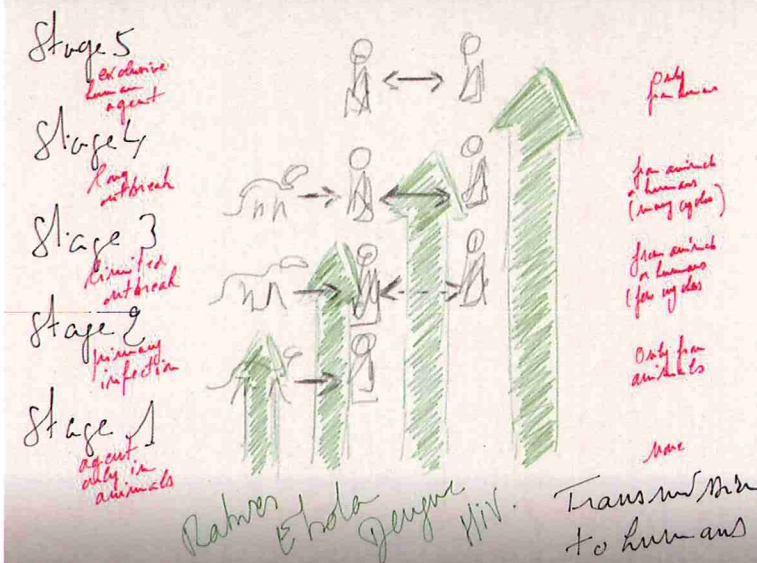


ZOONOSES

Risk at the human animal ecosystem interface

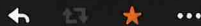


Franck C.J. Berthe @FranckCJBerthe

5/4/14

Wolfe et al., Nature 2007: five stages through which microbes of animals evolve to cause diseases confined to humans

1 RETWEET 2 FAVORITES



CORE TASKS FOR THE AHAW PANEL

Receive external requests from EU decision makers or internal requests, transform them into risk questions, and provide responses in the form of scientific advice

Develop and implement appropriate and proportionate methodology to conduct analysis needed for scientific advice

Bring evidence such as data, expert opinion and published scientific information to feed the analysis





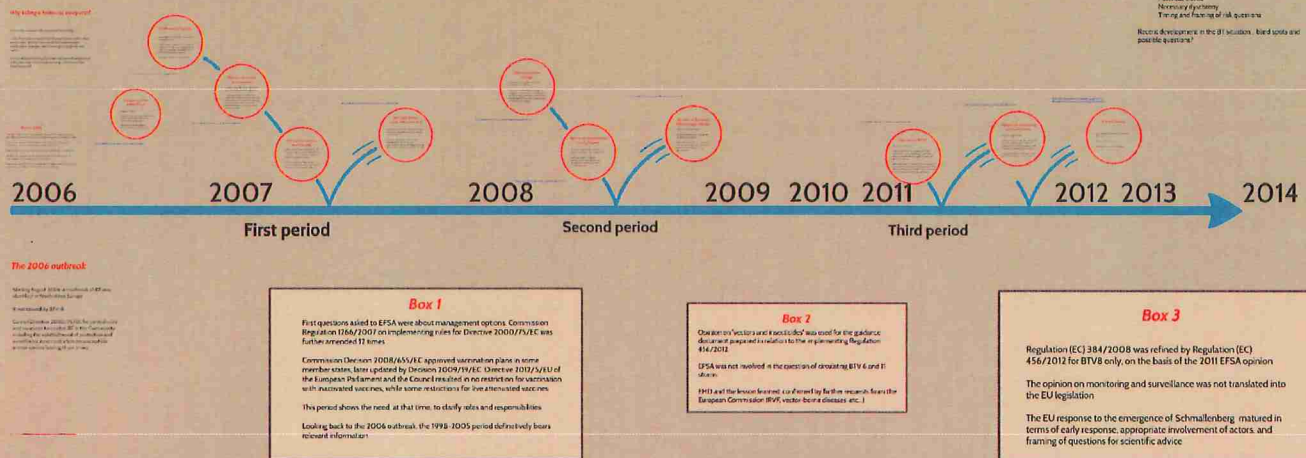
RECENT EXAMPLES OF ADVICE

- Risk of introduction and spread of the small hive beetle (*Aethina tumida*) and *Tropilaelaps* in the EU
- Risk of introduction and spread of Rift Valley Fever in the EU neighbouring countries of the Mediterranean region
- Possible risks posed by the influenza A (H3N2v) virus for animal health and its potential spread and implications for animal and human health
- Bovine tuberculosis vaccination
- Guidance document on assessing studies evaluating the efficacy of interventions regarding animal protection during stunning
- Welfare of bovine, pigs, sheep and goats, and poultry during the slaughter process

