



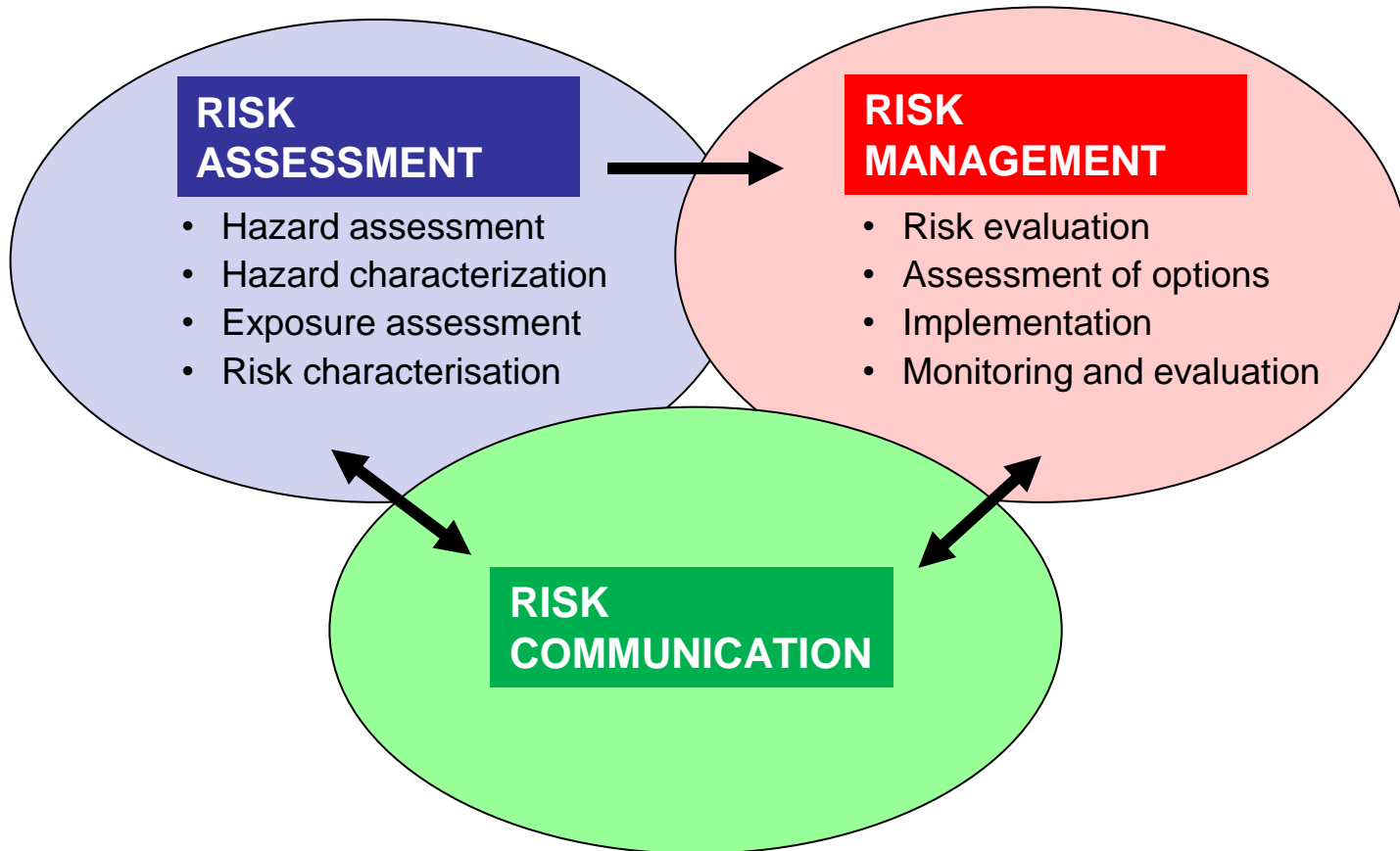
EU food safety system

Risk management and communication

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Risk analysis



Risk analysis in the EU

- ☐ **Regulation (EC) No 178/2002 (Articles 6 and 7)**
- ☐ **Functional separation (risk assessment > risk management)**
- ☐ **Risk assessment: independence of staff and experts**
- ☐ **Risk management:**
 - Based on:
 - international standards
 - risk assessment (science)
 - Taking into account
 - other legitimate factors
 - the precautionary principle
- ☐ **Risk communication**
- ☐ **Direct application**

Regulation (EC) No 178/2002

□ Article 6(1) – Risk analysis:

- is the basis of food law
- except where this would be inappropriate (to the circumstances or the nature of the measure to be taken)

