etc.)

# Modules and Software Programmes

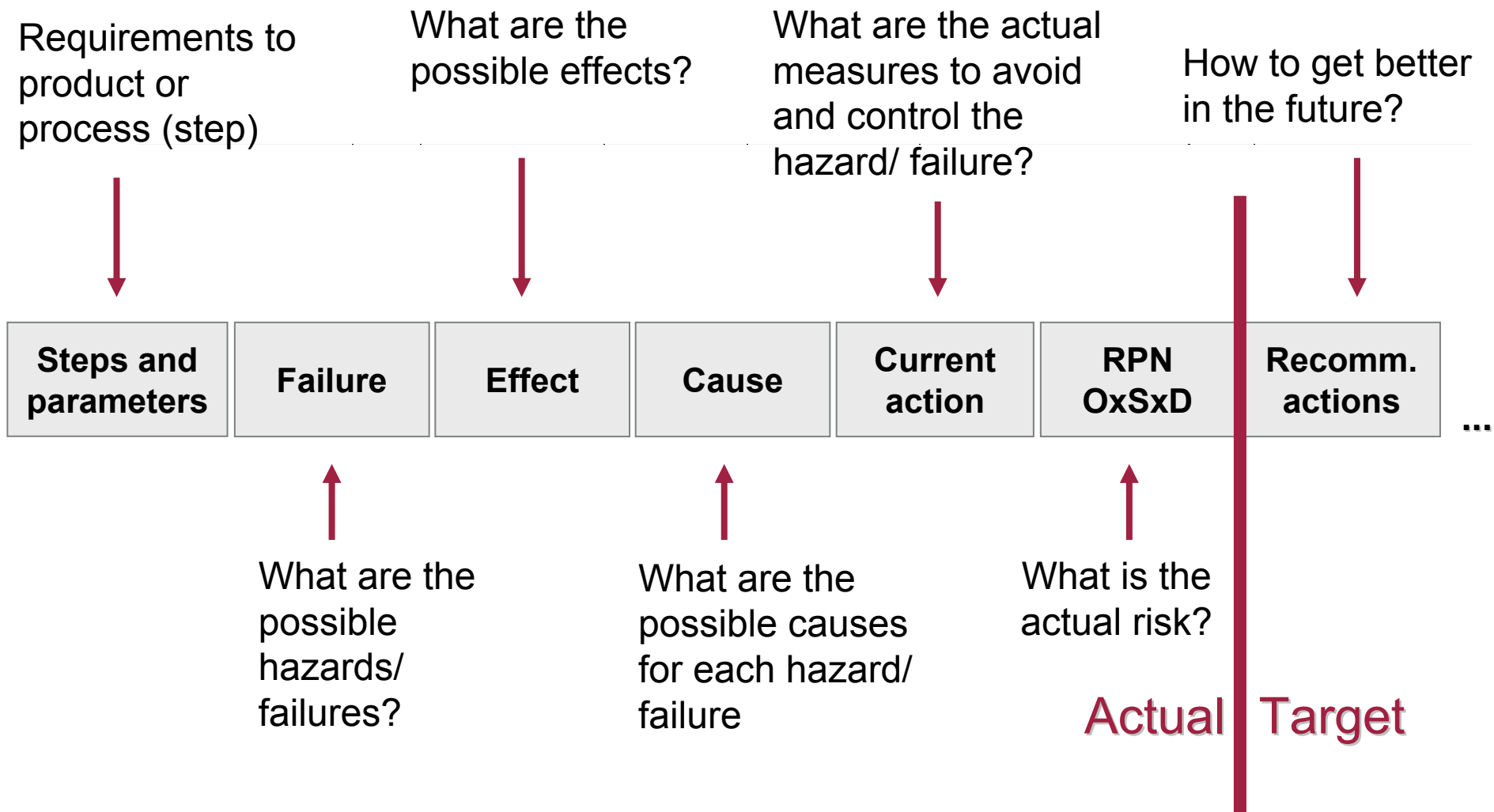




# Principles of the FMEA method



## A team documents the FMEA in a form



## ***How does it work?***



### **Case study:**

### **Minimising the bacteria growth in pork meat chains**

#### **Cold chain and process analysis**

- Analysis of the cold chain from processing to consumer (recommended or regulated storage, processing and transport temperature, type of transport, sojourn and transport time of the product)