<http://www.efsa.europa.eu/en/panels/ahaw.htm>

Scientific advice to policy makers: an EU experience on bluetongue

European Food Safety Authority *Franck Berthe, Ana Afonso, and Sofie Dhallander*



**Main animal welfare hazards in sheep
IWTO multistakeholder meeting - Brussels - December 2014**

1 **Problem formulation**

Background and context

Terms of reference

Sheep farming

2 **Methodological approach**

Characterisation of the target population and management systems

Identification of animal based measures

3 **Results**

Most important welfare consequences identified for ewes

Most important welfare consequences identified for lambs

From consequences to factors

Animal-based measures

Public consultation on the draft opinion

Conclusions

Acknowledgements

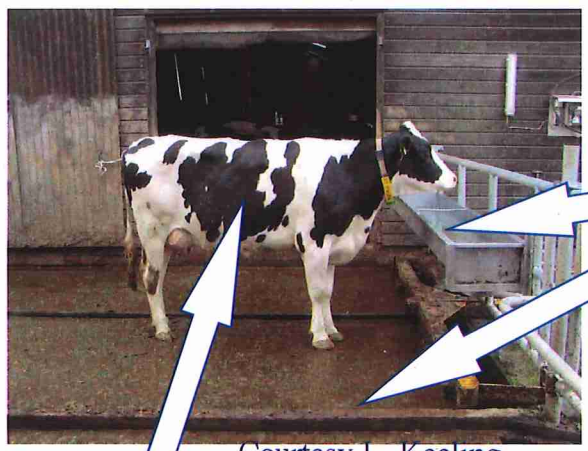
Take home message

Thank you for your attention

<https://prezi.com/dw-3ojjtx31/efsa-and-welfare-of-sheep/>



ANIMAL BASED INDICATORS

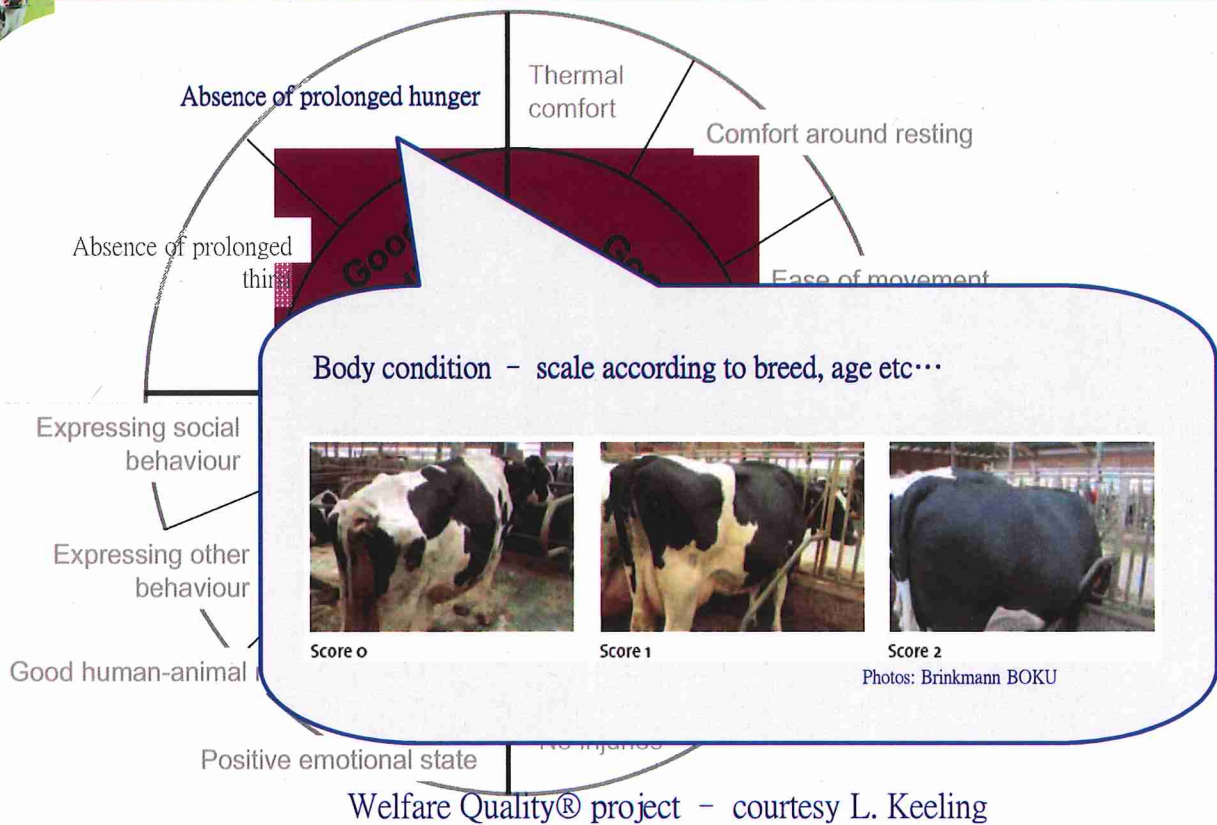


Courtesy L. Keeling

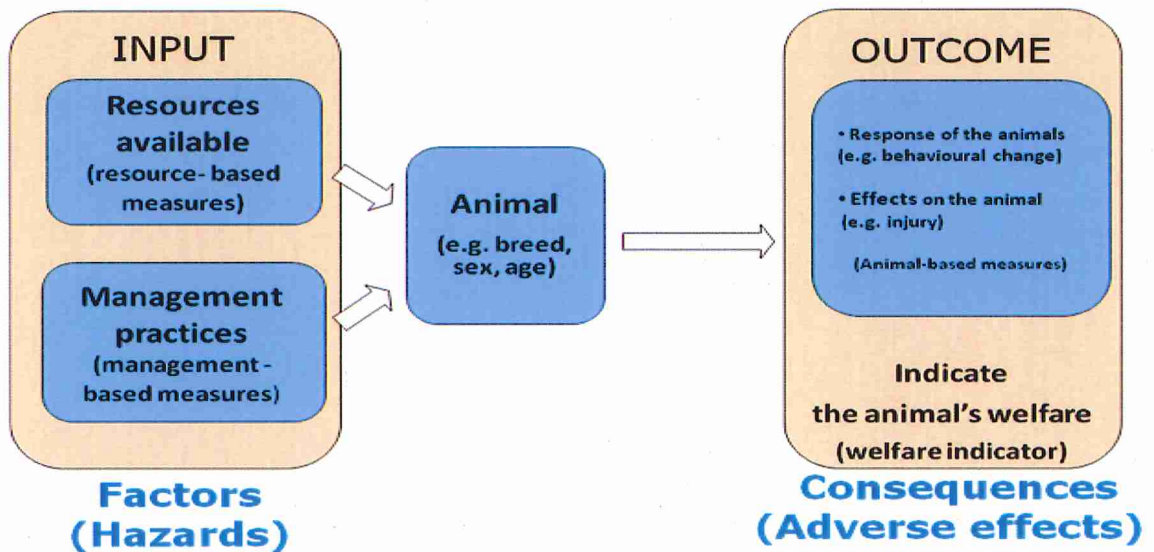
The input based approach to welfare assessment

