GERMAN FEDERAL INSTITUTE FOR RISK ASSESSMENT

BfR
Bundesinstitut für Risikobewertung

Workshop Microbiological risk assessment regarding Shiga toxin-producing Escherichia coli (STEC)

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Agenda

Foodborne outbreak (**FBO**)

- definition
- impact

Rapid outbreak / risk assessment (ROA / RRA)

- why?
- when?
- how?

Simulation of a FBO – are you prepared?

Foodborne outbreak (FBO)

an incidence, …, of **two or more** human **cases** of the **same disease** and/or infection, or a situation in which the **observed number of cases exceeds the expected number** and where the cases are **linked**, …, to the **same food** source

(Directive 2003/99/EC)

Impact of foodborne outbreak (FBO)

Cause **serious illnesses** and even **deaths**

Significant socio-economic **costs** related to

- medical treatment,
- hospitalization and
- lost productivity.

Consequences for food businesses can be:

- lost markets,
- loss of consumer confidence and food purchases,
- litigation and company closures.

Impediments to domestic **consumption** and international **trade**

Urgent need for a risk assessment as a basis for decisions!

Rapid risk assessment during an outbreak

Hazard identification ⇒ characterisation of causal agent

General background **information** about the **causal agent**

Hazard characterisation ⇒ characterisation of hazard potential

Information about **historic cases** and **outbreaks** caused by causal agent

Exposure assessment ⇒ estimation of exposure

Information on the **occurrence** of the agent in **food** in general and in the outbreak in particular

Risk characterisation ⇒ estimation probability of occurence and severity of adverse health effects

Threat assessment with a summary about all available information, results and possible management **options to reduce the risk**

Rapid outbreak / risk assessment (ROA/RRA) – when?

A “regular” risk assessment is not available

Not sufficient time for a full risk assessment

RRA or/and outbreak assessment (ROA) is more practical

A “light” version of a risk assessment

RRA includes the steps of a risk assessment

BUT

- It is based on the current data from the outbreak itself and
- if possible data from similar outbreaks
- there is no time for collecting new evidence/data to fill in data gaps or to conduct larger literature studies.

RRA **needs to be updated** regularly during the incident **as information becomes available**.

Rapid outbreak / risk assessment (ROA/RRA) - aim

European Centre for Disease Prevention and Control (ECDC)

- Rapid risk/outbreaks assessment **aim** at **supporting** the **countries** and the European Commission in their **preparedness** and **response** to a public health **threat**.
- They provide a **timely summary** and **risk assessment** of a public health threat for EU/EEA countries related to a specific event.
- They also include **potential options** for **response**.
- As outbreaks or public health events develop, ECDC may issue **updated** risk assessments.

European Food Safety Authority (EFSA)

- Rapid risk assessment tools for **animal disease outbreaks**
- Webinar availabe at https://www.efsa.europa.eu/en/events/event/171127

Rapid outbreak / risk assessment (ROA/RRA) - content

Historical information on the **prevalence** of the **hazard** in different **food**, in particular if the source of the ongoing food safety incident is not confirmed yet

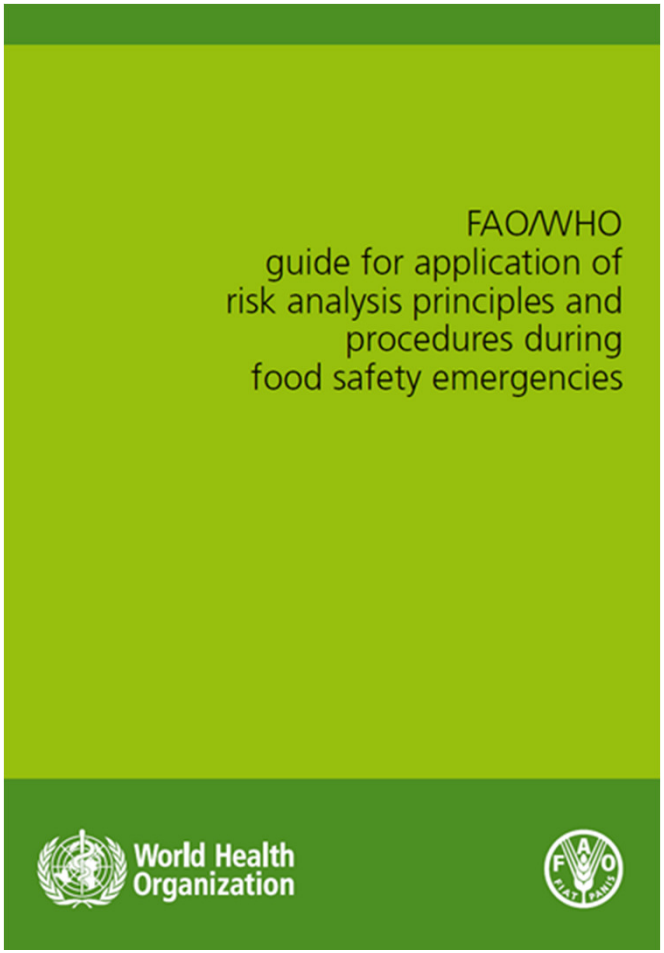
Results from **epidemiological** and **microbiological investigations** of human outbreak **cases**, considering severity, possible mortality, spread of cases and affected subgroups (e.g. elderly)

