

ПРЕЗЕНТАЦИЯ

PRESENTATION

International conference on
Food Safety Risk Analysis and
Antimicrobial Resistance

Moscow, Russian
Federation, 17- 18 12/2019

Международная
конференция по вопросам
анализа риска безопасности
пищевой продукции и
устойчивости к
противомикробным
препаратам

Москва, Российская
Федерация, 17 -18 12/2019

Getting organised at country level – capacities for risk assessment

Dr Rickard Bjerselius
Science Division
Swedish Food Agency

*International conference on Food Safety and Risk Analysis & Joint Efforts
on Reducing Antimicrobial Resistance, Moscow, December 17-18, 2019*



Content

- System approach – The Principles of Risk Analysis
- Swedish Food Agency - organisation
- Risk assessment – where science rule
- Risk management – where the decisions are taken



Principles of Risk Analysis

- “The key principles for transparent use of risk assessment in decision making are clear, and are set out in the **Codex Working Principles for Risk Analysis for Food Safety for Application Governments (2007)**, which are widely supported.”

Internationally recognised framework for Codex Alimentarius, EU ((EG) nr 178/2002) and the Swedish Food Agency



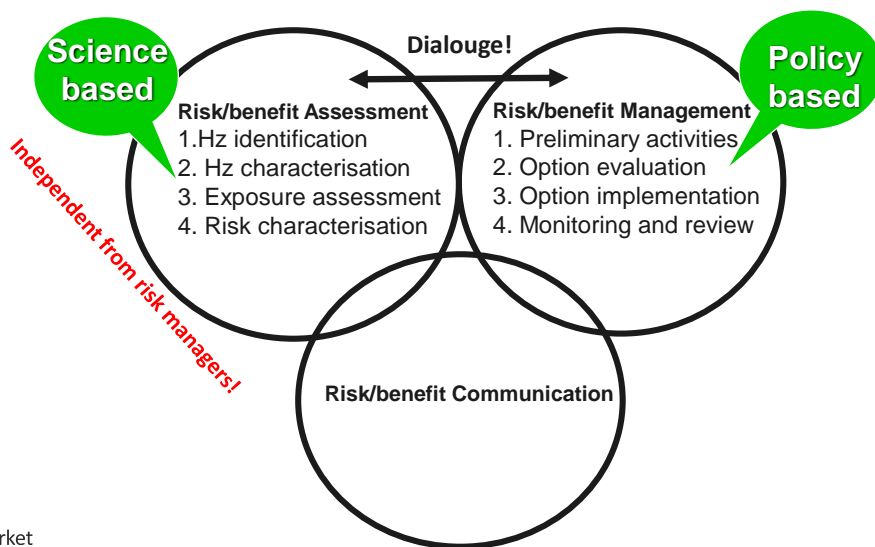
The Risk Analysis framework

- An approach to analyze and manage activities that may have negative consequences

Risk analysis in food safety:

- A tool, which in a systematic, formalized and transparent way, enables responsible authorities and international organizations to understand and if necessary evaluate options to reduce a health risk

Risk Analysis framework



The Principles – Risk analysis

The following principles in the *Codex Working Principles for Risk Analysis for Food Safety for Application Governments (2007)* are particularly relevant:

- All the three steps in Risk analysis should be applied consistently; *open, transparent and documented*
- There should be a *functional separation of risk assessment and risk management* to the degree practicable, in order to *ensure the scientific integrity of the risk assessment*, and to *reduce any conflict of interest*.
- [...] it is recognised that risk analysis is an iterative process, and *interaction between risk managers and risk assessors* is essential for practical application (para. 11)