The outcome based approach to welfare assessment

ANIMAL BASED INDICATORS: THE SHIFT

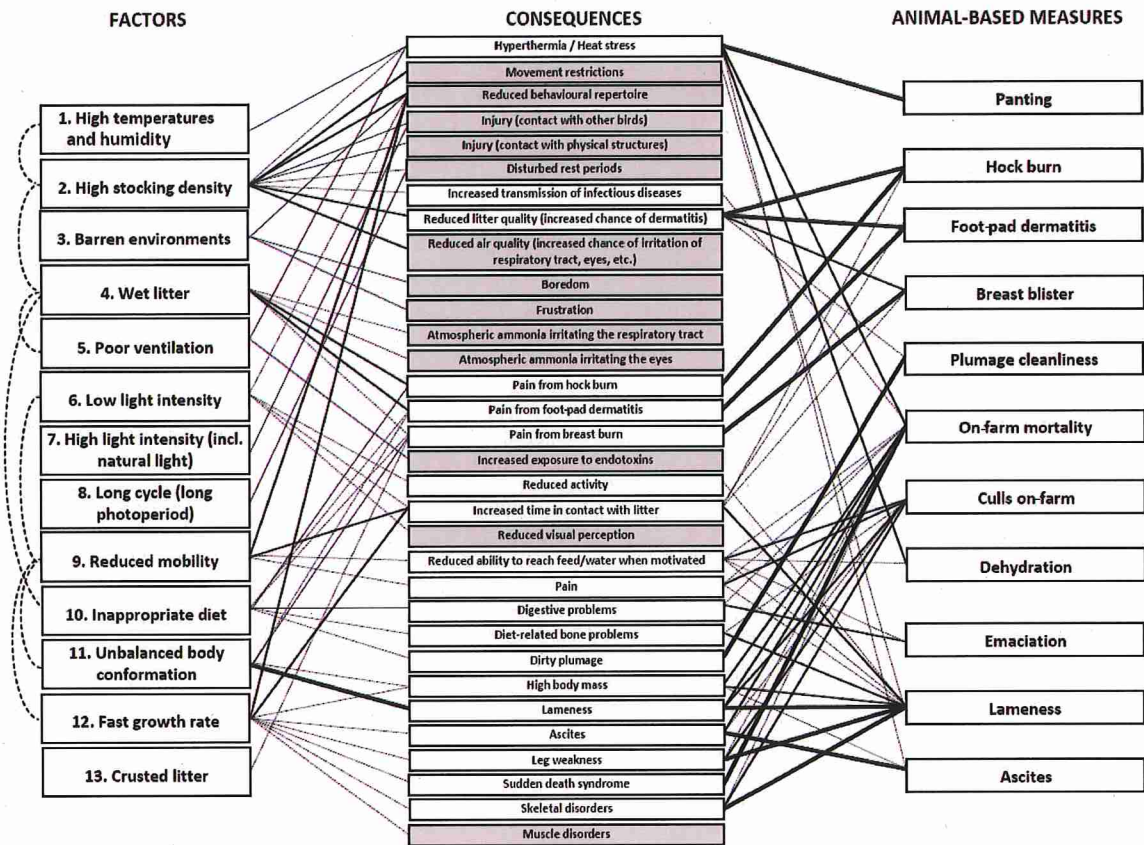


ANIMAL BASED INDICATORS IN THE RA FRAMEWORK





RELATIONS TO ANIMAL BASED INDICATORS

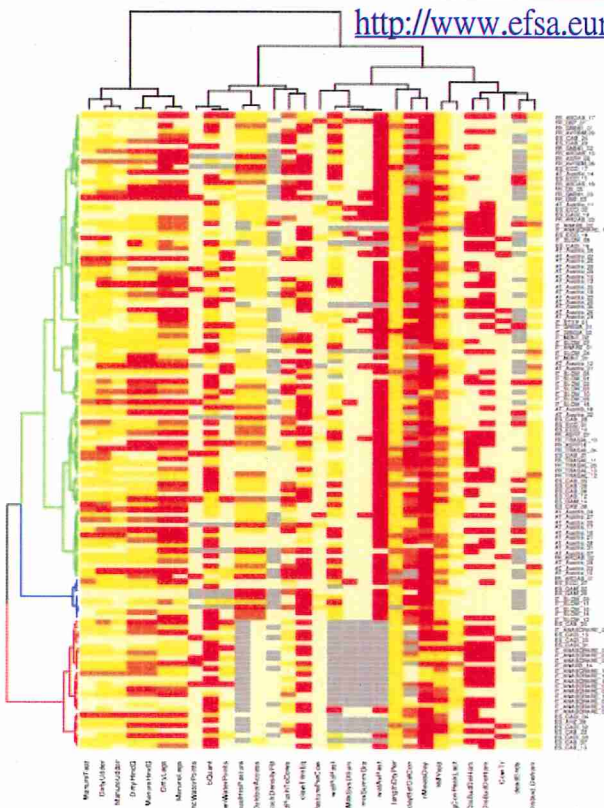


CRITERIA FOR VALID AND ROBUST ABMS

Criteria	Explanations and examples
They should accurately measure and indicate the welfare consequence for an animal Fit for purpose/Validity	There are several ways of assessing validity, such as expert opinion or (preferably) by deriving a study-based diagnostic validity related to the relationship between a specific welfare outcome indicator and an independently performed assessment of the welfare outcome
They should have low variability when repeatedly measured by the same observer Repeatability	This means low intra-observer variability and resulting high repeatability
They should be consistent when measured by different observers on the same animal Reproducibility	This means low inter-observer variability and high reproducibility. People should be trained to the “gold standard” for the measure and this training should be repeated at regular intervals so that observers are “recalibrated”
