EHEC crisis in Europe 2011
- a food safety crisis and its lessons learned

Dr. Anja Buschulte (BfR) and Dr. Milagros Nieto (AESAN)
Administrative background

Microbiological risk assessment (MRA) – general aspects

MRA using the EHEC crisis in Europe 2011 as a real example

Challenges for risk assessment and management

What about risk communication?

Lessons learned
Administrative background - GERMANY
Shared responsibility in Germany

- **Inspection, monitoring, surveillance** is within the responsibility of the 16 **federal states** *(regional and local level).*

- Their ministries and subordinate authorities act on their **own responsibility**.

- The 16 federal states coordinate their work in working groups and **invite** the **federal authorities** to **contribute** and **cooperate**.

- **Risk assessment** and risk **management** are **not divided**.
Germany within the global food safety network

**Risk Assessment**
- FAO & WHO expert committees

**Risk Management**
- Codex Alimentarius Commission & Member States
- FVO Food and Veterinary Office

**Global**
- European Food Safety Authority (EFSA)

**Europe**
- Federal Ministry of Food and Agriculture
- Federal Office of Consumer Protection and Food Safety

**Germany**
- Bundesinstitut für Risikobewertung (BfR)
- 16 Federal States
- Industry

- Risk assessment
- Risk communication
- EFSA Focal Point
- Research
- Risk management
- RASFF Contact Point

Inspection, monitoring, surveillance
- Self-monitoring, HACCP, GMP, GHP, QM

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Administrative context-SPAIN
Spanish Food Safety and Nutrition Agency (AESAN)

Risk Assessment
- Scientific committee
- Experts panels
- Data bases
- Food consumption
- Food composition

Risk Management
- Legislation
- Food register
- Codex secretariat
- RASFF/SCIRI
- Official control & coordination

Risk Communication
- Webpage
- Press office
- Publications
- Communication strategies

Risk Analysis
- EFSA FOCAL POINT
- RASFF FOCAL POINT
- INFOSAN

European Food Safety Authority
RASFF
INFOSAN
EC
Microbiological risk assessment (MRA) – general aspects
Risk Analysis framework

Risk Assessment
1. Hazard identification
2. Hazard characterisation
3. Exposure assessment
4. Risk characterisation

-Science based-

Risk Management
- Policy based -
- Risk evaluation
- Option assessment
- Option implementation
- Monitoring and review

Risk Communication
Exchange of information about risk between assessors and stakeholders
Philosophy of Risk Assessment

- **Identify** potentially **hazardous** situations
- **Estimate** the **uncertainty** associated with the analysis
- **Provide** alternative **options** to **reduce** a possible risk
- Estimate the **adequateness** of those **options**
- Application of the **precautionary principle** which means:

  Even when scientific knowledge is incomplete, consumer protection measures are frequently admissible and sometimes have to be taken very quickly!

**Particularly applicable during food-borne outbreaks**

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Microbiological Risk Assessment (MRA) scheme

Statement of Purpose

Hazard Identification
Identification of agents capable of causing adverse health effects and which may be present in a food

Exposure Assessment
Evaluation of the likely intake of agent(s) via food

Risk Characterization
Estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population

Hazard Characterization
Evaluation of the nature of the adverse health effects. A dose-response assessment should be performed if data is obtainable

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MRA using the EHEC crisis in Europe 2011 as a real example
E. coli O104:H4 outbreak Germany 2011 – at a glance

Cases: 3,793 (2353 hospitalized, 53 death) cases in Germany and cases in 12 EU Member States, Switzerland, Canada, USA (all with link to Germany)

Setting: Disseminated cases (restaurants, hotels, canteens, household)

Evidence: Cohort-stud, and network analyses (delivery chains of sprouts and seeds)

Causative food: Sprouted fenugreek seeds from Egypt
Activities in a foodborne outbreak:

Characterisation of the disease-causing microorganism

- ✓ Characteristics of the outbreak strain
- ✓ Occurrence of the agent in different matrices
- ✓ Tenacity of the agent and influence of food technology
  - no knowledge; assumption: comparable to EHEC O157:H7
- ✓ Treatment procedures for seeds
  - not all of them able to inactivate EHEC
Outbreak strain *E. coli* O104:H4 - characterisation

**Hybrid pathogenicity** characteristics EHEC/EAEC ► „EAHEC“

*stx2a* (Shigatoxin 2)-positive
enteroaggregative (AAF/I fimbrial cluster)

► Aggregative adherence (AA) means **effective** and **long colonization** of humans
► **Production** of *Stx2a associated* with effective and long intestinal colonization

High virulence
**E. coli O104:H4 - occurrence**

Germany and Europe:

- **Food:** none
- **Animals:** none
- **Environment:** none
- **Human:** 1 case Finland (2010)
  2 cases Germany (2001)
  (2 cases Georgia (2009))

Very rare strain
Never found in animals or food so far

**Assumption:** reservoir in humans
**E. coli** O104:H4 – occurrence during outbreak

### Laboratory investigations

#### Food samples
- 844 Cucumber
- 805 Tomatoes
- 947 Salad
- 170 Strawberries
- 165 Bell peppers
- 64 Asparagus
- 154 Seeds
- 1043 Sprouts
- 75 Milk
- 3433 Other food

#### Other samples
- 174 swab samples
- 172 water (irrigation and processing)
- 16 environmental samples

### Stage of sampling
- Food retail
- Whole sale
- Outbreak locations, e.g. restaurants, canteens

### Laboratory analyses at BfR

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Sample Number</th>
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<tbody>
<tr>
<td>DNA</td>
<td>14</td>
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<tr>
<td>Isolates</td>
<td>27</td>
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<tr>
<td>Vegetables*</td>
<td>73</td>
</tr>
<tr>
<td>Seeds</td>
<td>58</td>
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<tr>
<td>Sprouts</td>
<td>329</td>
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<tr>
<td>Swaps/environment</td>
<td>77</td>
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<tr>
<td>Water</td>
<td>41</td>
</tr>
<tr>
<td>Other</td>
<td>33</td>
</tr>
</tbody>
</table>

*Vegetables including cucumbers, tomatoes and lettuce

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### Total EU
- 10392 samples taken
- 41 samples stx positive
- **7 samples positive for O104:H4**

Recontamination from patients
E. coli O104:H4 - dose response assessment

Activities in a foodborne outbreak:

Characterisation of the hazard potential of the microorganism and the pathogenesis with consideration of the intended use

Infective dose of E. coli O104:H4: unknown?

EHEC O157:
- infection dose is very low and
- amounts to less than 100 germs

Assumption:
no multiplication in the environment or in food needed to infect humans
E. coli O104:H4 - severity and duration of disease

- **Severe** health impairments

- Symptoms: from **bloody diarrhoea, renal failure** with **dialysis** dependency to severe long lasting **neurological symptoms** and **death**

- During the acute phase, the **fatality rate** of HUS is approximately **2%**

- **How long** the damage to health continues, whether it leads to **chronic illness** (for example in the form of irreversible kidney damage) or whether the damage is **reversible** and what **long-term complications** can occur, could **not** be **assessed**
Exposure assessment

Activities in a foodborne outbreak:

Estimation of the exposure through the consumption of food

Goal
to determine the route, frequency, duration, and magnitude (amount) of exposure

- ✓ Production and distribution channels of the suspected seed batches
- ✓ Intended usage of the suspected seed batches – not complete known
- ✓ Influence of packaging units – see example
- ✓ Influence of eating habits - could not be limited to certain population groups
Influence of packaging units
15 tons of seeds – target quantity

Seed distributors
(1:2 mixes)

Sprout producers
(1:3 mixes)