Laboratory results and results from the **epidemiological** (including tracing back) **investigations**

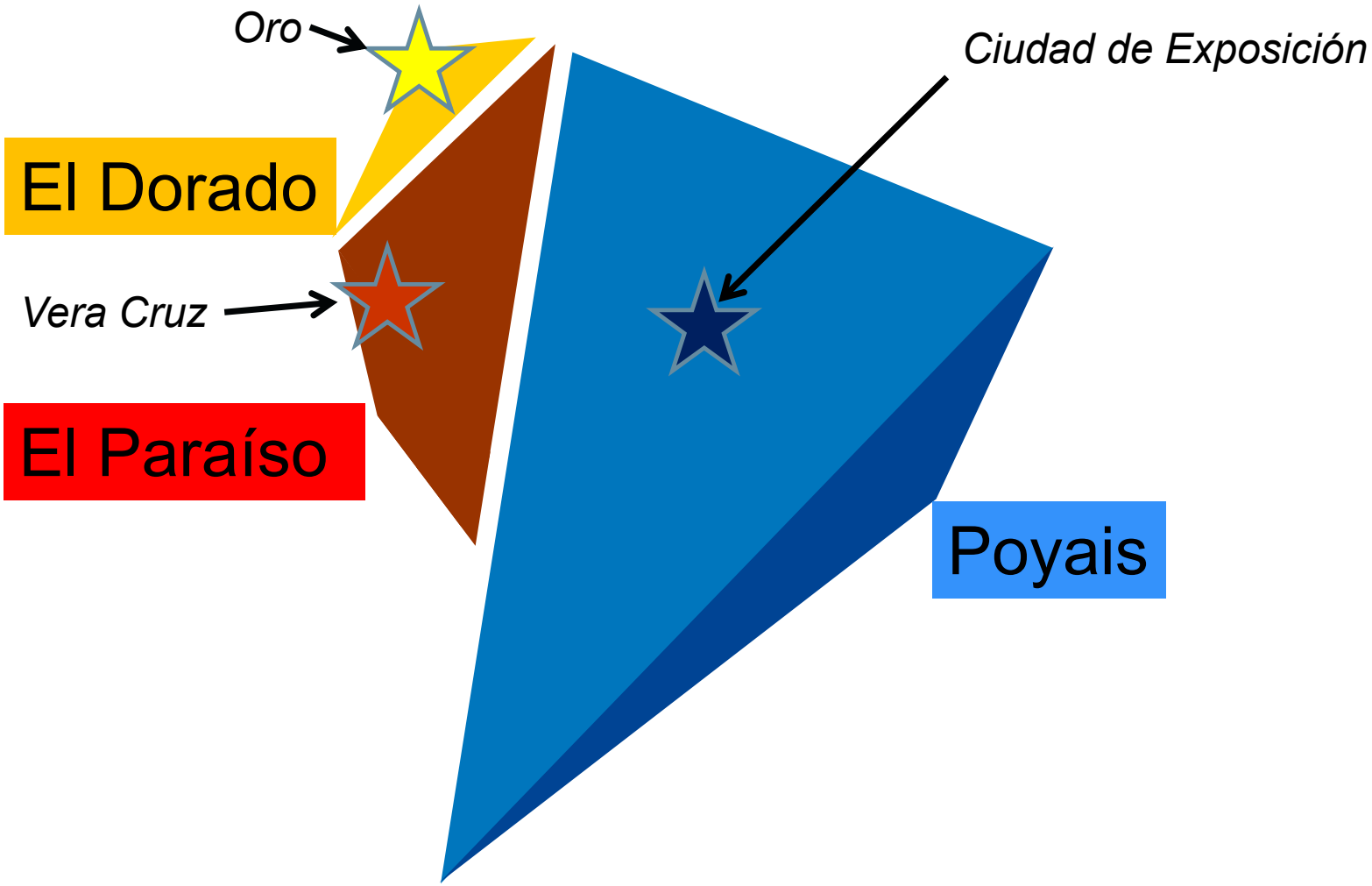
Risk **characterization** linked to the outbreak

If possible: **recommendations** to the consumers and to competent authorities on how to **mitigate the risk**.