They should not be affected by external factors that are not related to the welfare of the animals Robustness	If the welfare of the animals does not change with weather or time of year, then the measures should also not be affected by weather or time of the year. This indicates a high robustness
Taking the measures should be feasible for the purpose of the data collection Feasibility	They should not be costly to make and should not involve much observer/farmer time, making them practical and feasible
Where the measures vary over time, e.g. time of day, then the measures should be based on a representative time sample. Fit for use	This is particularly true for behavioural measures, e.g. how much time animals spend lying down. Furthermore, indicators which are valid at one part of the production cycle may not be applicable in other phases

EXAMPLE OF USE OF ANIMAL BASED INDICATORS

http://www.efsa.europa.eu/en/efsa_journal/pub/4137.htm



The emerging SBV



FLI, blood examination
CVI, Virus discovery microarray (faeces)
AHS, bact, parasit exam. (faeces)

FLI, whole genome sequencing (blood)
FLI: sequences orthobunya viruses

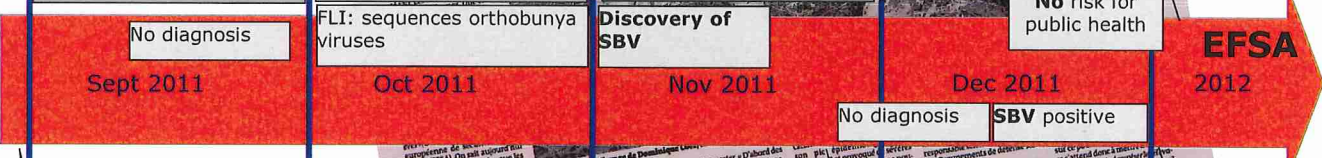
FLI, develop RT-PCR

Discovery of SBV

Rapid Risk Assessment by ECDC

SCoFCAH

No risk for public health



The Netherlands: dairy cows with sudden diarrhea, fever, reduced milk production
Germany: no diarrhea, but painful gait