# Cold chain and process analysis



| PLATO - SCIO-FMEA - [Cold chain pork meat]                                |     |  |                             |   |
|---|-----|--|-----------------------------|---|
| System Element Edit View Format Analysis Administration Tools Window Help |     |  |                             |   |
| Row   | No. | Process steps, parameters                    | Potential hazards, failures | C |
| 7   | 10  | Processing                                   |                             |   |
| 10  | 20  | Transport to cold store                      |                             |   |
| 13  | 30  | Cold storage                                 |                             |   |
| 16  | 40  | Loading into a refrigerating van             |                             |   |
| 19  | 50  | Transport                                    |                             |   |
| 22  | 60  | Wholesaler: unloading and product inspection |                             |   |

## Cold chain and process analysis



| Row | No. | Process steps, parameters   |
|-----|-----|---|
| 5   | 10  |  Processing<br>Specifications:<br>Temperature<br>= 2 °C (+2)<br>Sojourn<br>= 2 h<br>Specifications of affected products:<br>Temperature<br>≤ 7 °C<br>[ Cold chain pork meat ]<br>pork meat |
| 6   |     |   |
| 7   |     |   |
| 8   | 20  |  Transport to cold store<br>Specifications:<br>Transport time<br>= 5 min<br>Temperature<br>= 2 °C (+2)   |
| 9   |     |   |





- Identify possible hazards/ failures
- Identify possible causes for each hazard/ failure having an influence on the temperature conditions and the sojourn time of the meat.
- Analyse the possible effects on the next process steps and the consumers
- Identify current actions to avoid and control the hazard/ failure



- Estimate the **occurrence (O)** of rising temperature e. g. higher than 7°C
- Estimate the **occurrence (O)** of long sojourn time.
- Estimate the ability to **detect (D)** the rising temperature.
- Estimate the ability to **detect (D)** long sojourn time.
- Estimate the **severity (S)** of the effects.
- Calculate the **RPN = Risk Priority Number = O x S x D**