Rapid risk assessment (RRA) - information



Once upon a time in …



Background information

Each year an International **Conference on Gastrointestinal Diseases** takes place in Ciudad de Exposición, **Poyais**. Poyais is a fictious country in Latinamerica. In 2019 the conference took place on the 9th of April.

During a break, two participants noticed that in the past days an **above-average number** of **EHEC infected persons** had been diagnosed in their respective hospitals.

In the University Clinic of **Ciudad de Exposición**, **Poyais**, there were **16 EHEC** cases within 4 days (2 cases in April 2018).

In the central clinic of **Vera Cruz**, **El Paraíso**, **4 cases** occurred during the same period (1 case in April 2018).

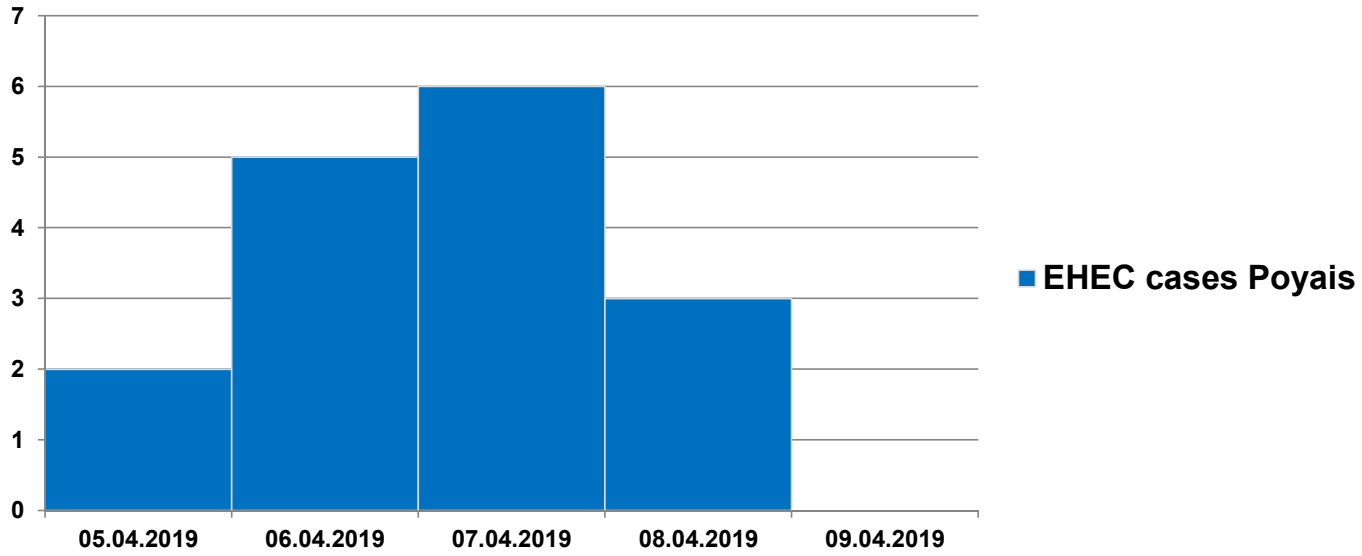
As **EHEC** cases are normally **rare** in both countries, physicians informed the **competent health authorities** of their countries to initiate more detailed **investigations**.