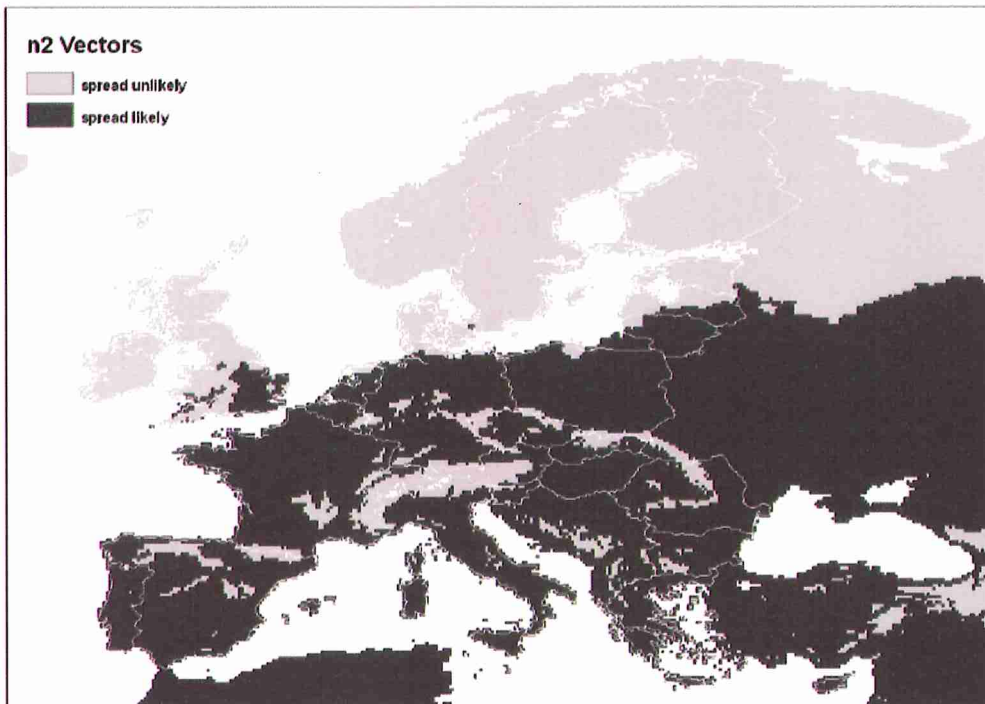
Full recovery dairy cows

First lambs with malformations in The Netherlands

Notification to the OIE

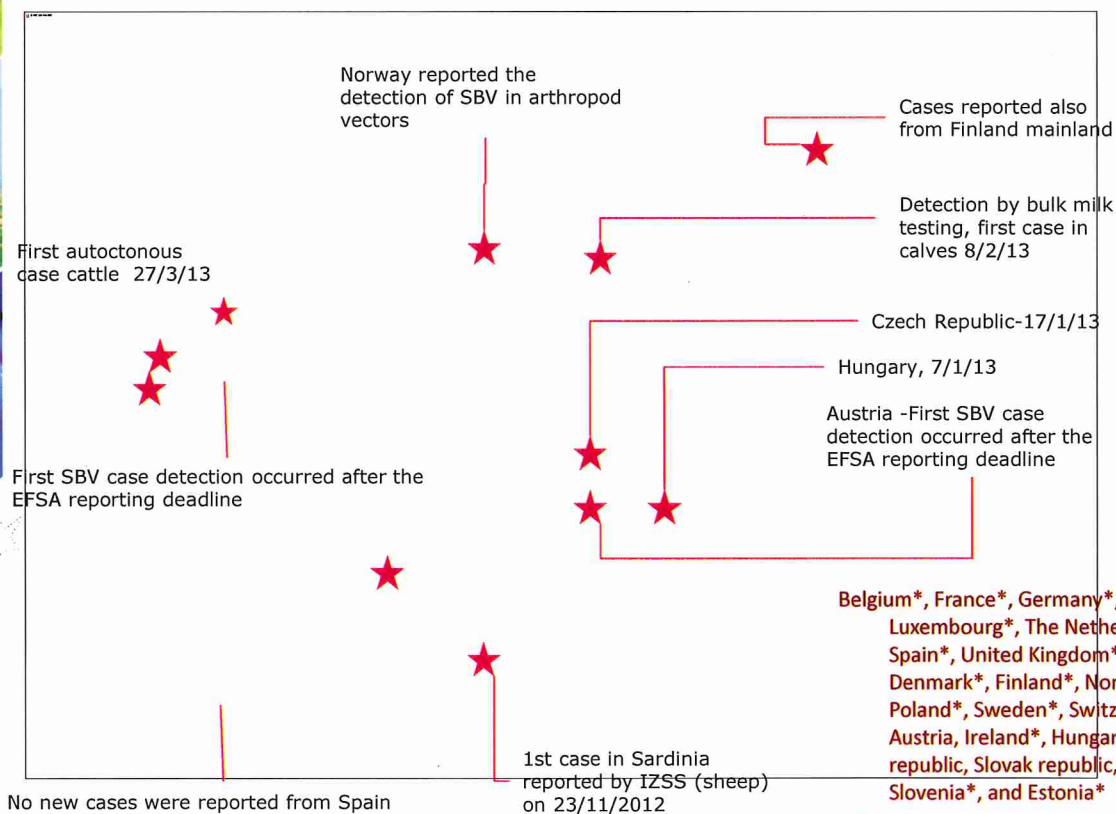
In January 2012, the European Commission asked EFSA to provide scientific and technical assistance on the possible risks for animal and public health caused by SBV

LIKELY SCENARIOS FOR SBV GEOGRAPHICAL SPREAD



EFSA; "Schmallenberg" virus: likely epidemiological scenarios and data needs. Supporting Publications 2012:EN-241. [31 pp.]. Available online: www.efsa.europa.eu/publications

SBV GEOGRAPHIC DISTRIBUTION



* Data reported to EFSA (09/04/2013)



DRIVERS FOR SPILLOVER OF EBOLA VIRUS

- » The **outbreak** in West Africa began in Guinea (Dec 2013) /subsequent spread to Liberia, Sierra Leone
- » **Spillover** is defined as the passage from animals to humans
- » **Transmission** to humans is thought to occur by contact with dead or living infected animals; hunting and butchering of infected animals is a potential source of infection
- » The current outbreak is believed to have happened after a single spillover event
- » EFSA was requested to analyse the drivers of the spillover

EFSA output:

<http://www.efsa.europa.eu/en/efsa-journal/pub/4161.htm>

EFSA SciencesPo project:

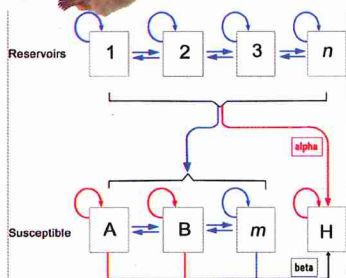
<https://drive.google.com/file/d/0BxbcQLNpkPSIUzZBQVI3d09xUW8/view?pli=1>



DRIVERS FOR SPILLOVER OF EBOLA VIRUS



adapted from Groseth et al. (2007) by Pigott et al. (2014)



TYPE OF SPILLOVER

- α Alpha: Spillover from reservoir species to humans
- β Beta: Spillover from non-human susceptible host species to humans