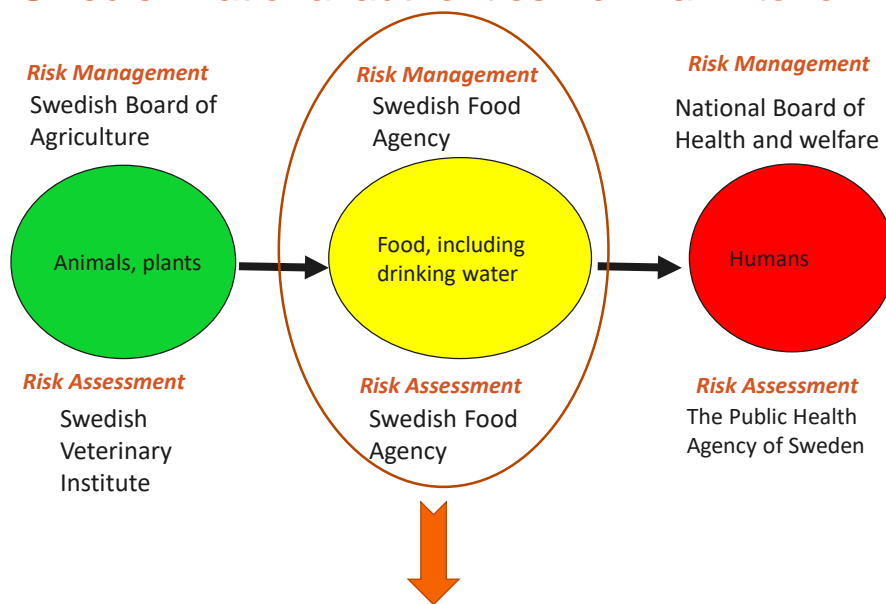
The Principles –Risk/benefit assessment

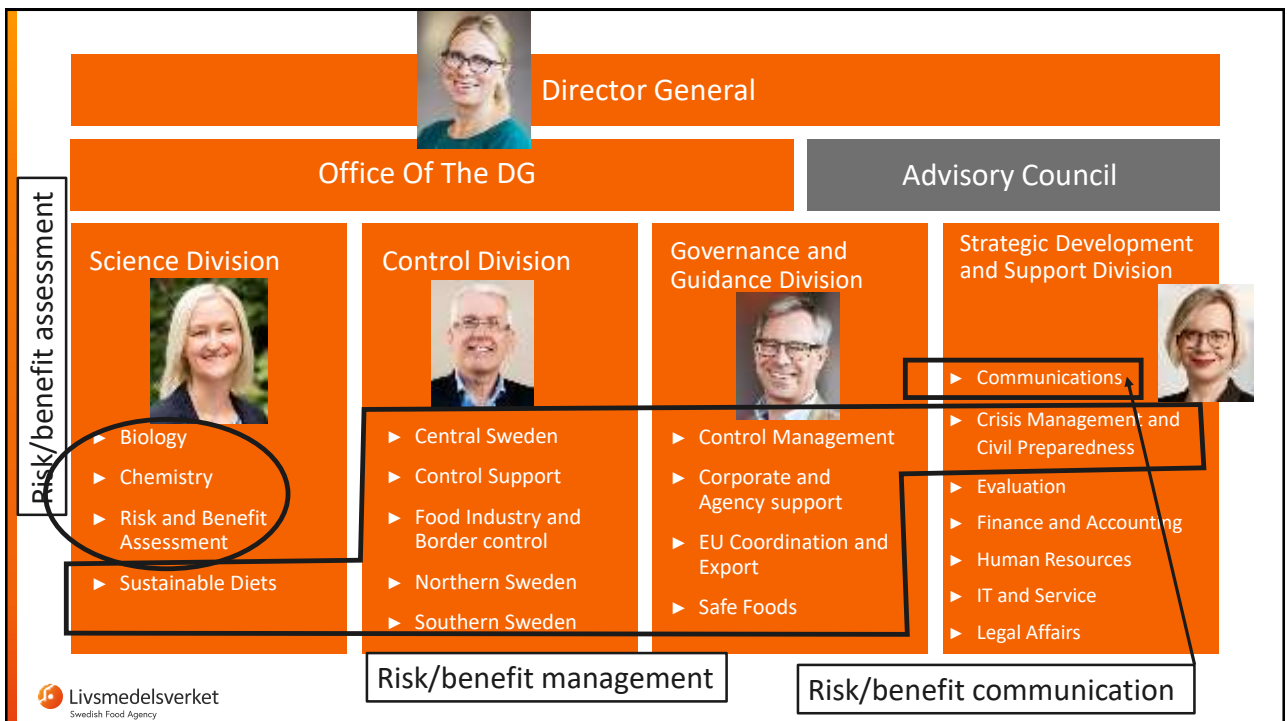
- Experts involved in risk assessment including government officials and experts from outside government should be *objective in their scientific work* and not be subject to any conflict of interest that may compromise the integrity of the assessment.
- Risk assessment should *incorporate the four steps of risk assessment*, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.
- Risk assessment should be based on scientific *data most relevant to the national context*.
- *Constraints, uncertainties and assumptions* having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and *documented* in a *transparent* manner.
- Risk assessments should include *consideration of susceptible and high-risk population groups*.....