Self sprouting
End consumer

3 person household

Packaging units:
25 g

1.800.000 bags

15 t

15 t

Packaging units:
50 g

5.400.000 bags

5.4 million people

16.2 million people

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Risk Characterisation

Is a process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment (CAC, 1999)

Activities in a foodborne outbreak:
Encompass summarised information on all relevant topics
Risk characterisation

Available at:
Assessment of data quality

- The **quality** of the **data** relating to the outbreak strain was highly **insufficient**

- Microbiological **testing** of fenugreek **seeds** from Egypt for *E. coli* O104:H4 was marked by great **uncertainty** and could not be conclusively assessed

- The **information** on the subsequent **distribution** stages and on **intended uses** of the fenugreek seeds was **incomplete**

- BfR was therefore **unable to assess** what **quantities** of the seed batches were **returned, destroyed, sold** or **eaten**
Challenges for risk assessment and risk management

Risk Assessment
1. Hazard identification
2. Hazard characterisation
3. Exposure assessment
4. Risk characterisation

-Science based-

Risk Management
• Risk evaluation
• Option assessment
• Option implementation
• Monitoring and review

-Policy based-

Risk Communication
Exchange of information about risk between assessors and stakeholders
Consumption recommendations: raw tomatoes, cucumbers and green salads
Consumption recommendation of 25 May 2011: regarding raw cucumbers, tomatoes, and green salads

State of knowledge about the food source:

Results of a case control study conducted in Hamburg:

- **cases** have eaten raw **tomatoes**, **cucumbers**, and **green salads** significantly more often than healthy persons.

- Vehicle is eaten predominantly by adults and mainly in northern Germany.

Questions to be answered:

- Vehicle (all of them, only one, others?)
- Origin and distribution?
- Source of infection?
Chronology through the eyes of AESAN

- **22nd May**: Germany EWRS
- **26th May**: Media: Hamburg Senator statement
- **27th May**: OFFICIAL RASFF NOTIFICATION
  - Traceability, Analytical results
  - Adopted measures
- **27th – 31st May**: 1st June
  - Clousure and withdrawal of the alerts

No cases of HUS/STEC in Spain
Risk management

22nd May 2011:
Notification by Germany to the EWRS (alert and early response system) on a significant increase in the number of patients with HUS and diarrhea caused by verotoxigenic E. coli.

23rd-26th May 2011:

✓ Some news appeared in the media.
✓ AESAN informed the Public Health Authorities of the Autonomous Communities.
Risk management

26th May 2011:

- A senator from Hamburg made a media statement in Germany, implicating Spanish cucumbers from Andalusia as responsible for the German outbreak.

- Commission’s phone call to AESAN.- Advance information. Germany informed through RASFF that the cucumbers origin of the outbreaks came from Spain.

- Coordination at national level. Request for additional information to the German Authorities and Press release in Spain and statements to the media.

Up until this moment, there was still no notification in RASFF
27th May (11:39h): Official Notification through RASFF (2 alerts)

ENTEROHAEMORRHAGIC ESCHERICHIA COLI IN CUCUMBERS FROM SPAIN, PACKAGED IN GERMANY:

✓ Non-organic cucumbers
✓ Batch L1803TD-TF
✓ 13 Greenhouses in Almería

ENTEROHAEMORRHAGIC ESCHERICHIA COLI IN CUCUMBERS FROM SPAIN, PACKAGED IN GERMANY:

✓ Company of Málaga
✓ Ecological cucumbers
✓ Almería’s Greenhouses
Risk management

28th and 30 May 2011

- German analytical results of Spanish cucumbers positive to E. coli enterohaemorrhagic
- New declaration in the media by the Hamburg senator reporting that the pathogen causing the outbreak were not in Spanish cucumbers.
- Analytical results of the samples taken (ground, irrigation waters and cucumbers): All of them negatives to EHEC!

There are no cases of HUS / STEC in Spain.

