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CAST analysis of the 2003 critical baby food disastrous event in Israel

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The Importance of Thiamine (vitamin B1) in critical food for babies

- **Thiamine plays a key role** in maintaining memory, the health of the nervous system, and heart muscle and is important for growth, mental development, and learning skills in children

- Thiamine acts as an important cofactor in metabolism and energy production.
- It is required for the biosynthesis of neurotransmitters and the production of substances used in defense against oxidant stress.

The Importance of Thiamine (vitamin B1) in critical food for babies /cont.

- The **only source of Thiamine in the human body is from food**. Therefore the composition of diary-free milk substitutes given to babies who are not breastfed, **is safety critical**.
- Vitamin B1 is stored in the liver in infants, but it decreases rapidly.
- **Thiamine deficiency can develop within 2–3 months** from a deficient intake and can cause illness and death.

The Importance of Thiamine (vitamin B1) in critical food for babies /cont.

- The onset of symptoms can be very rapid and the fatality rate can be very high with death often occurring within a few days from the onset of symptoms.
- The **symptoms of subclinical** (mild or partial) Thiamine deficiency are vague and nonspecific, making it **difficult to diagnose**.
- **Infants who survive** Thiamine-deficient related illnesses have a poor prognosis, with **motor and cognitive impairment and epilepsy**.

The Importance of Thiamine (vitamin B1) in critical food for babies /cont.

- Infantile Thiamine deficiency (**Beriberi**), is **rarely seen today** in developed countries after decades of strong public health attention.
- Beriberi poses **difficult diagnostic issues** and can be a missed diagnosis, as it can mimic critical illness or polyneuropathies. In addition, clinical manifestations such as tachypnea, chest indrawing, tachycardia and cardiomegaly can suggest other diagnoses.

The Path in The USA and Globally to Perceive "Critical Food"

- Standards and regulations for infant formula and other infant foods aim at **ensuring high levels of safety** and are much **more rigorous** than regulations for other food products.
- In fact, it was a **serious safety issue** that led to the adoption of the US **Infant Formula Act in 1980**.
- The issue was the **change in the formulation** of two soy infant formula which were introduced in 1978 by a major infant formula manufacturer in the USA.

The Path in The USA and Globally to Perceive "Critical Food" / cont.

- These deficient formulations induced metabolic illnesses and growth faltering in the babies who received them, and they were later also found to be associated with adverse long-term effects on developmental outcomes and with behavioral problems.
- The **United States Congress** reviewed the matter and determined that **protection of infants** fed infant formulae needed to be improved by **greater regulatory control** over infant formula, which led to the US Infant Formula Act of 1980.

The Path in The USA and Globally to Perceive "Critical Food" / cont.

- This act first established minimum nutrient requirements for infant formulae, defined adulteration and **quality control** procedures, and specified **inspection** requirements as well as recall procedures.
- The establishment of this and further **national, regional, and global standards and regulations on infant formulae** and baby foods has contributed to the very high level of safety of such products that exists today.

The Israeli Case-Study

- **A new** on-the-market vitamin B1-deficient non-dairy soy-based infant formula was marketed in Israel in 2003.
- The deficient formula, exposing infants to clinical or subclinical B1 deficiency, was apparently sold in Israel for about 6 months, from May 2003 to November 7, 2003.
- In November 2003, following a report of unexplained encephalopathy in a cluster of infants in a tertiary medical center in Israel, the **Israeli Ministry of Health** initiated an investigation.

The Israeli Case-Study /cont.

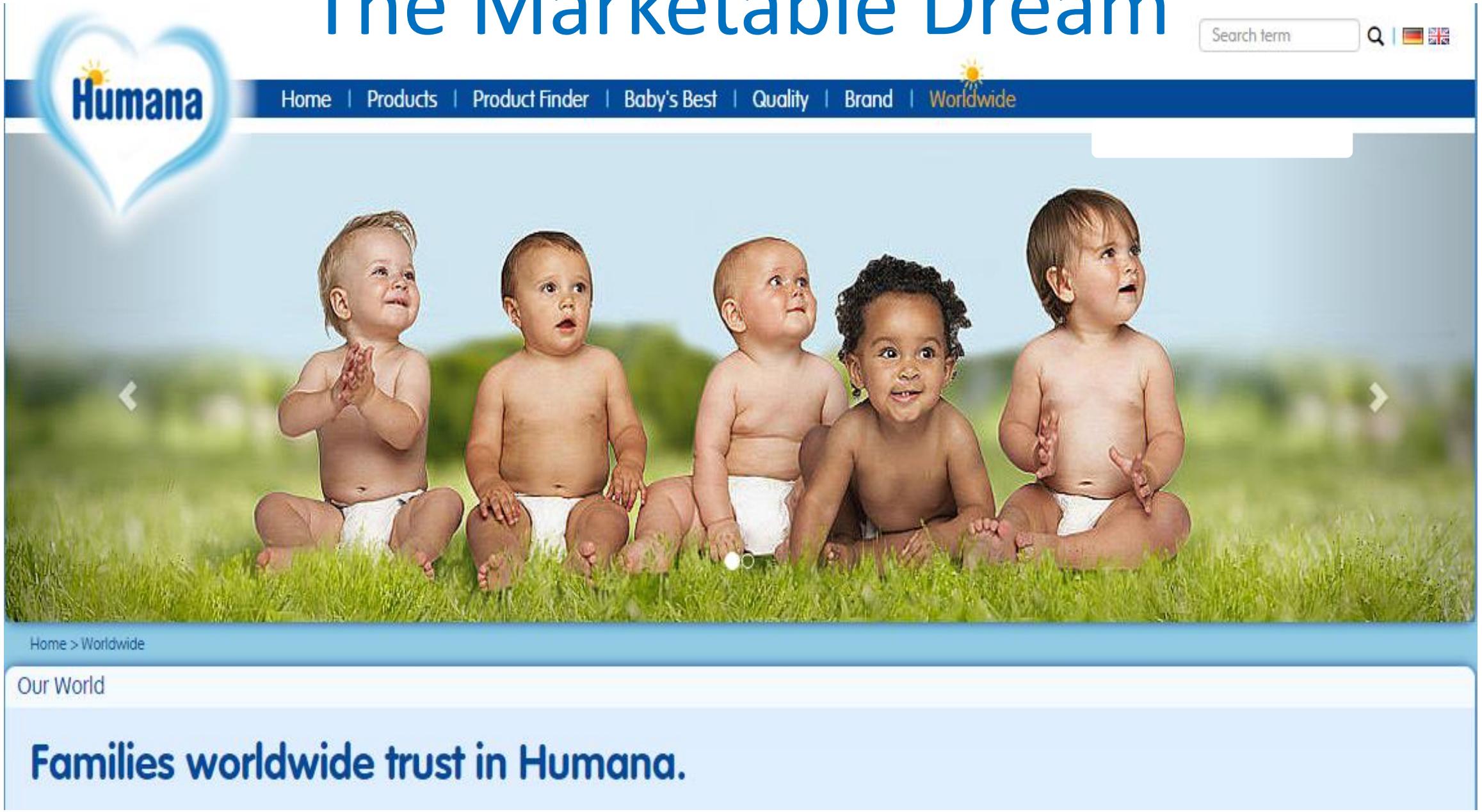
- The cause was found (within few days) to be a new on the market soy-based infant formula (manufactured by ***Humana*** in Herford, Germany) for distribution in Israel by ***Remedia*** *(Co Venture with Heinz)*, lacking vitamin B1 due to a **change** in May 2003 in the formula composition.
- Thus, the Israel infantile Thiamine deficiency outbreaks was due to Thiamine deficient new soya formula, with a relative high fatality and morbidity rate and long term consequences.

The Israeli Case-Study / cont.

- The victims are children who were exposed to a diet based exclusively on a vitamin B1-deficient soy-based formula during their first year and hence have suffered clinical or subclinical Thiamine deficiency.