# Hazard analysis in SCIO™-FMEA

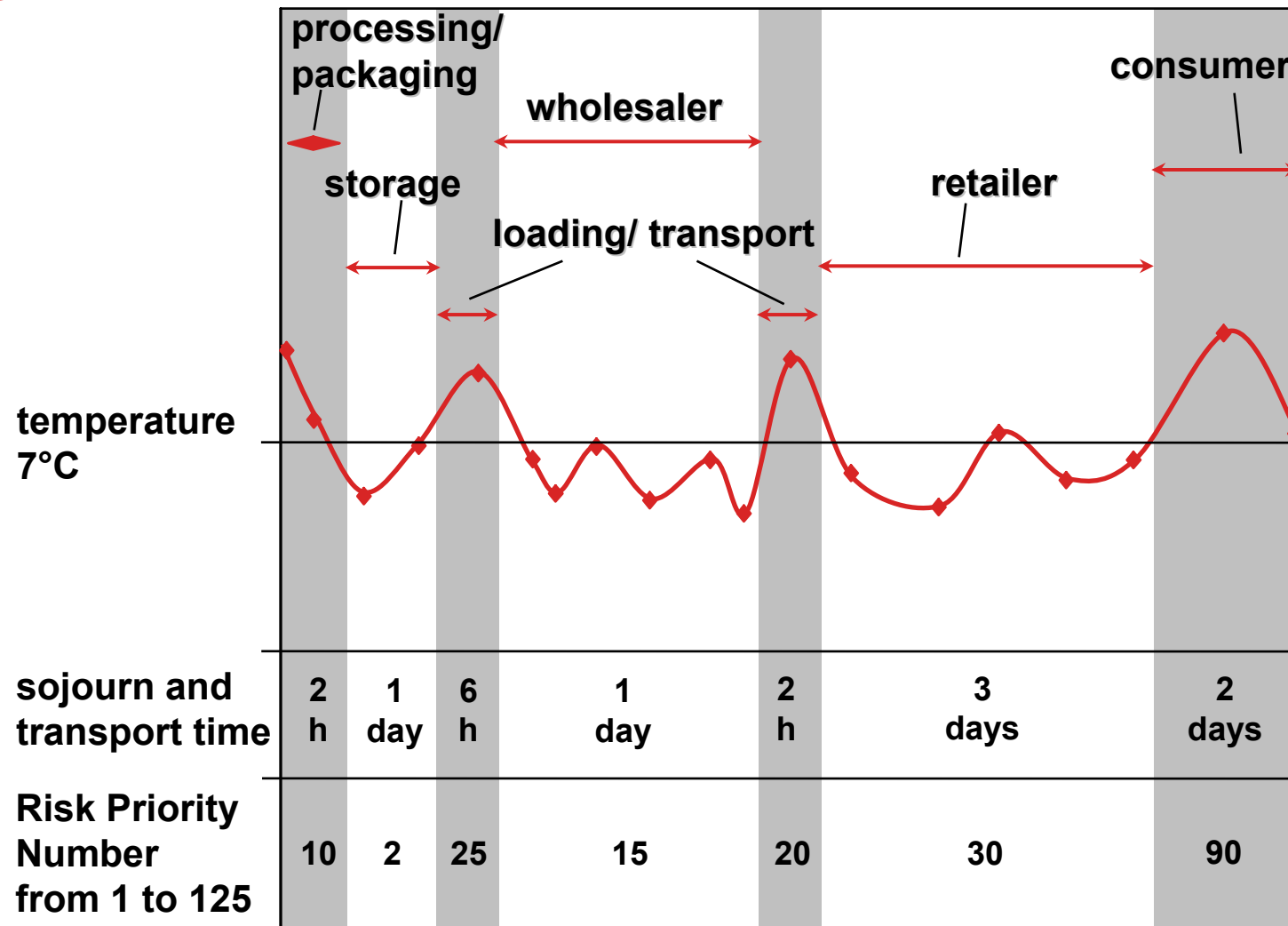


| No. | Process steps, parameters  | Potential hazards, failures         | Control point | Potential effects                                  | Potential causes  | O                 | S | D | RPN |
|-----|--|-------------------------------------|---------------|--|---|-------------------|---|---|-----|
| 10  | <p>Processing</p> <p><b>Specifications:</b><br/>Temperature = 2 °C (+2)<br/>Sojourn = 2 h</p> <p><b>Specifications of affected products:</b><br/>Temperature ≤ 7 °C<br/>[ Cold chain pork meat ]<br/>pork meat</p> | Growth of pathogenic microorganisms | CP            | Consumers may come down with an infectious disease | Exceeding the temperature limit                             | State: 02.05.2006 |   |   |     |
|     |  | Cross-contamination with pathogen   |               | spreading of pathogens                             | Bad hygiene practice (personnel, devices, environment etc.) | 2                 | 5 | 1 | 10  |
|     |  |                                     |               |  |   | 2                 | 4 | 3 | 24  |