Daily Audioconferences with DG SANCO, ECDC, EFSA, MS

1st June (20:00):
The Commission Services announced through the RASFF the withdrawal of one alert and the closure of the other.
Immobilization of cucumbers

Investigations of traceability

Sampling and analysis in the warehouses and greenhouses.
Traceability

26th-27th May 2011

DISCREPANCES: departure date, Kg, number of truck registration, number of trailer

CMR RASFF 09/05/2011 23.728 KG

CMR EMPRESA 04/05/2011 23.109 KG

13 Greenhouses (ALMERIA)

(ALMERIA) 23.109 KG
Brushing, shrink wrapping, packaging

SAMPLES:
- From 3 Greenhouses
- Irrigation water from 13 greenhouses
- ground 13 greenhouses

Company (COLONIA)

LABORATORY (ATARFE-GRANADA) PCR
**Analytical results**

<table>
<thead>
<tr>
<th>SAMPLE</th>
<th>Nº</th>
<th>RESULTS</th>
<th>LABORATORY</th>
</tr>
</thead>
<tbody>
<tr>
<td>CUCUMBERS</td>
<td>15</td>
<td>NEGATIVE TO E. COLI PRESENCE</td>
<td>AGRO ALIMENTARIO ATARFE, Lab. Lugo, AINIA Y TECNOLAB</td>
</tr>
<tr>
<td>TOMATOES (SAMPLE TAKEN BY BIO FRUNET)</td>
<td>5</td>
<td>NEGATIVE TO E. COLI PRESENCE</td>
<td>AINIA Y TECNOLAB</td>
</tr>
<tr>
<td>MACHINERY SURFACE (SAMPLE TAKEN BY BIO FRUNET)</td>
<td>4</td>
<td>NEGATIVE TO E. COLI PRESENCE</td>
<td>AINIA Y TECNOLAB</td>
</tr>
<tr>
<td>SOIL (OFFICIAL SAMPLE)</td>
<td>13</td>
<td>NEGATIVE TO E. COLI PRESENCE</td>
<td>AGRO ALIMENTARIO ATARFE Y LABORATORIO DE LUGO (4 MUESTRAS)</td>
</tr>
<tr>
<td>IRRIGATION WATER (OFFICIAL SAMPLE)</td>
<td>13</td>
<td>NEGATIVE TO E. COLI PRESENCE</td>
<td>AGRO ALIMENTARIO ATARFE Y LABORATORIO DE LUGO</td>
</tr>
</tbody>
</table>
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Consumption recommendation of 10 June 2011: regarding raw sprouts

**Questions to be answered:**

Source of contamination (seeds, humans, animals, water)? Other vehicles?
Chronology through the eyes of BfR

July

01 02 03 04 05 06 07 08 09 10 11 12 13 14 15

BfR/RKI/BVL: opinion and joint press conference
updated FAQ of BfR
FAQ and statement of BfR (risk assessment)

EFSA: technical report
Commission implementing decision

July

16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

BfR, BVL, RKI: consumption recommendation
BfR: updated FAQ
RKI: declares end of outbreak and BfR dates statement up

Consumption recommendations:
- raw sprouts
- raw sprouts including home-grown raw sprouts and germ buds
- raw fenugreek seeds imported from Egypt and sprouts and germ buds grown from these

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Consumption recommendation of 21 July 2011: regarding fenugreek seeds from Egypt

EHEC: BfR, BVL and RKI issue specified consumption recommendations for uncooked sprouts and shoots (germ buds)


Consumers should continue to refrain from consumption of raw fenugreek seeds, sprouts and shoots imported from Egypt

According to the German federal authorities, further information made available by the Federal States has provided no grounds to continue to recommend that consumers generally refrain from the raw consumption of sprouts and shoots in order to protect against EHEC O104:H4 infections. The current investigation results provide no indications that other types of seeds besides fenugreek seeds are related to EHEC infections. However, consumers should continue to refrain from the consumption of fenugreek seeds imported from Egypt as well as sprouts and shoots (germ buds) that have been cultivated from these. After the trace back measures have been

Questions to be answered:

Intended uses of suspected fenugreek seeds?
Source of contamination in Egypt (humans, animals, water)?