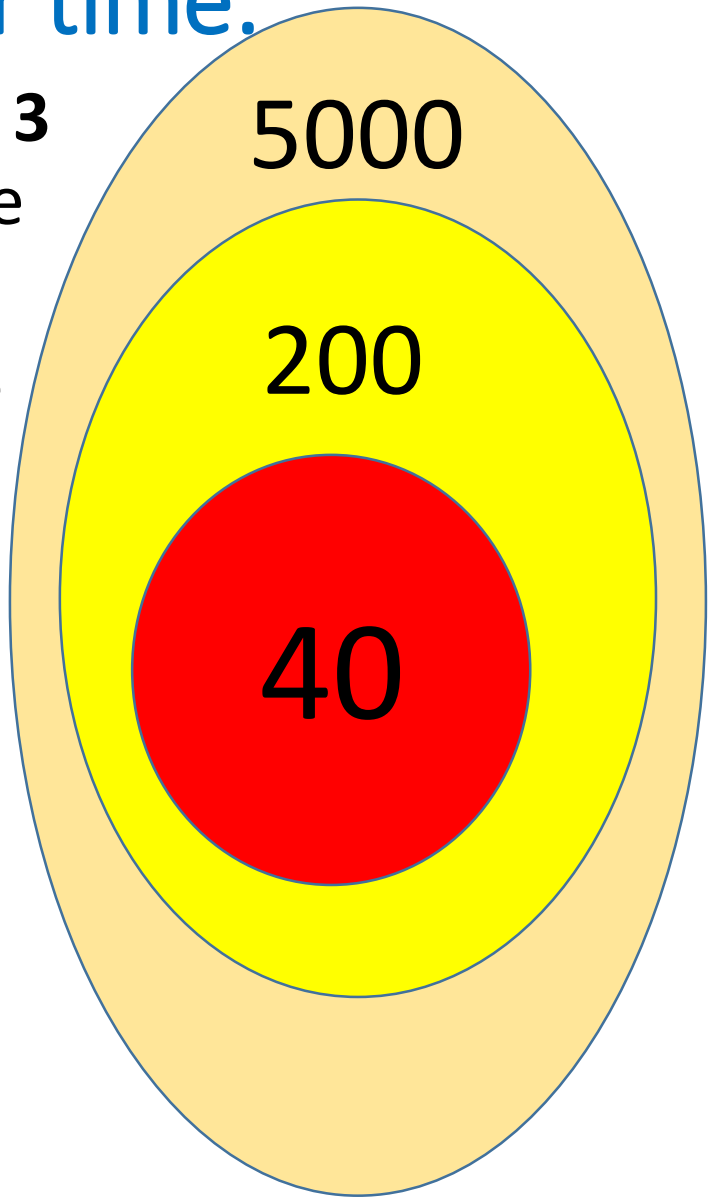
- At the instant the diagnosis of beriberi was established, the deficient formula was **legally withdrawn** from the market.

The Marketable Dream



The consequences of a lack of vitamin B1 (Thiamine) in critical food in Israel revealed over time:

- **First Circle**, "Immediate" findings. **40 infants**, of whom **3 died**, **8** suffered **very severe health impairments** and the rest **29 suffered severe morbidity**.
- **Second Circle**, after two years. About **200 babies** were diagnosed with seemingly minor harm. Although these babies were given Thiamine treatment at the time, yet worsening in their development can be observed.
- **Third circle**, 14 years after the event, and continues. **5,000** other **casualties** were identified. These teenagers today suffer from development problems and various cognitive impairment ADHD.
- **In total**, 65% of the infants who consumed plant-based ***Remedia*** have a medical condition one way or another.



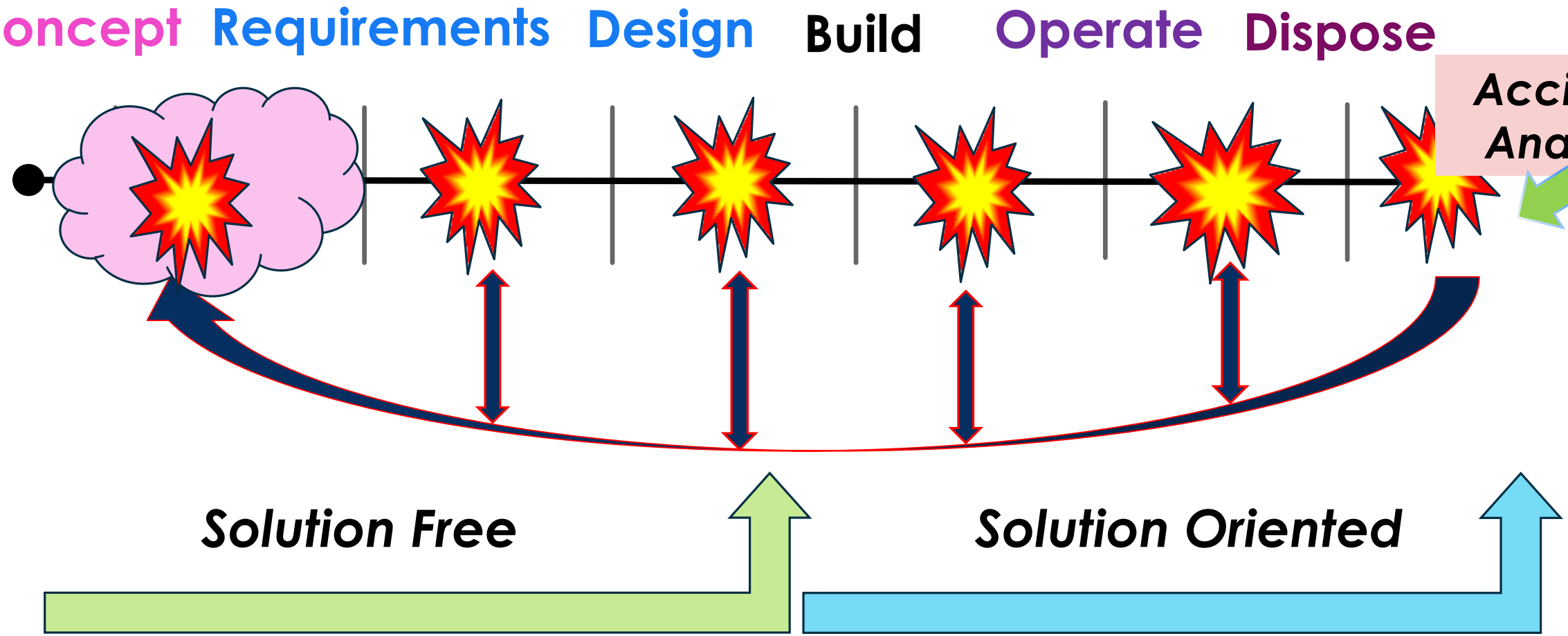
Accident Definitions - Remedia disaster

A Thiamine deficient soy protein-based infant formula led to severe Thiamine deficiency in recipient infants with lactic acidosis, encephalopathy, cardiomyopathy, and deaths, along with long-term neurologic problems in surviving children.

CAST

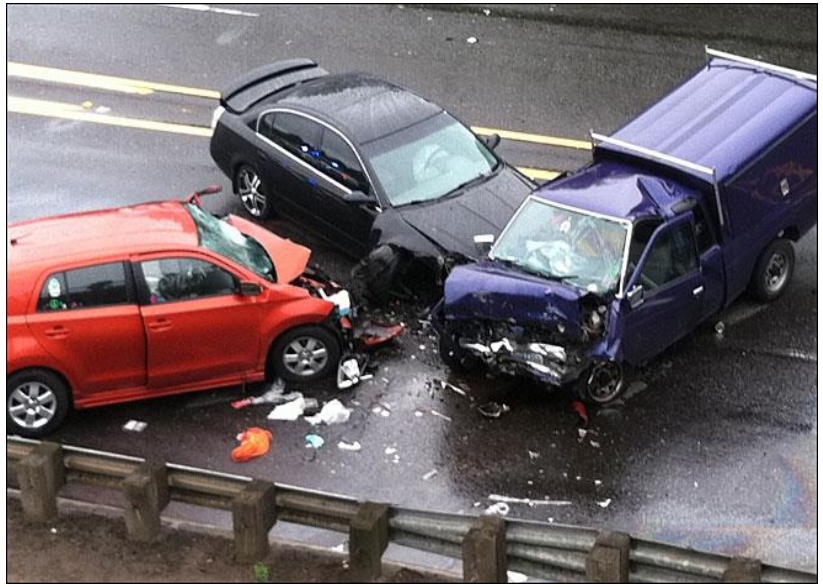
- **Illness and death of infants** who were **not nourished** by appropriate critical food, essential for their development, health and growth.
- **Illness and death of infants** **fed** by a critical **food** **negatively affecting** their health.
- **Illness and death of infants** **untreated in time** while suffering harms due to the defective critical food.