# Hazard estimation in SCIO™-FMEA



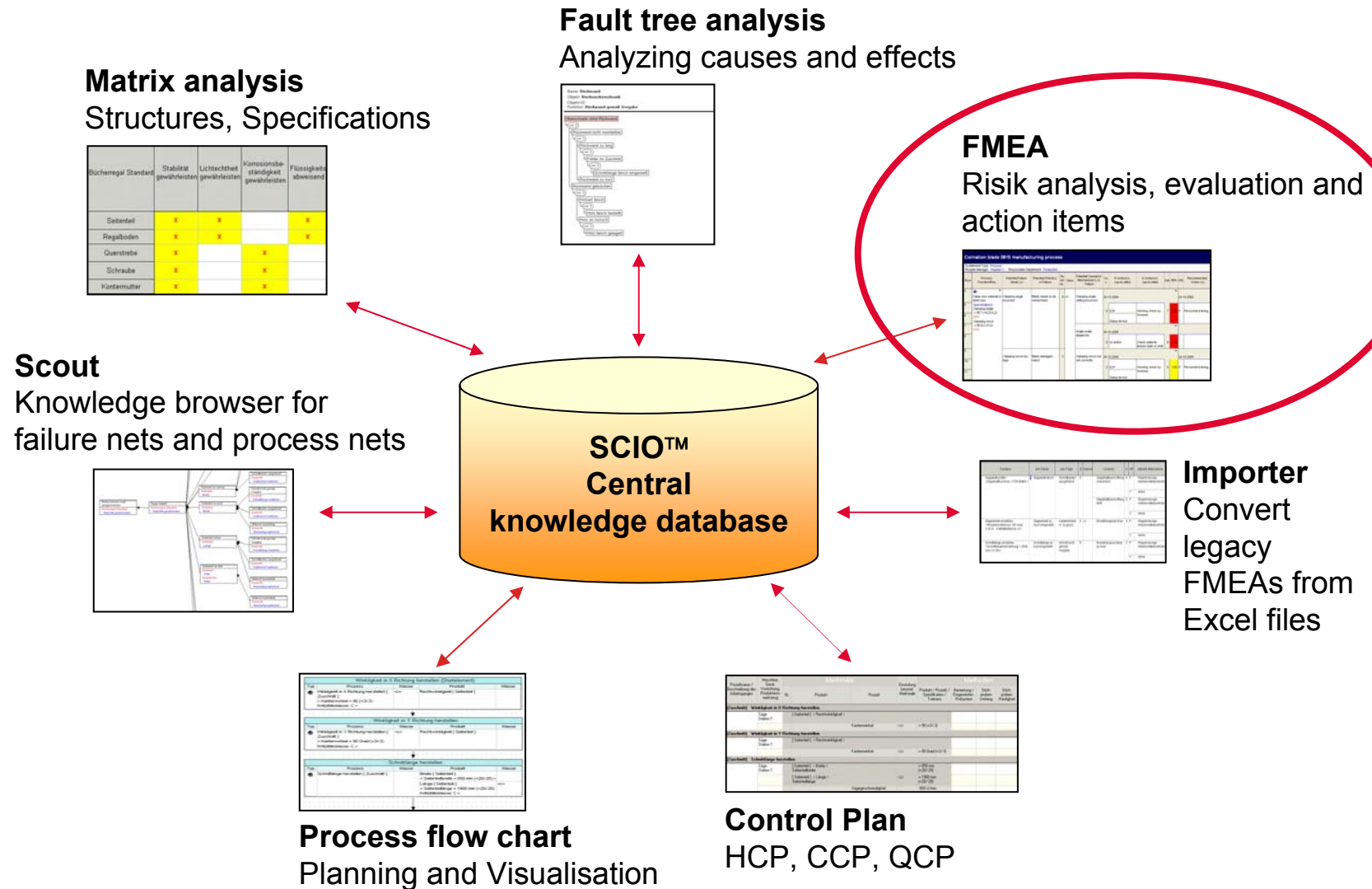
**Risk estimation according to temperature, sojourn and transport time of packaged pork meat**





- Severity and probability rankings will help the team to identify the Control Points of the process:
  - Hygienic Control Points (HCPs)
  - Critical Control Points (CCPs)
  - Quality Control Points (QCPs)and to establish a monitoring system
- When RPN exceeded a defined value, control actions for improvements have to be defined:
  - Preventive maintenance, training
  - Optimising hygiene practice
  - Planning and implementation of time-temperature control actions