Outbreak over?
What about risk communication?
At least 39 dead from killer bacteria outbreak: Germany

At least 2 more people die in German E. coli outbreak

Low risk of EHEC outbreak in China

E coli outbreak: the different effects through the world

Signs that E. coli cases are stabilising, say doctors

Scientists 'Find EHEC Bacteria at Sprout Farm'
Hamburg Institute for Hygiene and Environment (HU) identifies cucumbers as contaminated with EHEC

66 HUS-cases in Hamburg - Suspicion of O104 in EHEC strain confirmed by HU

26th May 2011
“The Spanish salad cucumber is to blame”

“Cucumbers from Spain have been identified as carriers of the Ehec germs”

“Spanish cucumbers are innocent”
"Weltweit größter Ausbruch von EHEC"

Prof. Dr. Dr. Hensel vom Bundesinstitut für Risikobewertung schätzt die Welle der EHEC-Erkrankungen als "sehr untypisch" ein, da zahlreiche Erwachsene erkrankten. Normalerweise treffe es Kinder.

We have indeed found a so-called EHEC pathogen on cucumbers.

But that doesn't mean they're responsible for the entire outbreak now.

Prof. Dr. Dr. Hensel on TV (morgenmagazin, 30.05.2011 08:40)
Pepinos españoles provocan un brote letal de ‘E. coli’ en Alemania

La infección ha causado al menos tres muertos y cientos de hospitalizaciones
Las autoridades europeas apuntan a dos empresas andaluzas como responsables

Alemania culpa a los pepinos españoles de una bacteria mortal
Una peligrosa cepa ha causado la muerte de tres personas y decenas de infecciones intestinales en el norte del país

La bacteria que ha causado tres muertes en Alemania salió de pepinos españoles, según las investigaciones del Instituto de Higiene de Hamburgo. La senadora (ministra) de Sanidad de Hamburgo, la socialdemócrata Cornelia Fritzsch (SPD), ha explicado que los científicos brasileños encuentran evidencias de contaminación en tres pepinos importados de España. Uno de ellos era de la denominada ‘orgánico’. La cepa peligrosa de Escherichia coli es una de las denominadas ‘más mortales para el ser humano’. Ha hecho estragos en años 10 días a unas 600 personas en Alemania, de las cuales alrededor de 140 padecen el peligroso síndrome urémico hemolítico, más conocido por el acrónimo inglés HUS. El Instituto de Higiene de Hamburgo tiene un cuarto pepino contaminado cuya procedencia es, de momento, desconocida. Los resultados dados a conocer hoy debemos completarlos con nuevos estudios. La senadora advirtió además de que “puede que otros productos estén también intoxicados.”

Contaminación por estiércol

Es una de los cientos de cepas de la ‘Escherichia coli’, bacteria intestinal habitualmente inocua en el estómago de ruminantes y que se contagia a través de la leche o las heces. Produce una potente toxina que ocasiona el síndrome urémico hemolítico, con dolores intestinales agudos, diarrea sangrante, y en el transcurso de pocas horas insuficiencia renal o anemia. La particularidad de esta cepa es la rapidez de su desarrollo y transmisión. El Instituto Robert Koch de Berlín considera que se está transmitiendo a través de alimentos crudos abonados con estiércol, lo que apunta a los productos bio.