The Principles – Risk/benefit management

- the [risk management] decisions should be **based on risk assessment**, and should be **proportionate** to the assessed risk, taking into account, where appropriate, **other legitimate factors** relevant for the health protection of consumers and for the promotion of fair practices in food trade
- “also” the risk management process should be **transparent, consistent and fully documented**. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties

Swedish national authorities from farm to fork





Three overall objectives of the Swedish Food Agency

The SFA assesses, manages and communicates food values and risk in order to enable

- safe food and drinking water
- healthy eating habits
- fair practices in the food sector

During **everyday** normal circumstances as well as in **crisis**

Swedish Food Agency – Working principles for the Risk Analysis

Tillämpning av riskanalysens principer vid Livsmedelsverket

Inledning

Arbetet med och åtgärder rörande säker mat, vedligehåll och hanteringen ska ske enligt riskanalysens principer. Livsmedelsverkets syfte är att begränsa, undanröja eller undvika hälsofaror. För att uppnå detta används riskanalysens principer genom de tre sammanhängande delarna: risk- och nyttovärdering, riskhantering och riskkommunikation. Detta arbete ska tillämpas såväl när det gäller risk som andra risker som hälsa, miljö och andra relevanta områden.

Principer för tillämpningen av riskanalys inom Livsmedelsverket har tagits fram inom Codex Alimentarius och sammanfattat av EFSA. Definitioner av begrepp från i Europaparlamentets och rådets förordning (EG) nr 178/2002 och i Codex Alimentarius Commission, Procedural Manual. Arbetsmetoden bygger även på EFSA Scientific Opinion: Guidance on human health risk benefit assessment of food.

En förutsättning för förarbetet för den vetenskapliga grunden är att risk- och nyttovärderingen görs på ett objektivt, öppet och tydligt sätt och grundas på tillgängliga vetenskapliga uppgifter och data. På samma sätt är en förutsättning för förarbetet för riskhanteringsprocessen att den sker på ett systematiskt och transparent sätt, där motivet för val av hanteringsåtgärder redovisas tydligt.

Livsmedelsverket har i flera år arbetat enligt riskanalysens principer, vilket inte det gäller risker och i andra utvecklingar när det gäller nyttoperspektiv. Arbetsmetoden beskrivs dock utvecklas och därför behövs ett strukturerat arbetssätt, som beskrivs i denna instruktion.

Beskrivning av olika begrepp inom riskanalys


Riskprofil

Riskprofil är en beskrivning av ett säkerhetsproblem kopplat till ett livsmedel utifrån ett sammanhang. I en riskprofil dokumenteras tillgänglig kunskap och identifieras ytterligare kunskap som kan behövas. Riskprofilen används för att ge underlag till beslut om fortsatta åtgärder. Följande åtgärder är möjliga:

- riskprofilen ges ett tillräckligt underlag till beslut om eventuella riskhantering utan att en risk- och nyttovärdering behöver göras
- riskprofilen visar att tillräcklig kunskap finns för att göra en risk- och nyttovärdering utan behov av hanteringsåtgärder
- riskprofilen identifierar kunskapsluckor som motiverar att ytterligare vetenskapligt underlag samlas in från annan än risk- och nyttovärdering kan göras och beslut om eventuella riskhanteringsåtgärder fattas

Risk- och nyttovärdering

Risk- och nyttovärdering är en vetenskapligt arbetssätt som ska ge underlag för att kunna vidta åtgärder (tillåtelser). Risk definitionen utgörs av "sannolikheten för och konsekvenserna av en skada".

 Livsmedelsverket	Utgivet av: JARA 2011-02-03	Göras av: JARA 2011-03-03	Sid 1/10
	Enligt: Tillämpning nr. 2011-01-01	Dokumentation: Kunskapsgranskning av ELFI	

2011-03-03 utgåva på papper för 75-årsjubileet för att det ska vara enkelt att läsa

Swedish Food Agency – Risk/benefit assessment

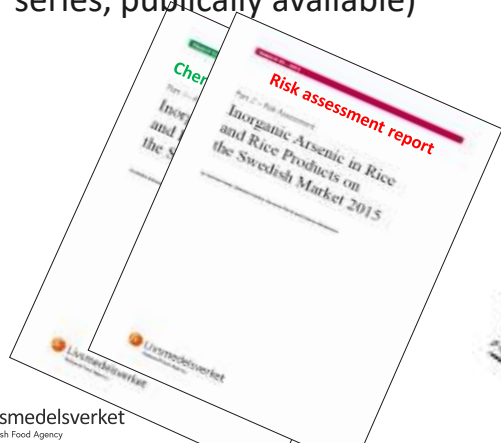
- Risk managers identify a food safety problem
- "Framing meeting" with risk assessors, where the question is discussed (e.g. scientific reports available, exposure assessment for consumers in Sweden, risk groups, new data necessary, etc.)
- Risk managers write a question to the Risk-benefit department, addressing the question and type of documentation, intended purpose for risk management, etc.