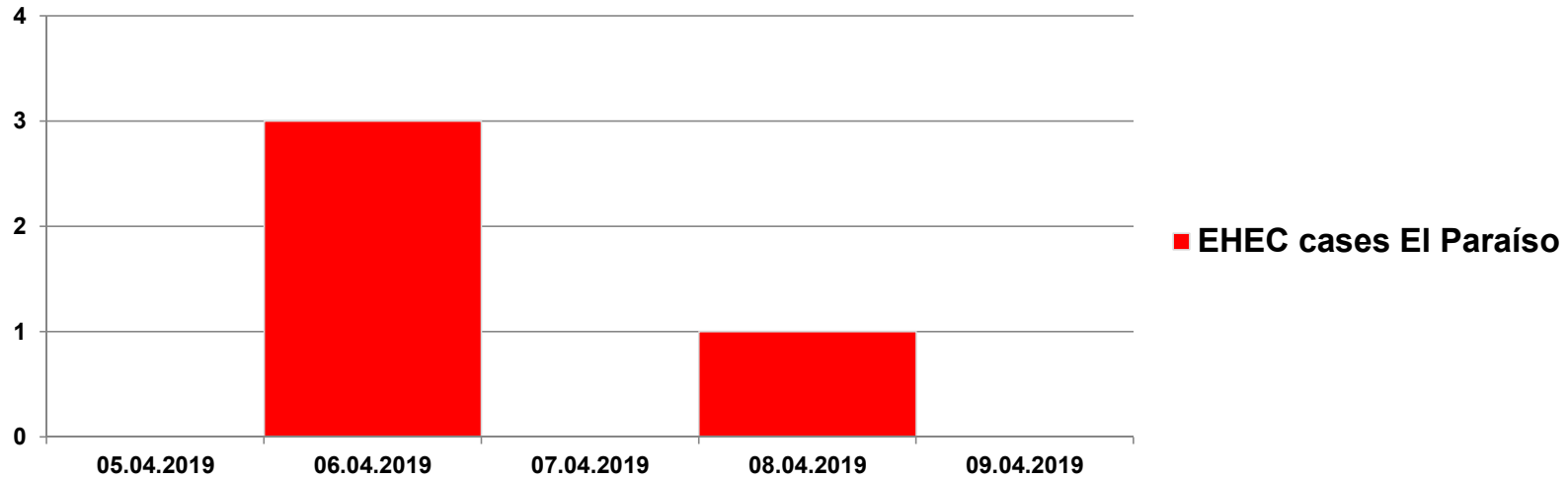
No epidemiological linkages between patients were found so far.

Summary of information about EHEC infections 9 April 2019

Date	Location	Cases	Age (Years)	Gender ♂	Gender ♀	Symptoms
5.4.	Poyais	2	72; 78	1	1	watery / bloody diarrhea, cramps
5.4	El Paraìso	0	-	-	-	-
6.4	Poyais	5	68; 72; 80; 82; 83	3	2	watery / bloody diarrhea, cramps
6.4	El Paraìso	3	75; 78; 78	3	-	-
7.4	Poyais	6	62; 67; 68; 70; 75; 76	4	2	watery / bloody diarrhea, adominal cramps, fewer
7.4	El Paraìso	0	-	-	-	-
8.4.	Poyais	3	67; 67; 72	1	2	watery / bloody diarrhea, adominal cramps, fewer
8.4.	El Paraìso	1	75	1	-	bloody diarrhea
	Total	**20**	**Average: 73**	**13**	**7**	

Epicurves of EHEC cases on 9 April 2019





What could be the cause of an increase in reported infections?

***Please choose* the right answer(s) from the following options**

- errors in data entry
- an increase in population size
- new detection methods
- laboratory error in identification
- contamination of cultures
- an increase in rate of infection due to random variation in incidence
- changes in reporting procedures
- initiation of new testing by laboratories
- changes in population characteristics (more persons at higher risk)
- an increase in rate of infection due to an outbreak
- all above

After the information received at the first stage of the event, do you think it is necessary to prepare a situation report of the outbreak?

***Please choose* one answer from the following options**

- NO
- YES
- It is not necessary, but it could be helpful
- I do not know

If yes, which agency / department is responsible for preparing and submitting the situation report on this outbreak in this first phase of the event?

***Please choose* one answer from the following options**

- Food safety department / agency
- Public health department / agency
- Both: food safety and public health departments/agencies
- National Reference Laboratory (NRL)