# Concept of chain oriented application



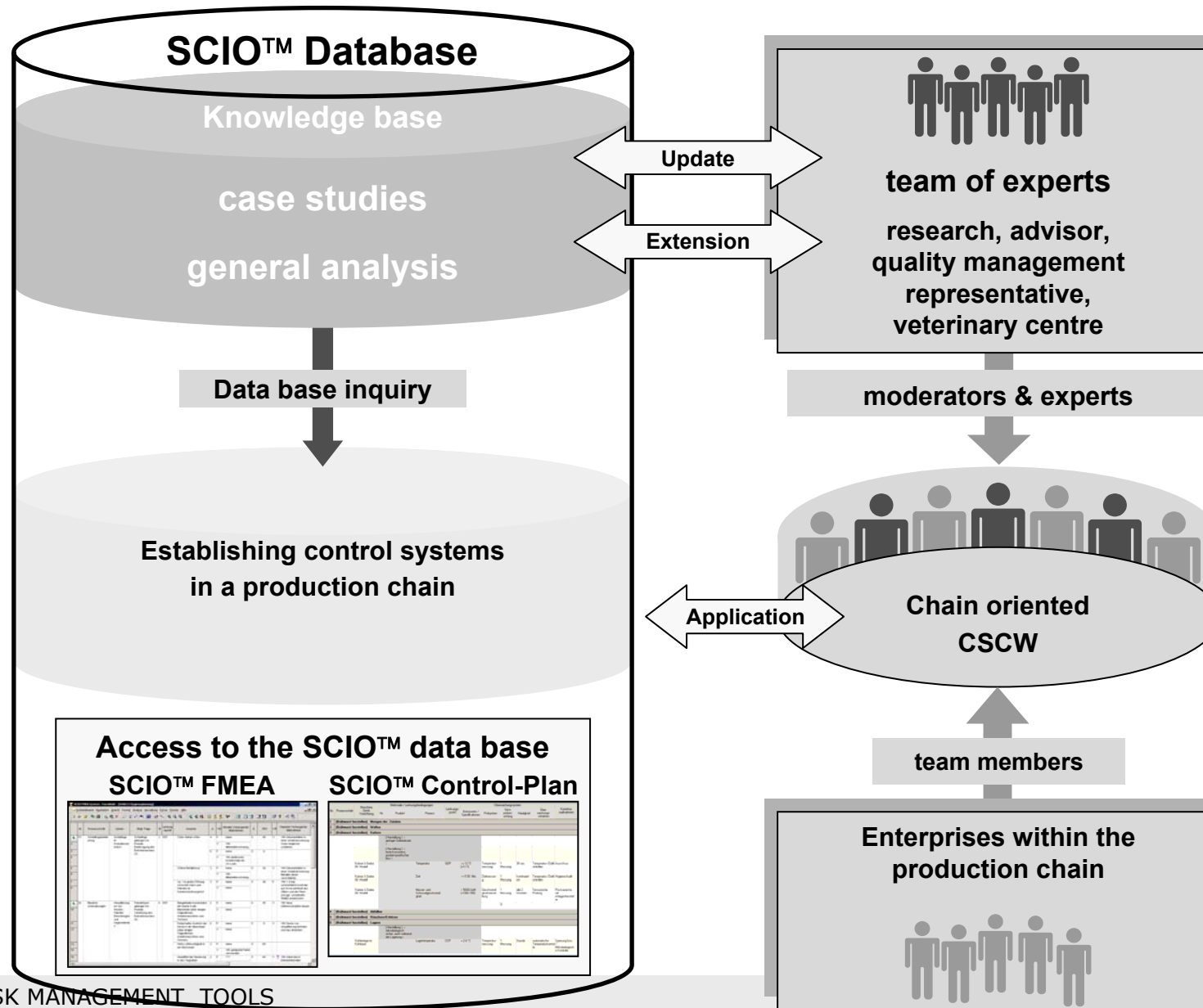


### **Identify and prioritise risks with one software-based method**

- New data are available immediately for all users
- Multiple users collaborate concurrently on the same form
- Knowledge becomes a corporate as well as a chain-wide asset
- All SCIO™ applications are using the same database
- Database size is unlimited

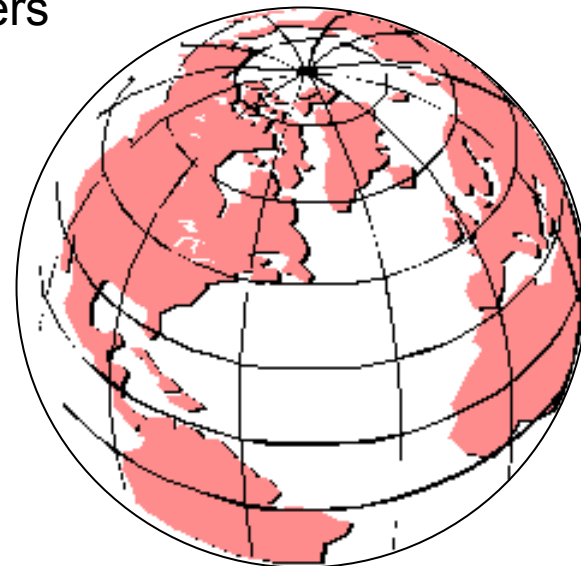


# Concept of chain oriented application





- Central database
- Worldwide availability of data
- Allows simultaneous access to several forms
- Allows collaboration of several team members in a single form
- All documents viewable via Web portal



## Conclusion



- Computer Supported Cooperative Work (CSCW) enables efficient support especially for modern forms of cooperation in and between teams of experts as well as enterprises and cold chains.
- Risk management tools support enterprises to plan, implement and optimise the cold chain
- Risk management ensures the integrity of the cold chain



*Thank you for your attention!*

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