□ Article 6(2) – Risk assessment is:

- based on the available scientific evidence
- undertaken in an independent, objective and transparent manner

□ Article 6(3) – Risk management takes into account:

- (international standards : Article 5(3))
- the results of risk assessment
- other factors legitimate to the issue under consideration
- the precautionary principle

Functional separation between



**RISK
MANAGEMENT**

**RISK
ASSESSMENT**

❑ Regulation (EC) No 178/2002

- does not require it,
- operates it at EU level

❑ At EU level (since 2002):

- Risk assessor = EFSA
- Risk manager = European Commission, European Parliament, Council of Ministers, Standing Committee

RISK ASSESSMENT

Independence of experts/staff

☐ Management of conflict of interest by EFSA:

- Screening of candidates before appointment
- Requiring detailed declaration of interest
- Monitoring the outsourcing of services
- Policing gifts and invitations
- Training staff
- Mobility of staff in sensitive functions
- Addressing post-employment situations

**RISK
MANAGEMENT**

Based on international standards

□ Article 5(3) of Regulation (EU) No 178/2002

- "Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law
- Except:
 - where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law, or
 - where there is a scientific justification, or
 - where they would result in a different level of protection from the one determined as appropriate in the EU."

RISK MANAGEMENT

Based on risk assessment

☐ **Is the Commission obliged to follow a scientific opinion from EFSA?**

☐ **No:**

- the Commission can go beyond (be more prudent than) an EFSA opinion (e.g. Bisphenol A in baby bottles)
- the Commission can be less prudent than an EFSA opinion (e.g. BSE risk materials)

☐ **However:**

- the Commission would certainly have to fully motivate such a decision;
- respect conditions laid down in EU food law (e.g. precautionary principle)
 - proportionality
 - no more restrictions to trade than necessary
 - no arbitrary discrimination

RISK MANAGEMENT

Other legitimate factors

☐ What are the OLF?

- *Codex Alimentarius*: "factors relevant for:
 - the health protection of consumers and
 - for the promotion of fair trade practices"
- Regulation (EC) No 178/2002 – Article 6:
 - no example!
- Regulation (EC) No 178/2002 – Recital (19):
 - Societal
 - Economic
 - Traditional
 - Ethical
 - Environmental
 - Feasibility of controls

**RISK
MANAGEMENT**

Precautionary principle

Regulation (EC) No 178/2002 – Article 7

"In specific circumstances where,

- following an assessment of available information,
- the possibility of harmful effects on health is identified
- but scientific uncertainty persists,
- provisional risk management measures
- necessary to ensure the high level of health protection chosen in the [EU]
- may be adopted,
- pending further scientific information for a more comprehensive risk assessment.

Measures adopted [...] shall be:

- proportionate [...]
- no more restrictive of trade than is required [...]
- reviewed within a reasonable period of time [...]."

**RISK
MANAGEMENT**

Precautionary principle

Regulation (EC) No 178/2002 – Article 7

- ☐ Provides a legal basis for risk management measures based on the precautionary principle to protect:
 - human health,
 - animal and
 - plant health
- ☐ Provides a legal basis for challenging measures abusing the precautionary principle to protect:
 - the internal market (e.g. ECJ judgement of 13 December 2001 in Case C-1/00)
 - international trade.

**RISK
COMMUNICATION**

Transparency principles

❑ Public consultation

Regulation No 178/2002 – Article 9

There shall be open and transparent **public consultation**:

- **directly** or through **representative** bodies,
- during the **preparation**, **evaluation** and **revision** of food law,
- except where the **urgency** of the matter does not allow it.

RISK COMMUNICATION

Transparency principles

❑ Public information

Regulation No 178/2002 – Article 10

- where there are reasonable grounds to suspect that a food or feed **may present a risk** for human or animal health, then, depending on the nature, seriousness and extent of that risk,
- **public authorities** shall take appropriate steps to **inform the general public** of the nature of the risk to health,
- identifying to the fullest extent possible:
 - the food or feed, or type of food or feed,
 - the risk that it may present, and
 - the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

**RISK
COMMUNICATION**

Transparency principles

□ Access to documents / disclosure

Regulation No 178/2002 – Article 10

- Without prejudice to the applicable EU and national law on access to documents...
- Important judicial developments:
 - Disclosure of application data by EMA: protection of commercially confidential information
 - Disclosure of consultation data by EFSA: protection of personal data

RISK COMMUNICATION

EU-RASFF

Key facts

- ❑ EU **Rapid Alert System for Food** (RASf) was created in the EU in 1979.
- ❑ It is essentially a network to circulate rapidly, amongst food safety regulators, information about food-borne risks.
- ❑ Over the years, the RASf has proved its usefulness in:
 - disseminating key information and mitigating the impact of food safety crisis;
 - providing crucial information on the source and nature of food-borne risks in the EU.
- ❑ In **2002**, the RASf was:
 - ❑ enshrined in legislation (Regulation 178/2002)
 - ❑ extended to the **feed sector**, and became: the **RASFF**.