The outbreak continues – new cases

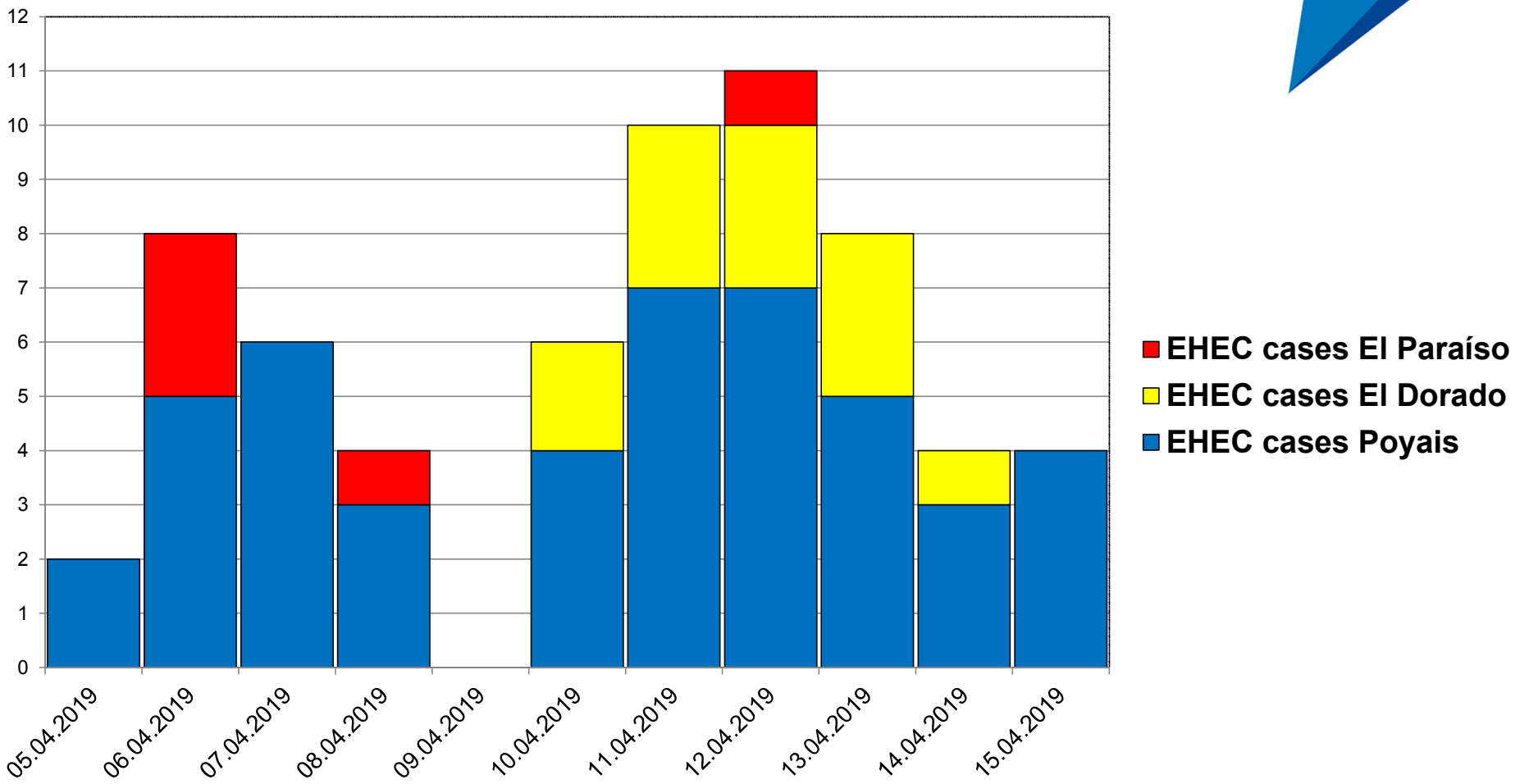
Between 9 and 15 April **30** new **EHEC** cases are identified (age 65 to 83 years) in **Ciudad de Exposición**, **Poyais**, **6** of which developed the serious hemolytic uremic syndrome (**HUS**).

A former German Deputy **Minister** of Food and Agriculture who was one of the first cases (age 80) **died** in the evening on April 14. Already on April 12 **another patient** (age 85) from the same travel group **died.**

In **Vera Cruz, El Paraíso, 1** new case is suffering from bloody diarrhea and abdominal pain during the same period of time and develops **HUS**. The age is 69,5 years.

A **child** (age 8) is searching for medical help at the hospital of **Oro, El Dorado,** on April 10. The child has a high fever and is dehydrated due to watery diarrhea. The **grandfather** also came to the clinic with bloody diarrhea, severe abdominal cramps and in poor general condition. These are the first 2 of a **total** of **12** cases of infection with EHEC in El Dorado, **2** of which developed **HUS**.

Epicurves of EHEC cases on 15 April 2019



The outbreak investigation

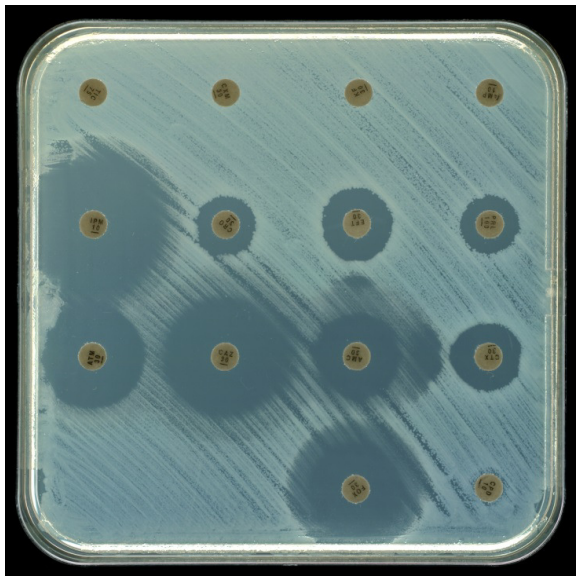
Laboratory investigations:

The **outbreak strain** ***E. coli*** 157:H7 is **characterised**

Based on PFGE findings the suspected EHEC cases resulted from a **common source** which is **not identified** yet.