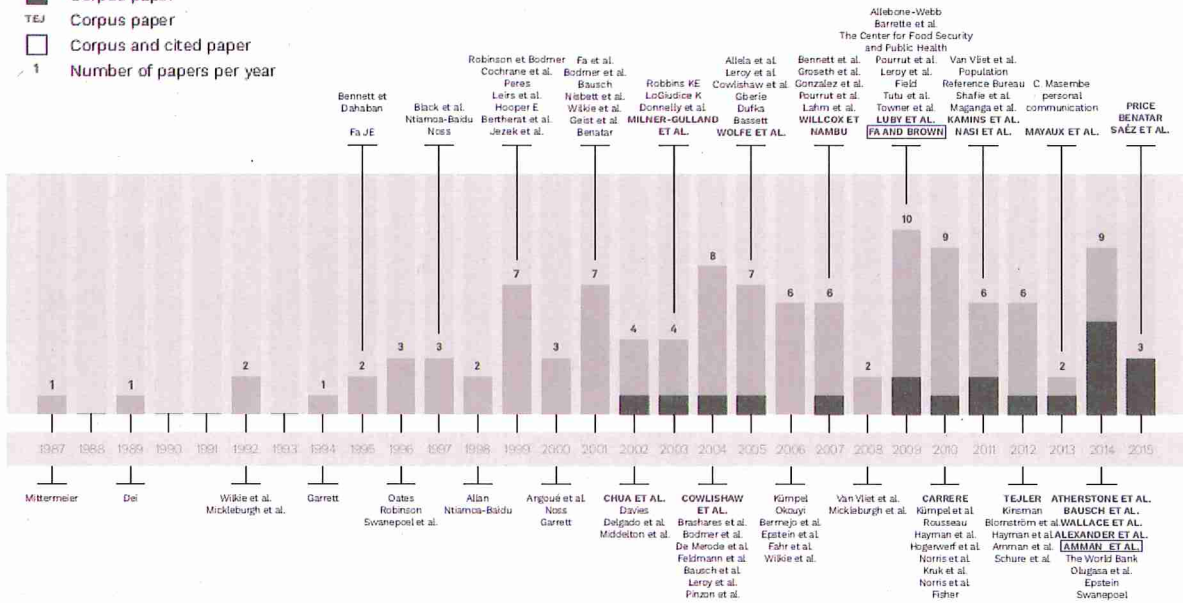




DRIVERS FOR SPILLOVER OF EBOLA VIRUS

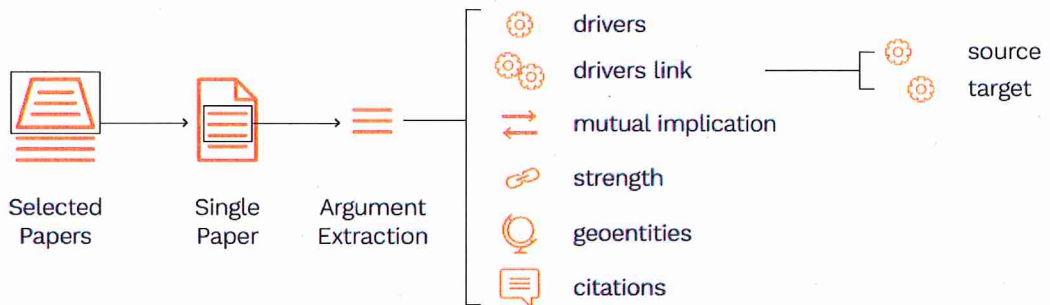
LEGEND

- Cited paper
- Cited paper
- Corpus paper
- Corpus paper
- Corpus and cited paper
- 1 Number of papers per year