RISK COMMUNICATION

EU-RASFF

☐ Contact point in each Member Country

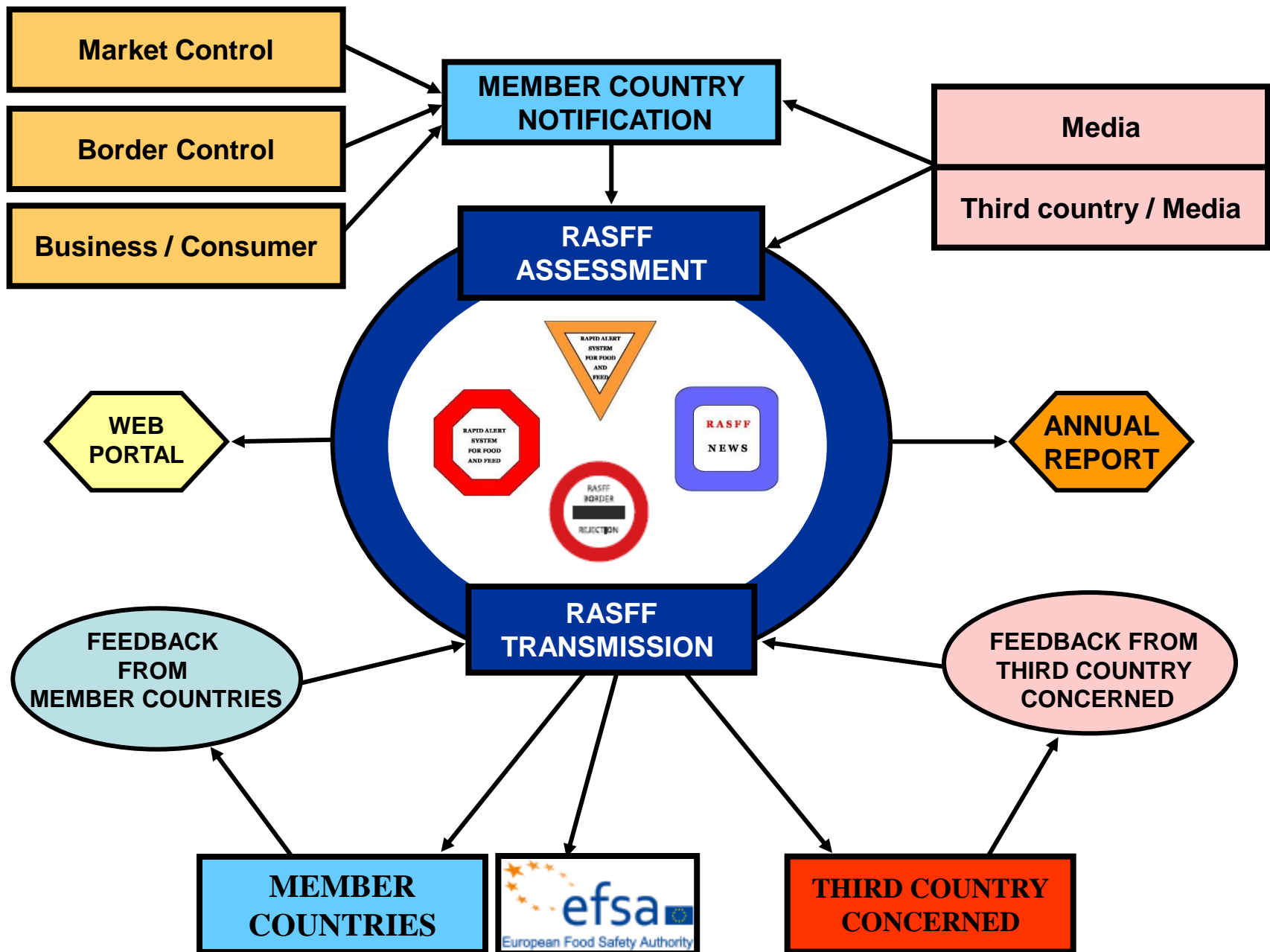
Austria	Greece	Poland	Iceland Norway Liechtenstein (Switzerland)
Belgium	Hungary	Portugal	
Cyprus	Ireland	Slovakia	
Czech Republic	Italy	Slovenia	
Denmark	Latvia	Sweden	
Estonia	Lithuania	Spain	
Finland	Luxembourg	United Kingdom	
France	Malta	Bulgaria	
Germany	Netherlands	Rumania	