Value Chain, System's Lifecycle & Evidence Based Safety

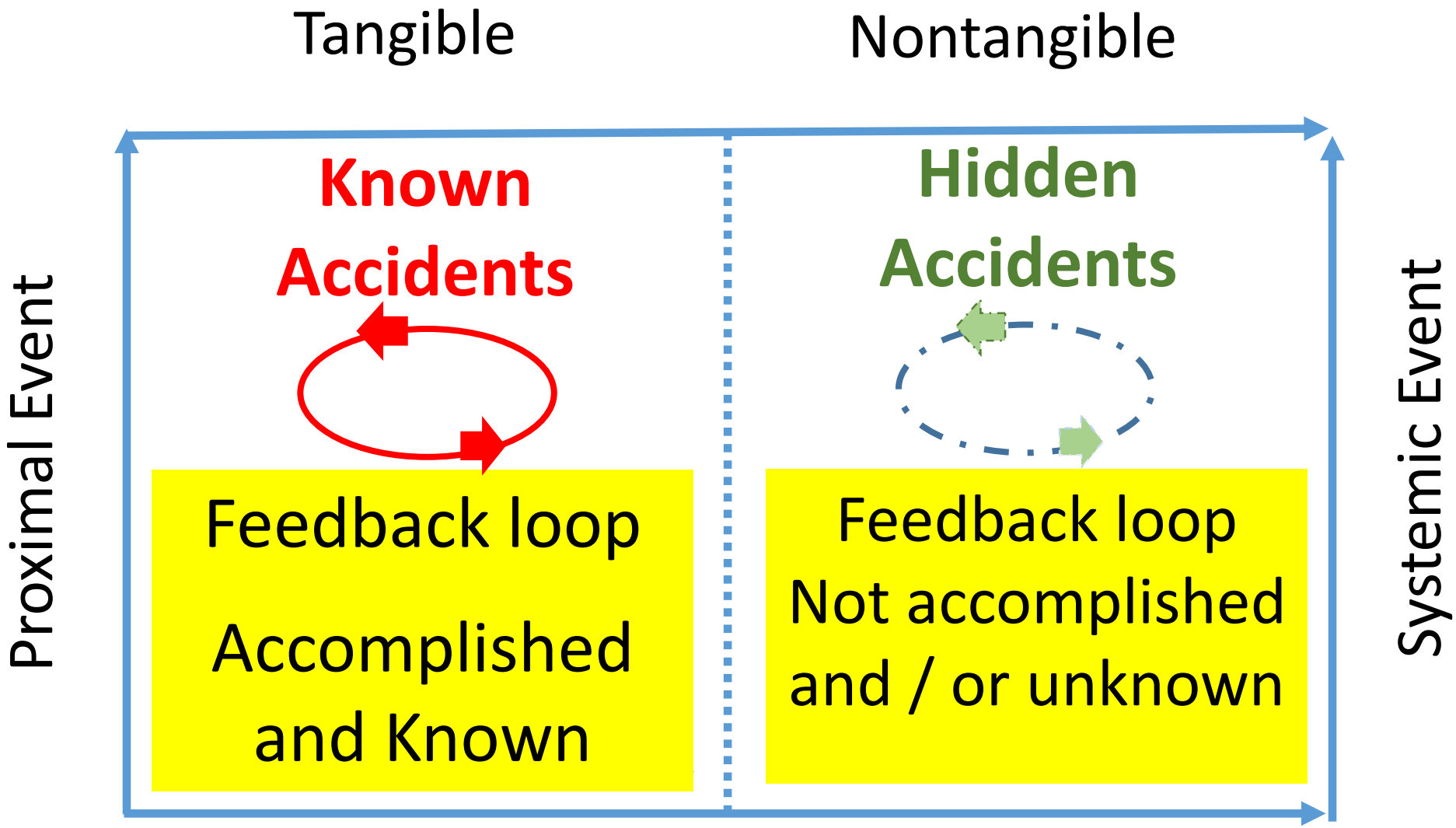


Proximal or Immediate Event

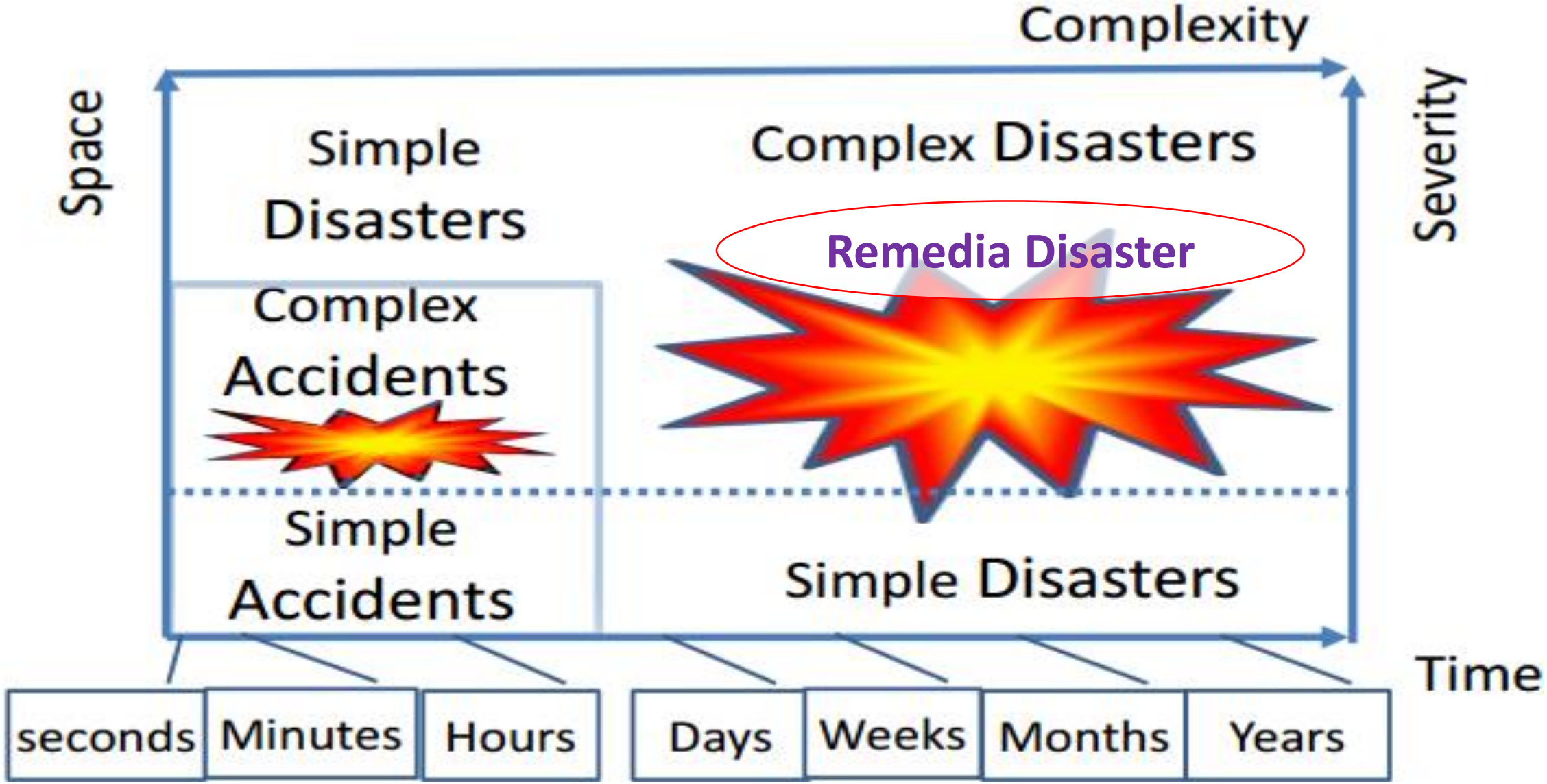
- An immediate / proximal event, is defined by us as an event that represents the very fast closing of a feedback loop in a particular type of accident.
- In reasonably "simple" accidents, for example a car , train or airplane crash, it is relatively very easy to define the tangible immediate events that preceded the accident and the moments of the accident itself.
- In Disastrous events such as the Remedia accident, the scope of timelines and places are much broader.
- The duration and location of the loss event and its consequences are not instant, and are not reflected immediately and revealed by clear feedback loops.