DRIVERS FOR SPILLOVER OF EBOLA VIRUS

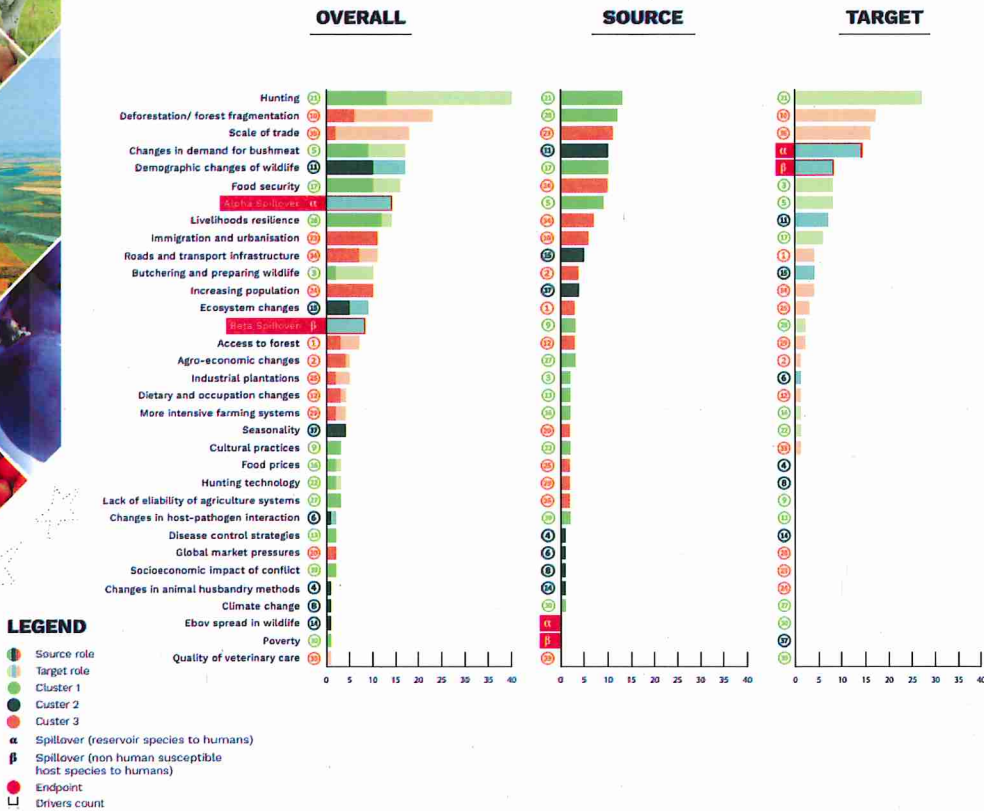
DATA EXTRACTION



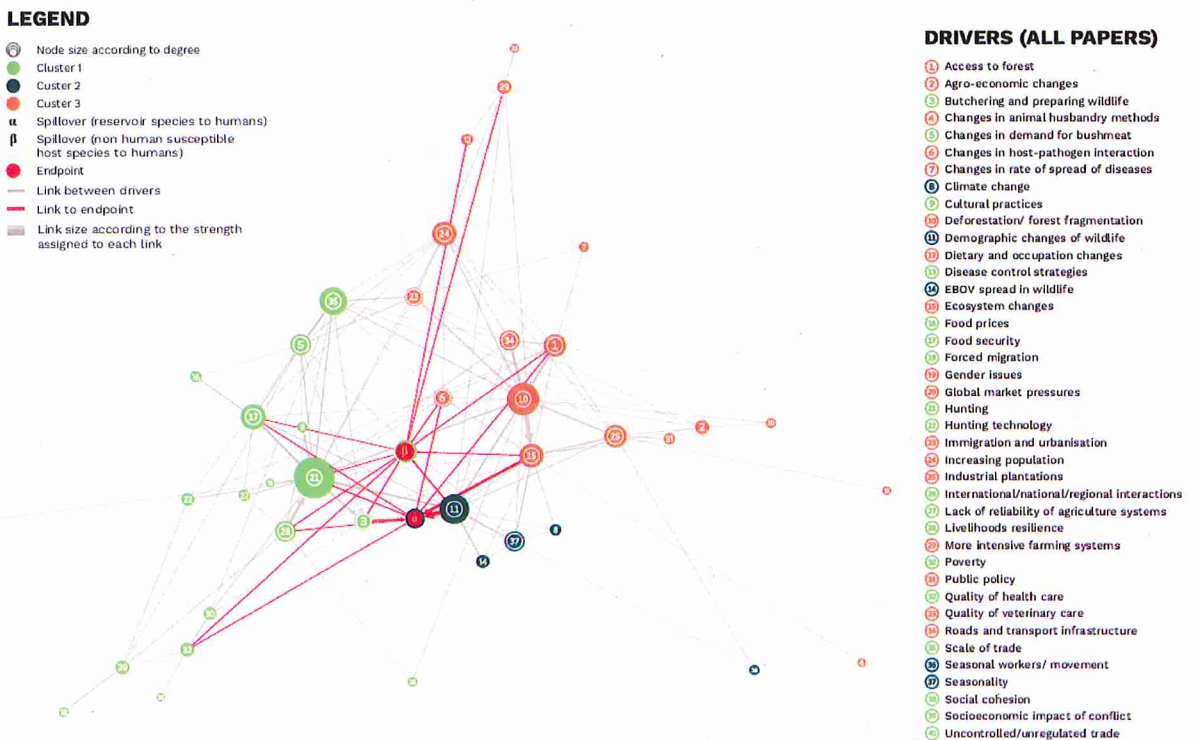
DATA EXTRACTION TABLE

ID	ORIGINAL ID (1) OR LINK REVIEW (2)	LINK: For multiple link then use this syntax: A>B<C (A implies B which implies C) or A>B,C (A implies B and C)	SOURCE	TARGET	MUTUAL IMPLICATION (y/z)	STRENGTH (1-3) (implies: 1, internal support: 2, external support: 3)	GEO ENTITY	CITATION
1	R	1	Lack of reliability of agriculture systems > Hunting	Lack of reliability of agriculture systems	Hunting	0	Tropical forest	non
1	R	2	Lack of reliability of agriculture systems > Hunting	Lack of reliability of agriculture systems	Hunting	0	Tropical forest	non
1	R	3	Increasing population > changes in demand for bushmeat > Hunting	Increasing population	Changes in demand for bushmeat	0	West Africa	Fa & Peres 2001
1	R	3	Increasing population > changes in demand for bushmeat > Hunting	Changes in demand for bushmeat	Hunting	0		
1	R	4	Increasing population, Roads and transport infrastructure, Hunting technology > Hunting, Access to forest	Increasing population	Hunting	0	Africa	non