European Food Safety Authority



European Commission



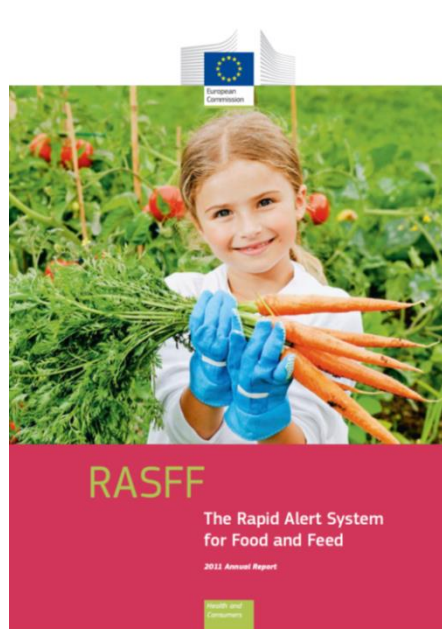
**RISK
COMMUNICATION**

EU-RASFF

**WEB
PORTAL**

<https://webgate.ec.europa.eu/rasff-window/portal/>

**ANNUAL
REPORT**



RISK COMMUNICATION

EU-RASFF

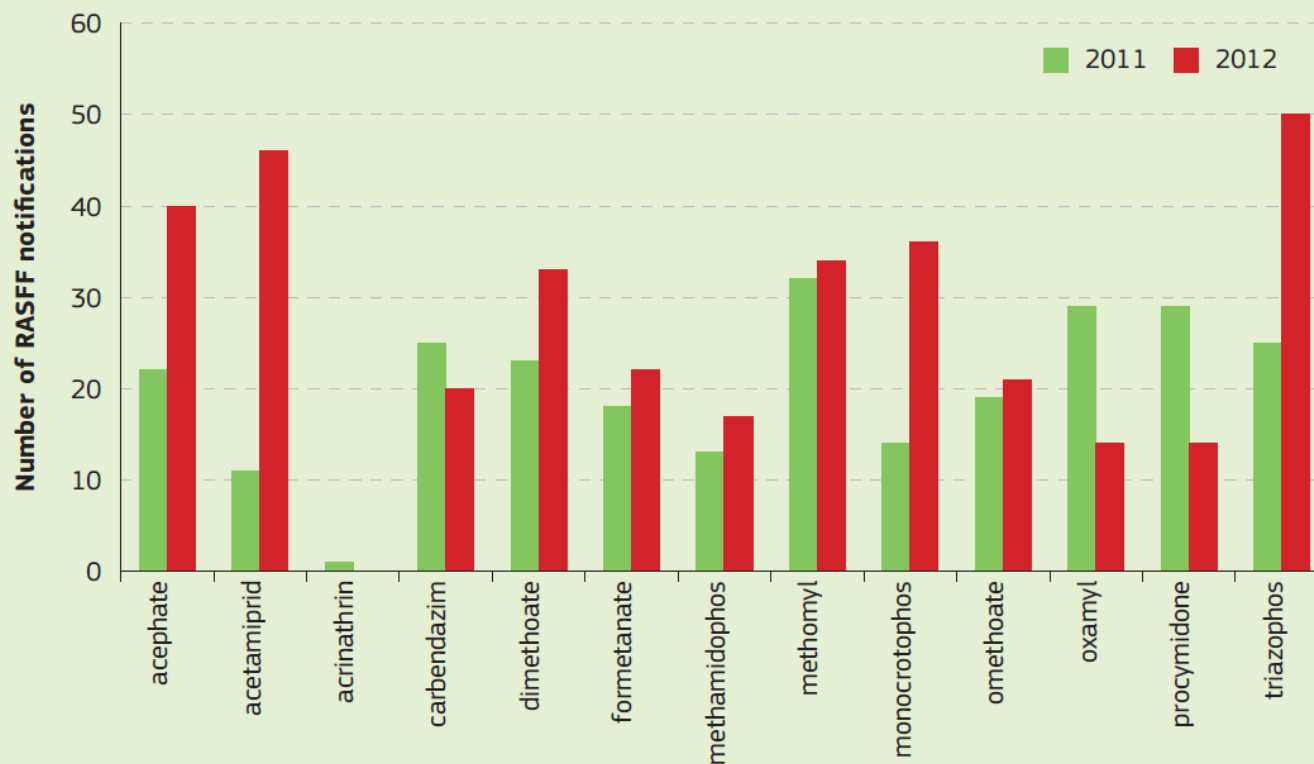
Table 11 – 2012 notifications by product category and by classification