On the basis of a **multinational agreement** in the event of a crisis, the **comparison of strains** was done by the **NRL *E. coli* of Poyais**.

The NRL compared the isolates from Poyais, El Paraíso and El Dorado.

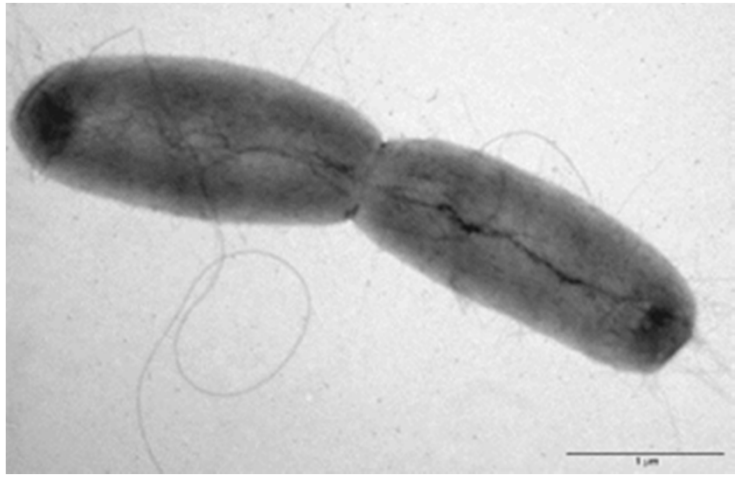


Epidemiological studies:

Focus on identification of a common food source

After **explorative questioning** to identify similarities in food consumption, **case control studies** are intitiated for several outbreak cluster

Outbreak strain: EHEC O157:H7



Agent is a Shiga toxin(STX)-producing *E. coli*

- gram-negative rod of the familiy *Enterobacteriaceae*
- motile, non-spore forming, mesophilic, facultative anaerobic
- growth between zwischen 8°C and 48°C, optimal at 37°C
- cause of sporadic cases and foodborne outbreaks of EHEC infections in human
- **incubation time**: usually **1 to 3 days** (from 1 -10 days)
- **Infectious dose**: low (assumed less than **100 germs)**
- **main symptoms**: fever, stomach cramps, severe diarrhea sometimes bloody
- **complications**:
  - hemolytic uremic syndrome (HUS; haemolytic anaemia, kidney failure; 5–10%)
  - neurological effects
  - seizures

Outbreak strain *E. coli* O157:H7

Specific characteristics:

- ***stx*2a** (Shigatoxin 2a)-positive → Toxine production
- **eae-**positive → Adhesin production
- **enteroaggregative** (AAF/I fimbrial cluster) → Long colonisation
- **ESBL** → Antibiotic resistant

→ high virulence
long colonisation

→ **extremly serious clinical picture**

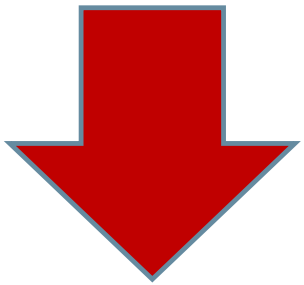
Summary of information on April 15

In total

- **63 EHEC** infections (average age: 68 years)
- **9 HUS** cases
- **2 deaths**

} Are reported from **three countries**

- Highly severe outbreak strain: *E. coli* 157:H7
- High rate of hospitalisation (30%) and HUS cases (14%)
- Epidemiological studies point to **meat** as the **causative food**



A **multinational disease outbreak** is emerging.

Due to the extraordinarily severe course of the disease, the **clarification** of the outbreak has the **highest priority**.

Outbreak investigation teams are set up.

Investigations are **substantially expanded**.

Which institutions should be involved in outbreak investigation?

Please choose the relevant institution(s) from the following list

- Food industry
- Competent food control authorities
- Public health authorities
- Non-governmental organisations (NGOs)
- Universities
- Private laboratories
- Official laboratories
- Ministry responsible for food safety
- Ministry responsible for human health
- Media associations
- All above

Who`s expertise is needed in an outbreak investigation team?