No obstante, los expertos de este centro de investigación han subrayado que por el momento no está clara la causa del contagio. En este sentido, un portavoz ha subrayado que podría haber otras vías de contagio, como el agua.
The real crisis

EHEC CRISIS: CASES NUMBER EHEC

E Coli Crisis by Number of Reported Cases (4 June 2011)

EHEC CRISIS: MEDIA IMPACT

E Coli Crisis by Media Impact Index (2 June 2011)

By MRI Universidad de Navarra
(source ECDC)
Conclusions regarding investigation and risk assessment

High requirements:

- clear competences and communication paths
- multidisciplinary outbreak investigation team
- joint analysis of investigation results
- adequately qualified staff
- adequate laboratory capacities
- appropriate analysis methods
- appropriate information management systems

MRA is a challenge in the light of data lacks, an ongoing outbreak and the media pressure
Conclusions or: What went wrong?

- Loss of confidence in RASFF
- Politics
- Media driven crisis
- Difficulties to identify this pathogen
Impact and Consequences

Consumers:

✓ Loss of confidence in the competent authorities because of the different messages provided by Spain and Germany.
✓ Low consumption of salads, cucumbers and raw tomatoes regardless of their origin.

Sector:

✓ Damage of the image of the fresh vegetable products (MARCA ESPAÑA)
✓ Economic losses up to millions of euro per day
✓ Thousands of jobs lost
✓ Andalusia and, in particular, the province of Almeria, was the most affected region, which exports more than 62% of its fruit and vegetable production and sells more than 40% of the vegetables exported by Spain.

Trade:

✓ Massive trade restrictions for European vegetables: Russian Federation, USA, Ukraine and Saudi Arabia banned the trade of vegetables.
Impact and Consequences

SECTOR: Exceptional measures

47 millions of euro:

- Andalucía (32, 97 millions),
- Murcia (7,68 millions),
- Valencia (4,61 millions),
- Navarra (706.448 euros),
- Extremadura (279.246 euros),
- Canarias (260.751 euros),
- Baleares (236.015 euros),
- Castilla-La Mancha (137.178 euros),
- Cataluña (33.131 euros),
- Aragón (2.761 euros), y Castilla y León (2.515 euros).
Lessons learned at European level – sprouts related

Implementing Regulation (EU) No 208/2013 … on traceability requirements for sprouts and seeds intended for the production of sprouts

Regulation (EU) No 209/2013 … as regards microbiological criteria for sprouts

Regulation (EU) No 210/2013 … on the approval of establishments producing sprouts

Regulation (EU) No 211/2013 … on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts

Missions from de HFAA unit of the Commission to gather information about sprouts productions

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Lessons learned at European level

- EFSA prioritized the work on the risk of pathogens in food of non-animal origin (FoNao) in coordination with ECDC (Listeria)
- Regular use and standardization of Rapid Outbreak Assessments (ROA) by EFSA and ECDC
- Publication of several scientific opinions of FoNao
Lessons learned at European level

Training

✓ BTSF trainings on Food borne outbreaks.
✓ BTSF on hygiene of primary production

Analytic

✓ Efforts on the development of the analytical technics for pathogens in Food of non-animal origin (proficiency test, methods and validation by the EURLs)
✓ WHOLE GENOME SEQUENCE Data molecular database to link human, food and animal isolates
Lessons learned at European level – crisis related

✓ Commission implementing Decision 2019/300, to establish a general plan for crisis management in the field of safety of food and feed.

✓ Reactivate the EU crisis coordinator group (periodical meetings, audios to share good practices, etc.).

✓ Intersectorial preparedness exercises on outbreak coordination and response involving Public Health and Food Safety (EDESIA y JIFEE).
Lessons learned at national level

Revisions of the national rules on cooperation between health and food control authorities
New federal-Länder agreement for crisis management
Update of consumer recommendations
Further development of software tools
Ring trials and proficiency tests
Research projects on pathogens in plant based food
Improvement of detection methods

Additional Nomination of the University of Santiago de Compostela as National Reference Laboratory (NRL) for E. coli
Updated of the national Crisis Management and Communication Procedures
Reinforcing the collaboration agreements between national Public Health and Food safety authorities
Thank you for your attention

Dr. Anja Buschulte (BfR) and Dr. Milagros Nieto (AESAN)