Product Category	Alert	Border Rejection	Information For Attention	Information For Follow-Up	Total 2012	2011	2010	2009
Alcoholic Beverages	4	2	0	1	7	14	7	3
Animal By-Products	0	2	1	5	8	0	2	5
Bivalve Molluscs And Products Thereof	22	13	13	5	53	68	78	52
Cephalopods And Products Thereof	5	41	5	2	53	78	44	39
Cereals And Bakery Products	36	69	33	34	172	180	172	165
Cocoa And Cocoa Preparations, Coffee And Tea	14	52	5	7	78	43	33	74
Compound Feeds	4	0	5	17	26	13	7	12
Confectionery	16	37	9	9	71	66	50	60
Crustaceans And Products Thereof	4	36	11	9	60	75	78	176
Dietetic Foods, Food Supplements, Fortified Foods	56	52	42	33	183	138	141	119
Eggs And Egg Products	5	0	6	6	17	13	16	15
Fats And Oils	4	11	1	1	17	20	25	21
Feed Additives	0	0	2	7	9	13	7	8
Feed For Food-Producing Animals – (Obsolete)	0	0	0	0	0	2	0	0
Feed Materials	8	103	35	89	235	260	112	122

RISK COMMUNICATION

EU-RASFF

Figure 10 – Most reported pesticide residues in 2011 and 2012



RISK COMMUNICATION

EU-RASFF

Country Of Origin	2010	2011	2012
China	450	561	540
India	251	336	338
Turkey	255	319	310
Germany	156	152	103
United States	160	113	127
Spain	138	129	126
Italy	121	116	112
Thailand	131	95	120
France	116	122	90
Brazil	102	94	109
Argentina	158	93	51
Poland	75	98	118
Viet Nam	71	108	72
Netherlands	52	74	97
Ukraine	50	93	68
United Kingdom	71	65	63
Morocco	56	73	60
Belgium	40	61	63
Bangladesh	13	77	56

Country Of Origin	2010	2011	2012
Sweden	12	17	24
Russian Federation	14	15	24
Sri Lanka	20	9	23
Hungary	17	15	19
Czech Republic	20	22	8
Japan	4	30	16
Ecuador	23	10	12
Mauritania	22	13	10
Portugal	16	13	13
Lithuania	15	7	18
Israel	14	14	12
Croatia	19	12	8
Canada	16	12	10
Hong Kong	5	19	13
Slovakia	13	8	13
Romania	6	12	16
Taiwan	12	4	17
Philippines	8	12	12
Latvia	9	14	7

RISK COMMUNICATION

EU-RASFF

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Hong Kong	5	19	13
Slovakia	13	8	13
Romania	6	12	16
Taiwan	12	4	17
Philippines	8	12	12
Latvia	9	14	7

RISK COMMUNICATION

TRACES

□ What is TRACES?

- A multilingual online application for the **control** and **certification** of trade in live animals, animal products (semen and embryos included), non-animal products (food and feed) and plants, seeds and propagating material.
- An **e-government** system "in progress" following the requirements of the EU Digital Agenda towards **dematerialisation of the health documents**, and is an efficient tool to ensure:
 - **Traceability**: TRACES keeps track of the movements both in the EU and from non-EU countries of trade of live animals, animal and non-animal products
 - **Exchange of information**: traders and national authorities use TRACES for free to easily obtain information on the movement of the consignment; TRACES informs competent authorities in case of import into the EU and speeds up formalities
 - **Risk management**: TRACES reacts rapidly in case of health threats by tracing the movements of animals and animal products and by facilitating the risk management of rejected consignments

RISK COMMUNICATION

TRACES

❑ Facts and figures about TRACES

- Compulsory for **EU Member States** since 1 January 2005
 - Voluntary for **non-EU countries** (currently: 33)
- **Multilingual**: 32 languages (23 EU official languages plus Albanian, Bosnian, Chinese, Icelandic, Macedonian, Norwegian, Russian, Serbian, Turkish)
- **Statistics** automation and **electronic transmission** of information
- Number of **registered users** (September 2012): 21.933
- Number of registered **establishments** (September 2012): 639.836
- Daily, around **1.000.000** electronic notifications are registered
- Dedicated **Helpdesk** able to guide TRACES users in different areas
- Dedicated bimonthly **newsletter** with more than 3400 subscribers

RISK COMMUNICATION

TRACES

☐ Coming soon:

- Single sanitary window
- Many more countries connected (Asia)
- E-Certificates





Thank you!