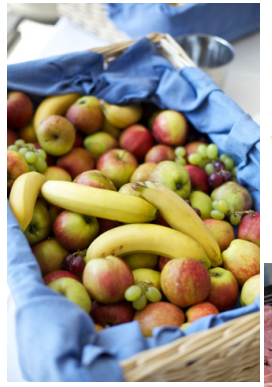
Please choose the right answer(s) from the following options

- Clinicians
- Epidemiologists
- Toxicologists
- Food inspectors
- Food industry
- Journalists
- Microbiologists
- Politicians
- Customs employee
- Public health service
- Competent food monitoring authorities
- All above

In case of a FBO - Which samples should be taken?

***Please choose* the right answer(s) from the following options**

- food of animal origin
- food of non-animal origin
- environmental samples
- waste water of clinics
- surface water
- all above
- as much samples as possible
- targeted sampling not possible at this point
- regional food
- imported food
- matrix dependend from outbreak strain





Where should the samples be taken?

Choose the right answer(s) from the following options

- household of patients
- restaurants
- canteens
- primary production cattle (farm)
- food companies
- targeted sampling not possible at this point





Does your country have a National Reference Laboratory (NRL) for *E. coli*?

***Please choose* the answer from the following options**

- YES
- NO
- I don`t know

Do you know who is responsible for the matching of human and food isolates?

Please choose the answer from the following options

- YES
- NO
- I don`t know
- We have no clear responsibility

Summary of information on April 22

In total

- **78 EHEC** infections (average age: 68 years)
- **16 HUS** cases
- **2 deaths**

} Are reported from **three countries**

- Highly severe outbreak strain: *E. coli* 157:H7
- **Epidemiological** studies point to **beef** as a possible **cause** of infection
- **Traceback investigations** from several outbreak clusters are **initiated to identify** which **beef** exactly (producer, brand)

Dialysis capacities are **scarce**

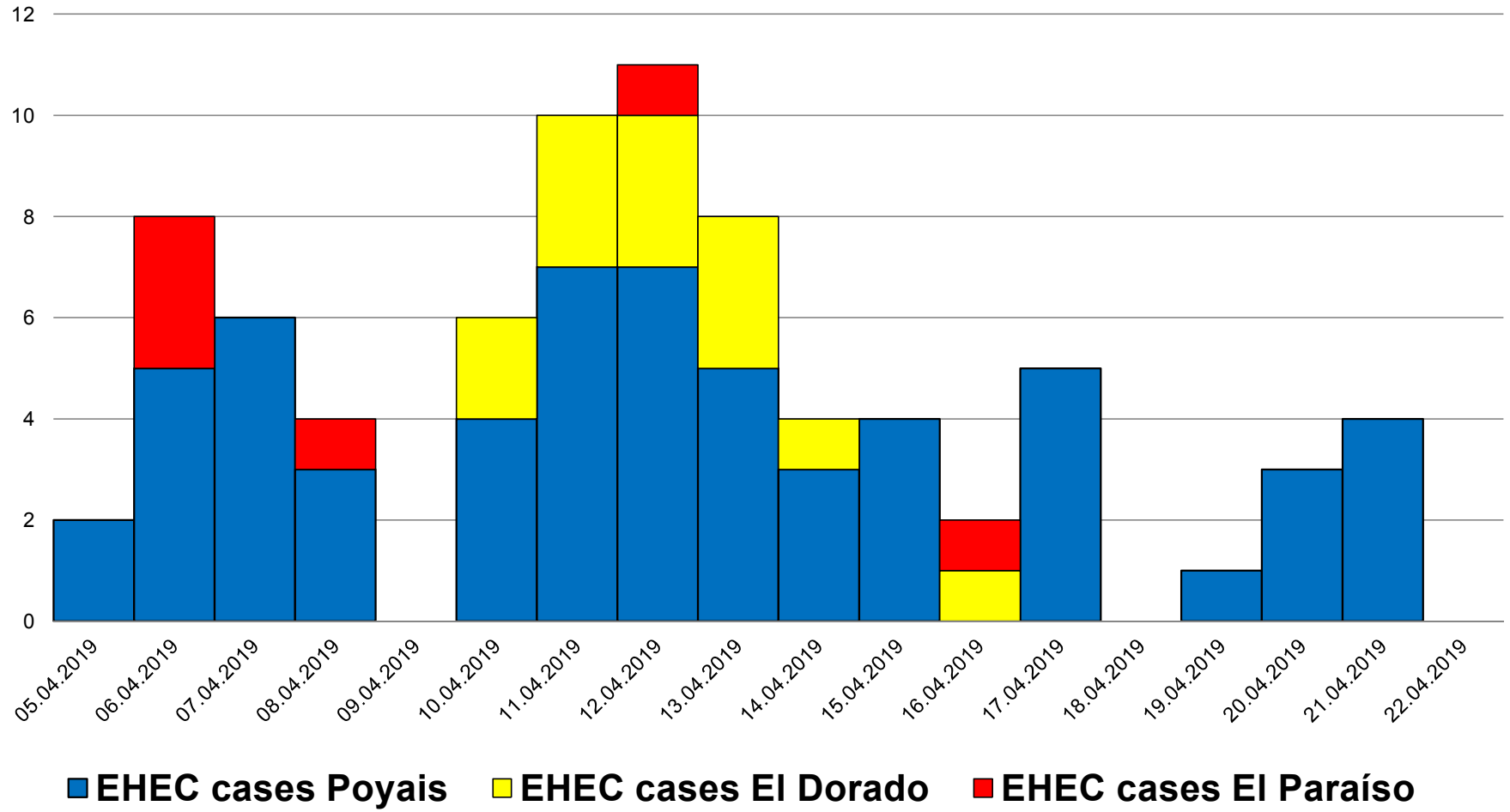
The **public** is extremly **concerned**