SFA risk/benefit manager question to risk assessors

Annex B1 National Food Agency, Sweden Question to Risk- and Benefit Department	
Question to Risk - and Benefit Department	
Send to NN, Assisting Head of R/B-Department (NN@slv.se)	
<hr/>	
Name of risk manager: Department/Unit:	
Registration number (the responsibility of the risk manager):	
Overall objective:	
Specific issues to address (E.g. risk groups, unit of risk/benefit):	
The response will be used for/target audience (for what and to whom is the report intended, e.g. EFSA, Department of Control):	
The responses will be presented as (type of oral/written delivery):	
Time frame	
Starting Date:	
Final Date (when is the response needed):	
Resources (e.g. account number for showing time and debiting):	
<hr/>	
Filled in by Risk- and Benefit Department:	
Internal id (E.g. RN001/2011):	
Person responsible:	Date when task given:
Level of Quality Assurance: Traceability, transparency, review (Colleague, Co-authors, Internal reference group, External expert(s), Peer review):	
Delivery of response	
Date response delivered:	
Response delivered in writing as a:	
Feedback from risk manager:	
Finalised/approved/publicised:	
Signature of person in charge:.....	

Swedish Food Agency – Risk/benefit assessment

- Risk assessment is performed independently and science based
- If necessary, dialogue between assessors and managers
- Risk assessment is handed over to risk managers (published in SFA report series, publically available)



Next step - a challenge in the Risk Analysis process



- **“The proper and transparent use of risk assessment in decision making is essential to maintaining and building trust and credibility of food regulation and the wider food system.”**
- **“This trust and credibility is undermined when risk managers and decision-makers selectively interpret or misrepresent the scientific aspects of risk assessments, particularly with regard to uncertainty, to justify decisions which are really based on political, social, economic or other factors”.**

*Heads of National Food Agencies Working Group on Transparent Use of Risk Assessment in Decision Making
Final report to the Heads of Agencies, April 2012*

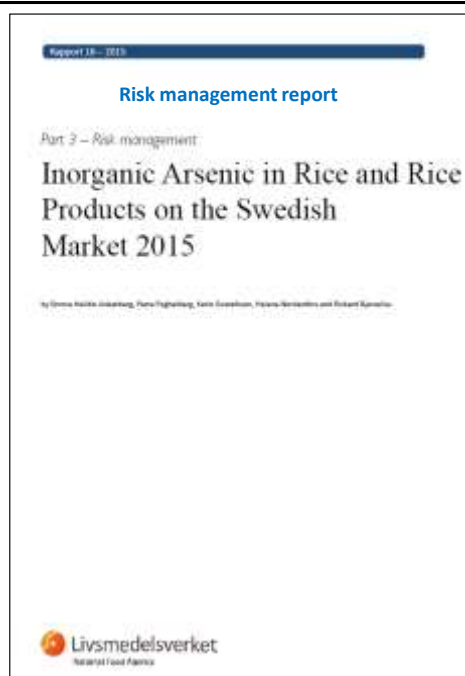
Swedish Food Agency – Risk/benefit management were the decisions are taken

A corresponding report for the risk management process

- Risk/benefit assessment included
- Other Legitimate Factors included
- Risk/benefit managers document what has been considered
- Finally a conclusion which clearly motivate the decision taken to e.g. reduce the risk or increase the benefit – or no action!

Documentation of the Risk/benefit management

The document also available to the public!



Transparent documentation of the Risk Analysis process



<http://www.livsmedelsverket.se/en/food-and-content/onskade-amnen/metaller/arsenik-i-ris/>

Take home messages

- Risk analysis (RA) enables a consistent and objective approach to management of risks and crises
- RA emphasizes operational separation (in responsibility and roles) of risk assessment and risk management
- Management decisions are science and risk based but also considers other legitimate factors, including environment and climate
- **Transparency and documentation – key words for the whole process**

Thank You for
your attention!