New Loss-Events / Accidents Classification



Accidents and Disasters



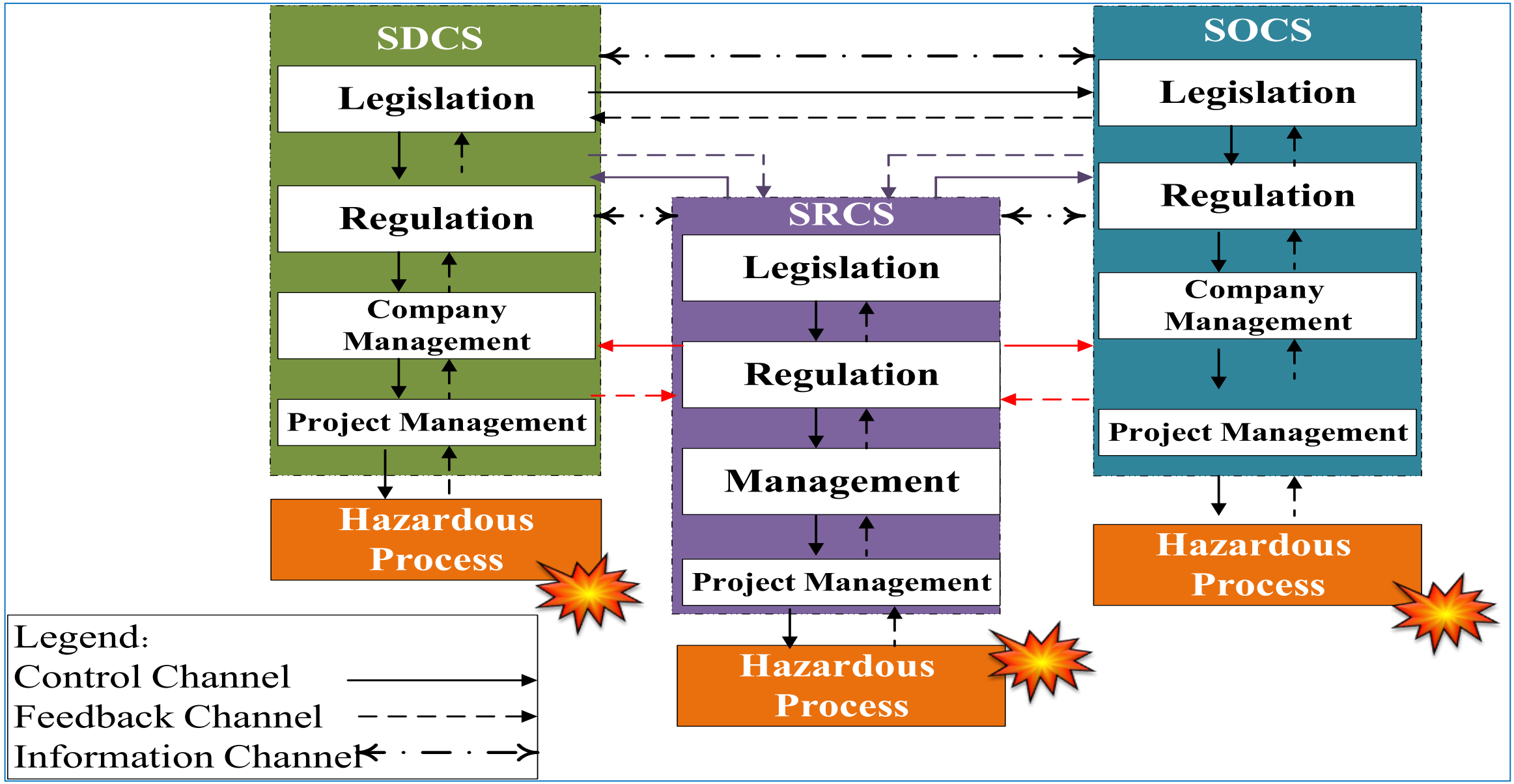
Course of Phases and Events in Time

- Events were divided into five Phases "time series“.
- Critical events (in **development and operation Safety Control Systems**) **preceding** the **proximal event** and spread out over a period longer than a decade.
- Other critical events (in **Response Safety Control System**) that contribute to the severity of the disaster, spread out well over a period of more than a decade after the immediate accident.

History and "time series“ related to the Remedia Disaster

Phases	Time Span	Duration	Activities – Hazardous Processes
The sequence of events **preceding** the disaster	1990 – November 2002	ca. 12 Years	Normal successful Business Activities (***Remedia*** & ***Humana***)
The sequence of events **leading** to disaster	December 2002 – 01.07.2003	ca. 5 Months	**New Product**: Design (***Remedia*** & ***Humana***), Production (***Humana***) & Marketing (***Remedia)***
Hidden Loss Events	July – 8.11.2003	ca. 4 Months	Unsafe Consume & Health Consequences
Proximal event	08.11. – 11.11.2003	ca. 4 Days	Disease Discovery & treatment onset
The sequence of events **following** the disaster	November 2003 – Present	ca. 14 Years	Disease Progress

The Complete Sociotechnical System as hierarchical control structures



System Hazards (SDCS, SOCS & SRCS):

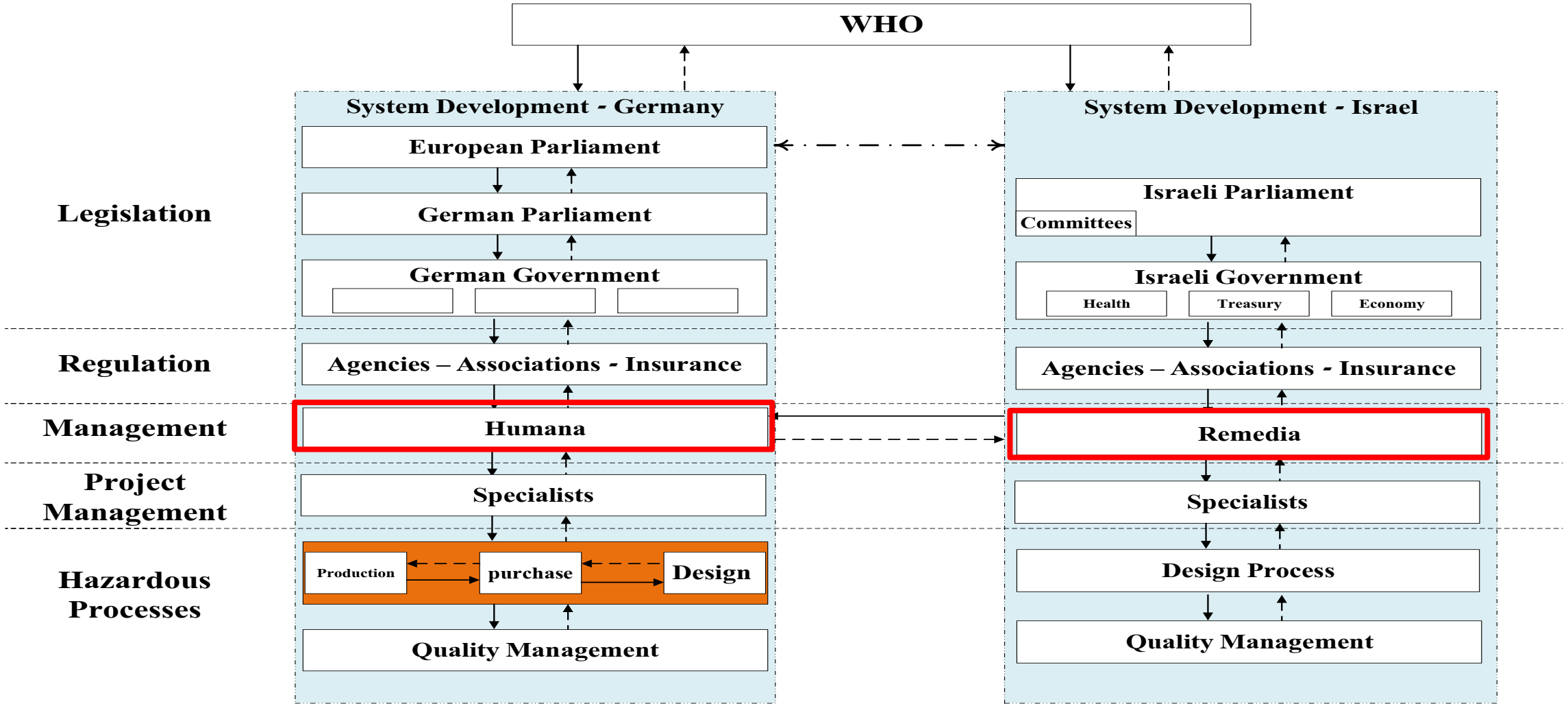
- H1 – infant critical safety formulas and products are designed and produced in an unsafe way
- H2 – Infants are fed with unsafe critical food
- H3 – Critical baby food is given in an unsafe way
- H4 – Infants do not receive safe critical food for their healthy development
- H5 – Infants do not receive adequate treatment to recover from damage caused by lack of critical food