Huge **export losses** due to **import bans** from **third countries**

Multinational **Task force** is created

Media is getting „out of control“

Epicurves of EHEC cases on 22 April 2019



Importance of measures?

Classify the following measures according to their importance (max. importance 1, least important 5)

- Communication to the consumer
- Withdrawal of food products involved in the outbreak from the market
- Notification of the national rapid alert system to inform other authorities (if such a system exists).
- Notification of other international food safety authorities by INFOSAN (International Food Safety Authorities Network)
- Coordination of public health and food safety authorities and other stakeholders to enable clear decision-making

Which channels do you use to inform the public about the risk?

Please rank **the risk communication channels from 1 (most effective) to 5 (least effective)**

- TV, radio
- Newspapers
- On line news
- Official websites
- Social networks: facebook, twitter

Do you think that a protocol for outbreak or crisis communication is necessary?

***Please choose* one answer from the following options**

- YES
- NO
- I do not know

The outbreak is declared to be over on May 22

In total

- **90 EHEC** infections (average age: 72 years)
- **18 HUS** cases
- **3 deaths**
- Outbreak strain: **E. coli 157:H7**

- **Evidence** was proved by:
  - Epidemiological studies
  - Traceback of suspicious beef
  - Laboratory evidence

- **Source** of **infection**: tenderized beef
  - The beef was sold frozen at retail shops and to restaurants
  - It was mostly consumed at family celebrations and in restaurants

- **The complete lot of beef is recalled**

Food chain of causative food

Slaughter

Slaughter of 50 cattle at the a slaughterhouse in Poyais

Processing

500 kg of beef is tenderized mechanically in company „Carne del Sur“

Packaging

1000 packages of 500 g tenderized beef

Distribution

- Retail shop Meat delicacies, Poyais: 200 packages
- Retail shop Meat delicacies, El Paraíso: 200 packages
- Retail shop, Oro: 50 packages
- Restaurant Butchers delight, Oro: 20 packages
- Restaurant Best Burger, Oro: 10 packages
- Export: Retail shops, New York, USA: 520 packages

Distribution of beef and link to outbreak cluster

Retail shop
Meat delicacies,
Poyais

Retail shop
Meat delicacies,
El Paraíso

Retail shop
Oro

Consumer households

Open questions:

- Additional cases?
- Recall of contaminated food sucessfull?
- Adequate information of all stakeholder (consumer)?

Several dishes

Restaurant
Butchers delight,
Oro

Restaurant
Best Burger,
Oro

When is the outbreak declared to be over?

Please choose the correct answer from the following options

- When there are no more cases
- When there are no more NEW cases
- When the hazard is identified
- When the involved food is identified
- When the number of cases decreases and the causative food has been withdrawn from the market
- When the number of cases decreases and control measures have been taken
- When the number of cases decreases, the causative food has been withdrawn from the market and control measures have been taken

How can the lessons learnt be identified?

***Please choose* one answer from the following options**

- Reviewing networking between different stakeholders
- Identifying weaknesses and the strengths in the assessment, management and communication of the outbreak
- Identifying the gaps between the different steps of the hazard analysis of the outbreak
- There are no lessons learnt
- I don´t know

Conclusion:
investigating and reporting of foodborne illness is crucial

- ✓correction of faulty practices in the food chain (e.g. in primary production, food processing plants, restaurants, homes)
- ✓ assessment of trends in etiologic agents and food vehicles
- ✓ detection of new agents of foodborne diseases
- ✓ better understanding of epidemiology of pathogens in food
- ✓identification and **removal of contaminated products** from market

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Thank you for your attention

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