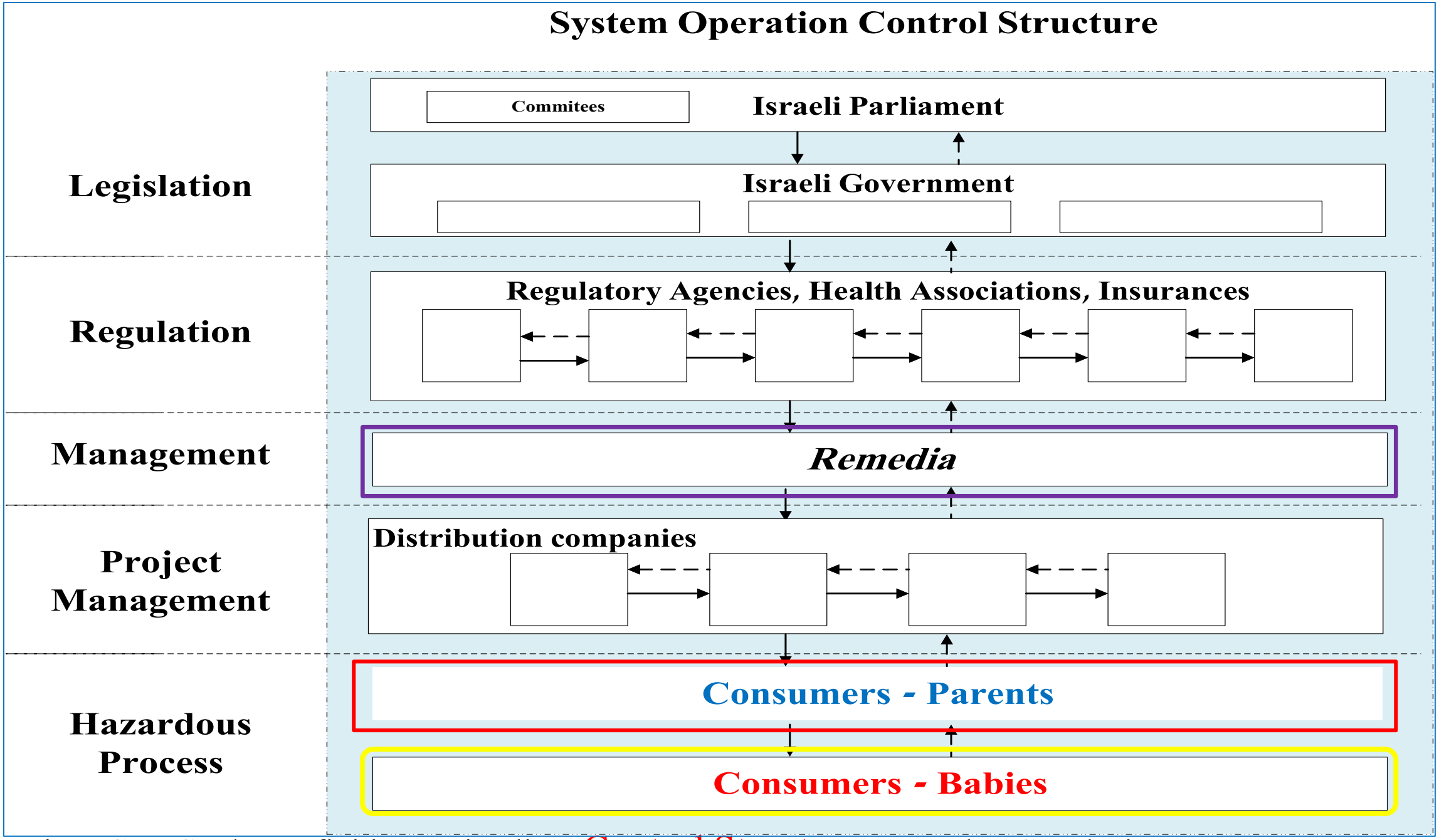
System Safety Constraints:

- SC1a - Infant formulas and products must be designed in a way that will give infants who consume them good health along their growth period
- SC1b - Infant formulas and products must be produced in a way that will give infants who consume them good health along their growth period
- SC2 - Food products for infants which are on the shelf must be safe and effective
- SC3 - Babies must be fed infant nutrition products in a beneficial way for their health and their normal development
- SC4 - Babies must be fed infant nutrition products in a safe and effective manner
- SC5 - When babies are fed non-safe critical food, appropriate medical measures and protocols must be take

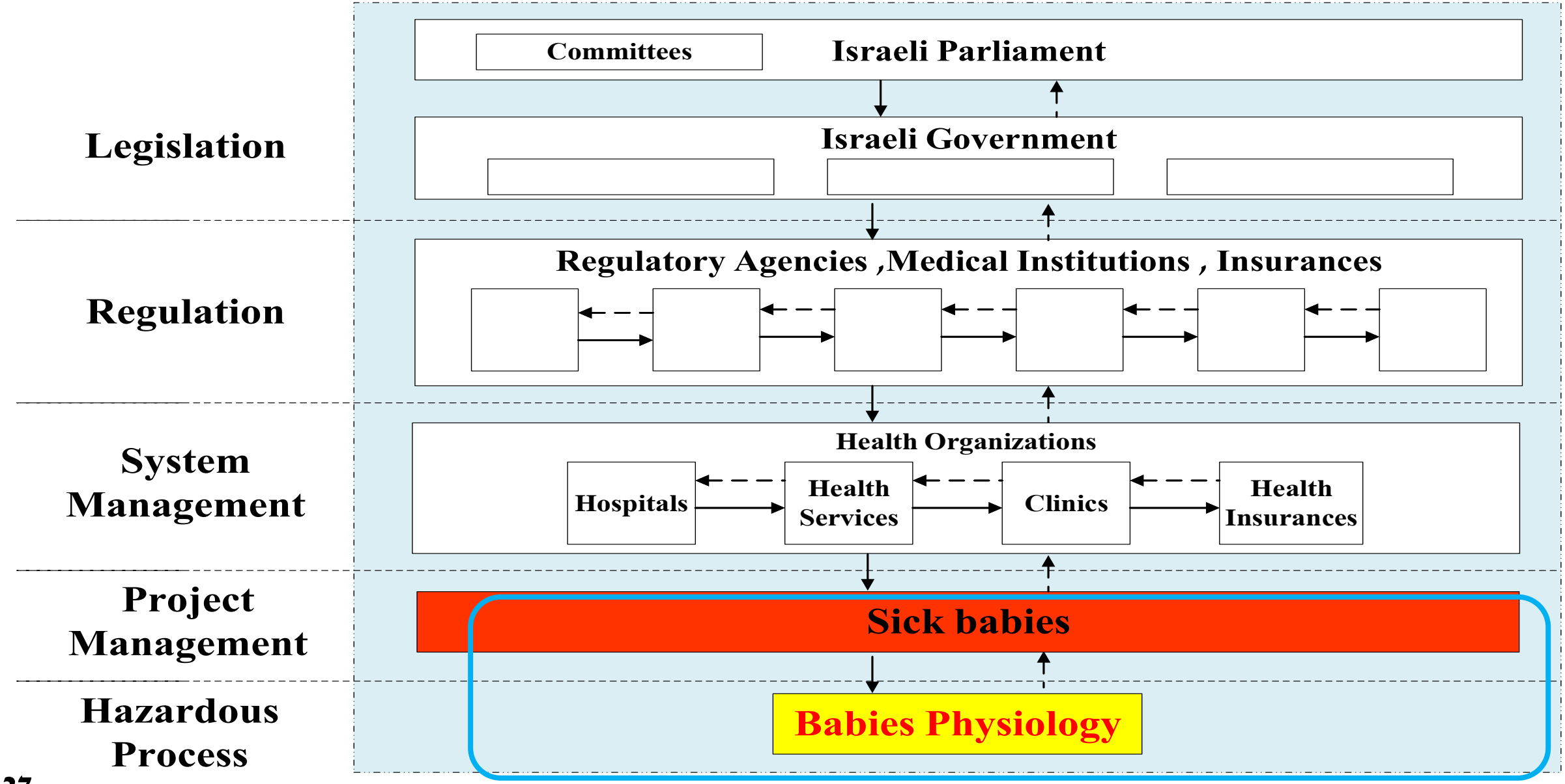
Hazards	Safety Constraints	Violation
H1 – Infants are fed with unsafe critical food	**SC1** - infant formulas and products must be designed and produced in a way that babies develop healthy along their growth period **SC2** - infants food products available on the market must be safe and effective **SC3** - Babies must be fed infant nutrition products in a beneficial way for their health and their normal development **SC4** - Babies must be fed infant nutrition products in a safe and effective manner	**SC1a - SDCS** **SC1b - SDCS** **SC2 - SOCS** **SC3 - SOCS** **SC4 – SOCS**
H2 - Critical baby food is given in an unsafe way	**SC3** - Babies must be fed infant nutrition products in a beneficial way for their health and their normal development **SC4** - Babies must be fed infant nutrition products in a safe and effective manner	**SC3 - SOCS** **SC4 - SOCS**
H3 – Infants do not receive safe critical food for their healthy development	**SC3** - Babies must be fed infant nutrition products in a beneficial way for their health and their normal development **SC4** - Babies must be fed infant nutrition products in a safe and effective manner	**SC3 - SOCS** **SC4 – SOCS**
H4 – Infants do not receive adequate treatment to recover from damage caused by lack of critical food	**SC5** - Appropriate medical protocols and measures must be taken to ensure the remediation of diagnosed babies fed with non-safe critical food.	**SC5 - SRCS**

System Development Control Structure

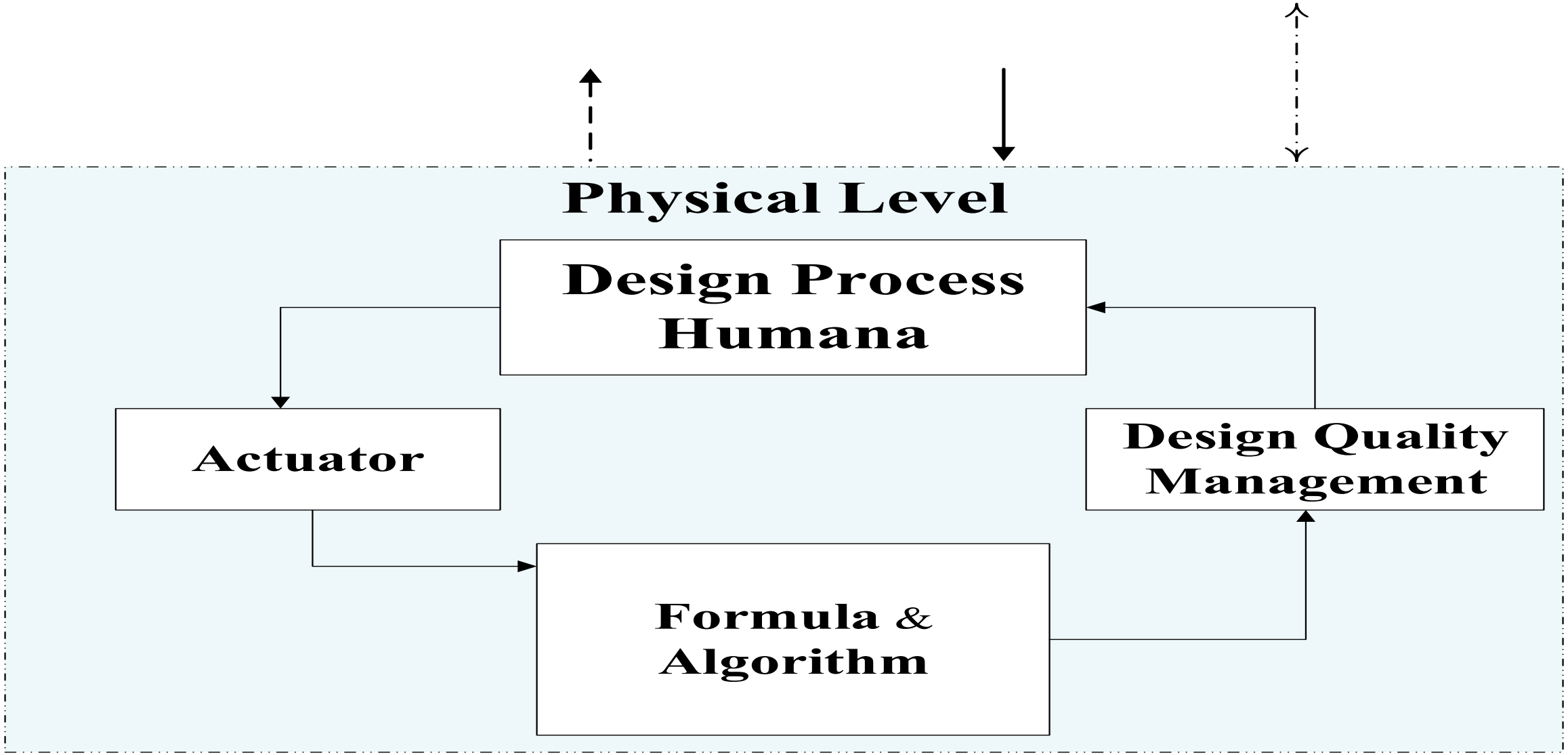



System Operation Control Structure
Legislation
Commitees
Israeli Parliament
Israeli Government
Regulation
Regulatory Agencies, Health Associations, Insurances
Management
Remedia
Project Management
Distribution companies
Hazardous Process
Consumers - Parents
Consumers - Babies

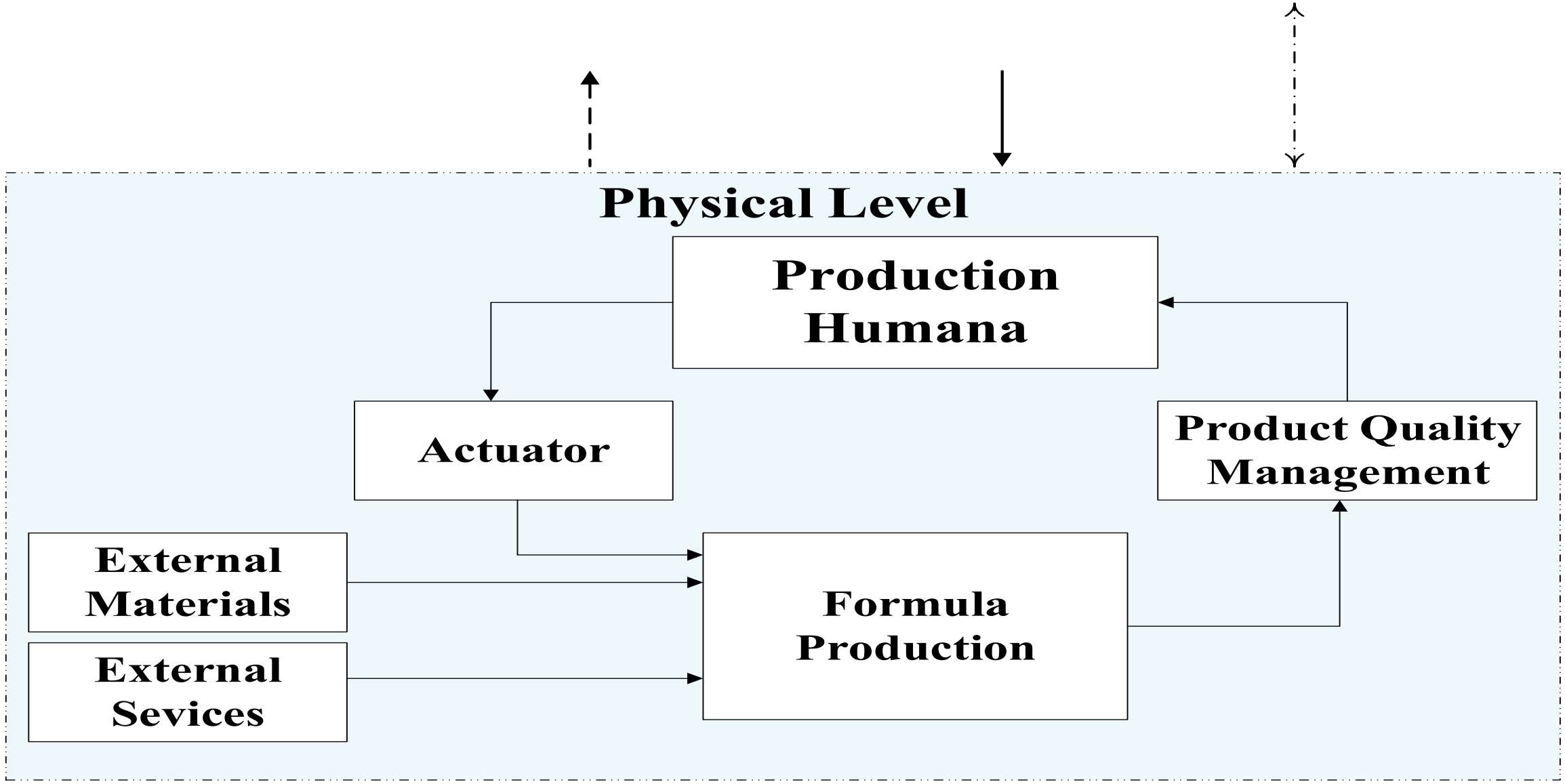
System Respond Control Structure



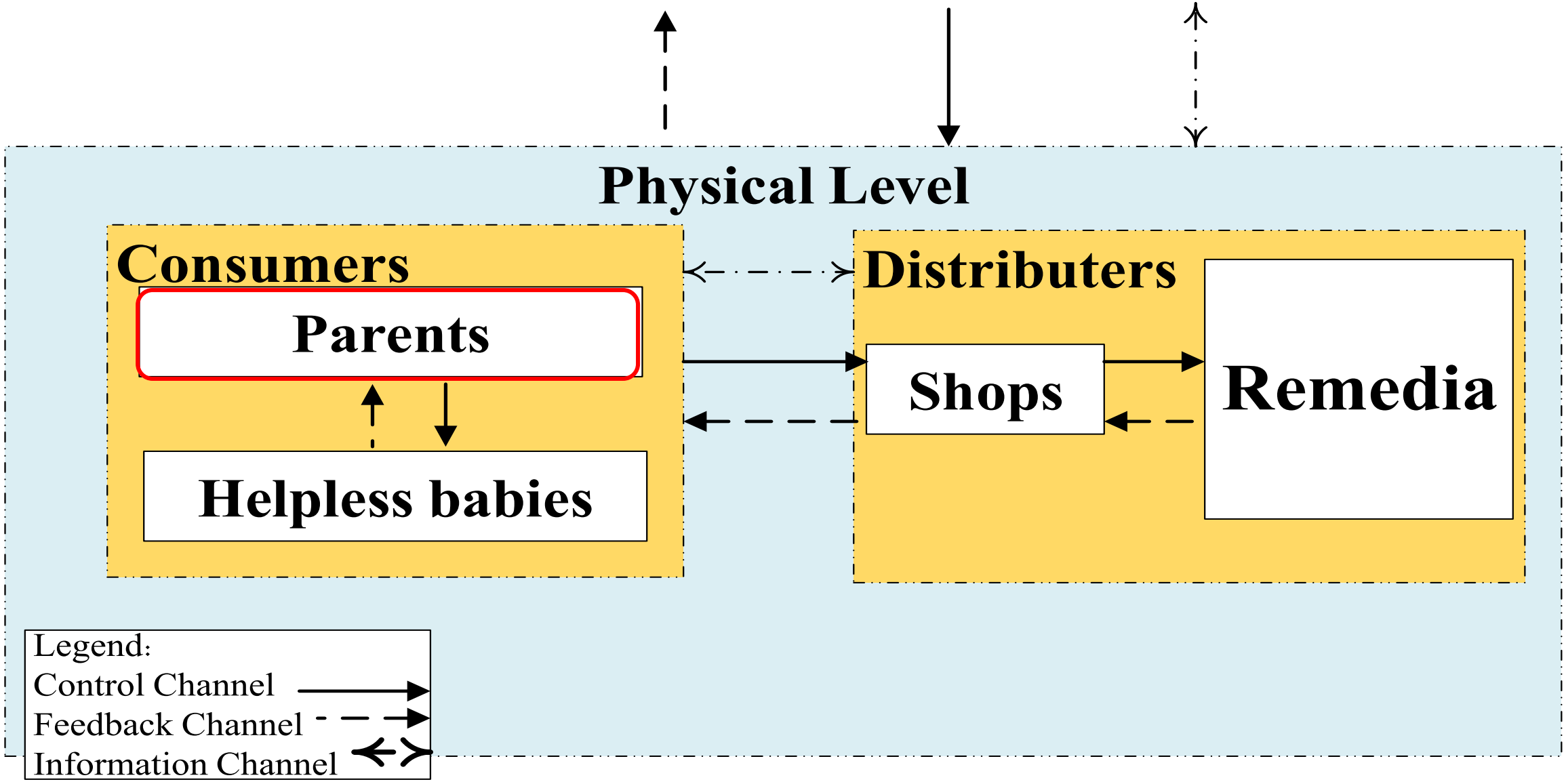
System Development (Design Phase) Control Structure



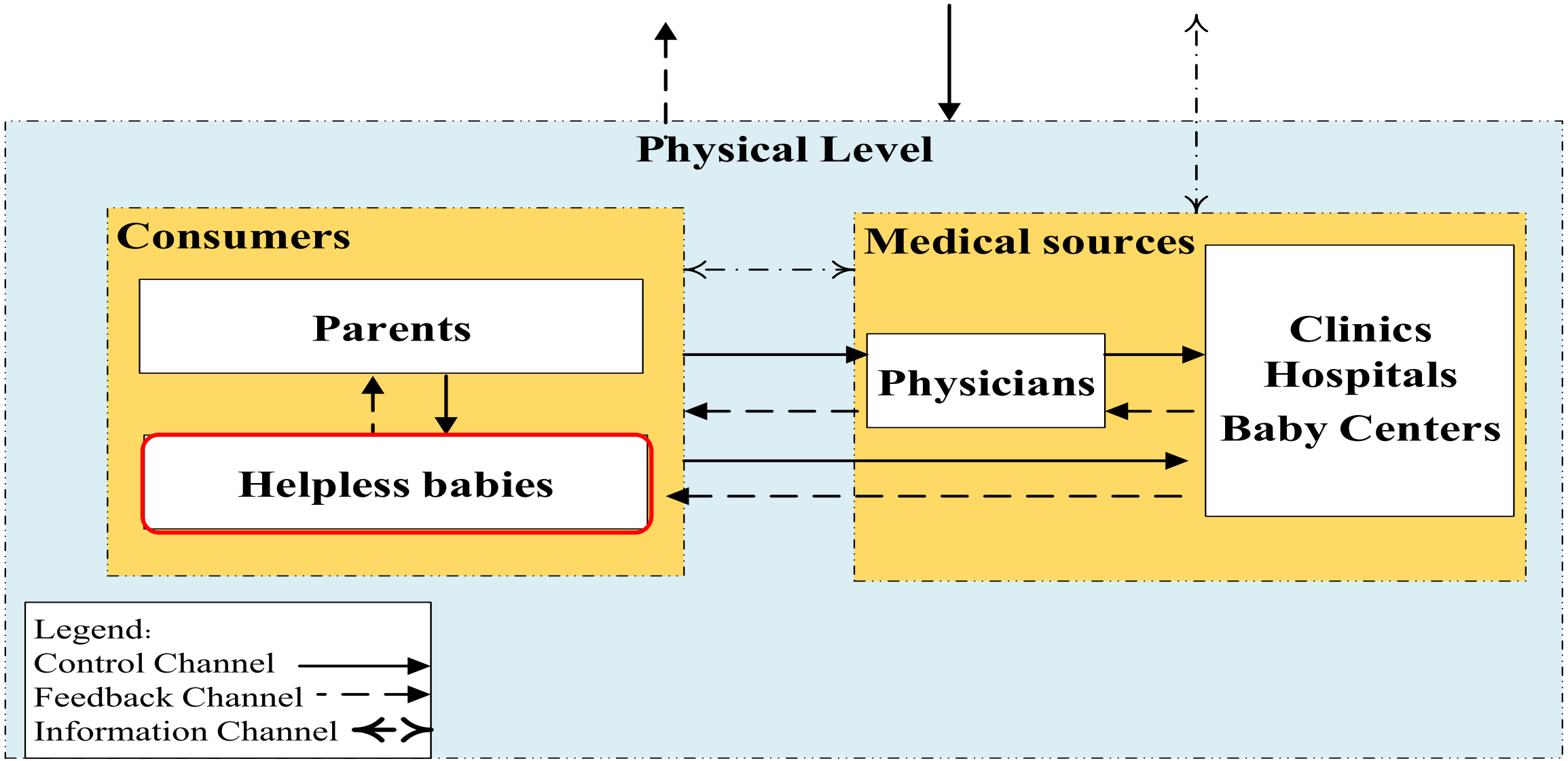
System Development (Production Phase) Control Structure



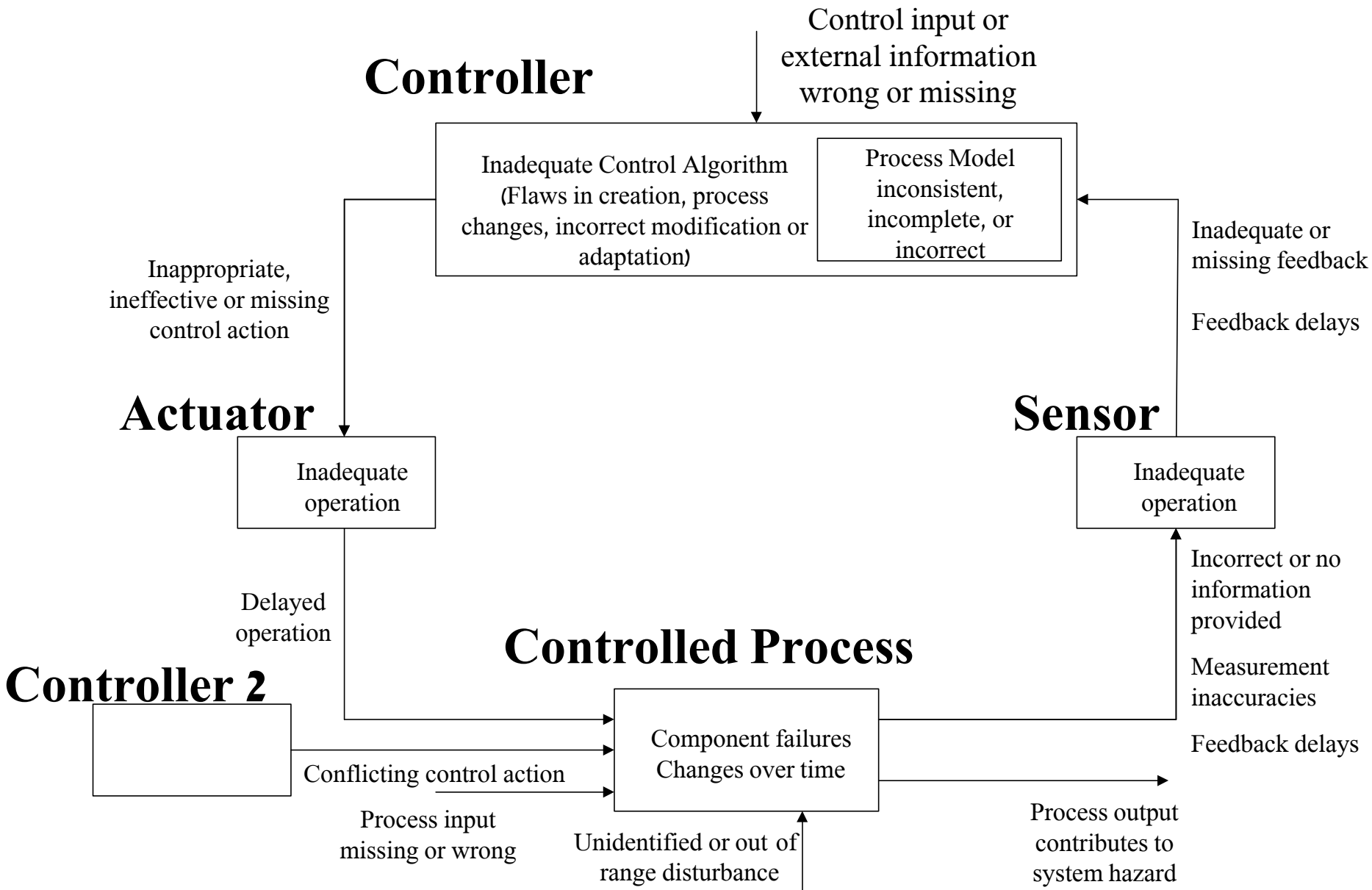
System Operation Control Structure



System Response Control Structure



Weak Control Structure



General Conclusions as to **SDCS** Physical Level

- Very complex and dispersed ST control structures.
- The organizations involved do not understand the full range of hazards and their potential consequences.
- No clearly defined Accountability and Responsibility in the SDCS.
- Structural weakness causing inconsistency in collecting and processing critical data, and in real time.
- Synchronization and Coordination problems due to structural problems.

General Conclusions as to **SDCS** Upper Levels

- Inefficient, bureaucratic ST systems.
- Regulations are outdated, inefficient and not involved in real life.
- A chronic shortage of resources to carry out policy.
- No effective inspection and enforcement.
- No change and / or drift management, and no understanding of their meaning regarding safety impact on the systems.

General Conclusions from **SOCS** Physical Level

- The organizations and persons involved do not understand the full range of hazards and their potential consequences.
- No clearly defined Accountability and Responsibility in the SOCS.
- Structural weakness causing inconsistency in collecting and processing data in real time.
- Synchronization and Coordination problems due to structural problems.

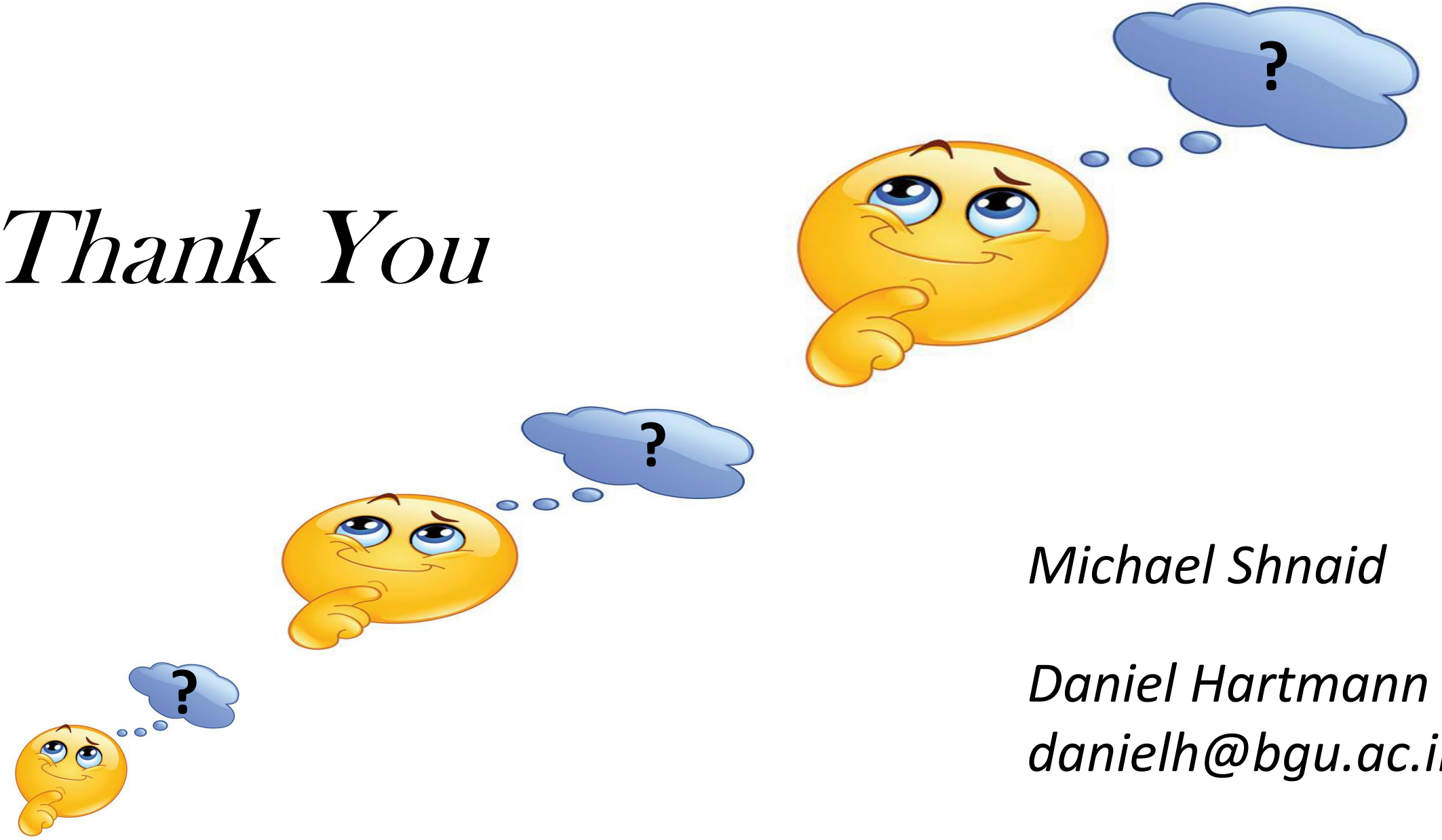
General Conclusions from **SOCS** Upper Levels

- Inefficient, bureaucratic systems.
- Regulations are outdated, inefficient and not involved in in real life.
- A chronic shortage of resources to carry out policy.
- No effective inspection and enforcement.
- No change and / or drift management, and no understanding of their meaning regarding safety impact on the systems.

Lessons Learned

- The need for **Evidence Based Safety**:
  - To achieve a “safer world”, input from accident analysis is crucial for any system hazard analysis.
- The entire Sociotechnical System comprising of **SDCS**, **SOCS** and **SRCS** and all their interactions should be considered and analyzed.
- Apart of the Physical level, most upper levels in the Socio-Technical System can contribute **generic** Hazards, Safety Constrains and problems that can be defined and contribute to any Hazard analysis of similar systems and domains of operation.
- The importance of Hazard analysis for any crucial **change** in systems.

Thank You



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