DRIVERS FOR SPILLOVER OF EBOLA VIRUS



DRIVERS FOR SPILLOVER OF EBOLA VIRUS





DRIVERS FOR SPILLOVER OF EBOLA VIRUS

DRIVERS IN ORIGINAL PAPERS

- Butchering and preparing wildlife (3)
- Changes in demand for bushmeat (5)
- Cultural practices (9)
- Disease control strategies (15)
- Food prices (16)
- Food security (17)
- Hunting (21)
- Hunting technology (22)
- Lack of reliability of agriculture systems (27)
- Livelihoods resilience (28)
- Poverty (29)
- Socioeconomic impact of conflict (30)
- Access to forest (1)
- Agro-economic changes (2)
- Deforestation/ forest fragmentation (10)
- Global market pressures (24)
- Immigration and urbanisation (25)
- Increasing population (26)
- Industrial plantations (23)
- Roads and transport infrastructure (20)
- Scale of trade (12)
- Dietary and occupation changes (11)
- More intensive farming systems (18)
- Quality of veterinary care (8)
- Changes in animal husbandry methods (4)
- Changes in host-pathogen interaction (6)
- Climate change (7)
- Demographic changes of wildlife (14)
- EBOV spread in wildlife (13)
- Ecosystem changes (19)
- Seasonality (10)

Drivers not present in the original papers

- Changes in rate of spread of diseases (7)
- Forced migration (11)
- Gender issues (19)
- International/national/regional interactions (10)
- Public policy (11)
- Quality of health care (15)
- Seasonal workers/ movement (13)
- Social cohesion (19)
- Uncontrolled/unregulated trade (10)

DRIVERS IN ALL PAPERS

- Butchering and preparing wildlife (3)
- Changes in demand for bushmeat (5)
- Cultural practices (9)
- Disease control strategies (15)
- Food prices (16)
- Food security (17)
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- EBOV spread in wildlife (13)
- Seasonal workers/ movement (13)
- Seasonality (10)

PAPERS

Original papers

- PAPER 2 Nasi & others, 2011
- PAPER 3 Atherstone & others, 2014
- PAPER 7 Kamins & others, 2011
- PAPER 9 Tejler, 2012
- PAPER 10 Chua & others, 2002
- PAPER 13 Cowlishaw & others, 2004
- PAPER 15 Willcox and Nambu, 2007
- PAPER 16 Saéz & others, 2015
- PAPER 17 Mayaux & others, 2013
- PAPER 19 Amman & others, 2014
- PAPER 20 Price, 2015

Reviewed papers

- PAPER 1 Fa and Brown, 2009
- PAPER 4 Milner-Gulland & others, 2003
- PAPER 5 Wolfe & others, 2009
- PAPER 6 Bausch & others, 2014
- PAPER 8 Wallace & others, 2014
- PAPER 11 Luby & others, 2009
- PAPER 12 Alexander & others, 2014
- PAPER 14 Carrere, 2010
- PAPER 18 Benatar, 2015



DRIVERS FOR SPILLOVER OF EBOLA VIRUS

distance to endpoint β



DRIVERS (ORIGINAL PAPERS)

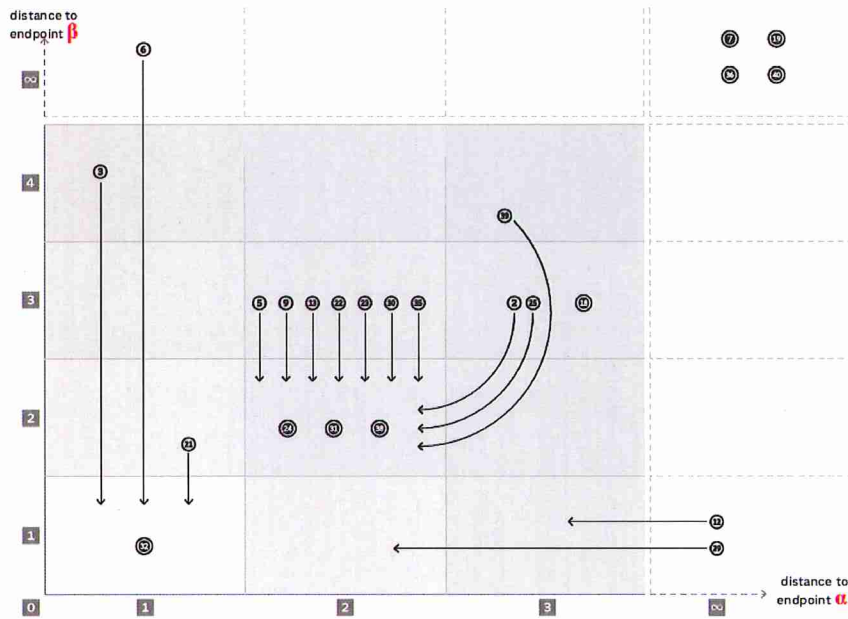
- 1 Access to forest
- 2 Agro-economic changes
- 3 Butchering and preparing wildlife
- 4 Changes in animal husbandry methods
- 5 Changes in demand for bushmeat
- 6 Changes in host-pathogen interaction
- 7 Climate change
- 8 Cultural practices
- 9 Deforestation/ forest fragmentation
- 10 Demographic changes of wildlife
- 11 Dietary and occupation changes
- 12 Disease control strategies
- 13 EBOV spread in wildlife
- 14 Ecosystem changes
- 15 Food prices
- 16 Food security
- 17 Global market pressures
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- 23 Lack of reliability of agriculture systems
- 24 Livelihoods resilience
- 25 More intensive farming systems
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- 27 Quality of veterinary care
- 28 Roads and transport infrastructure
- 29 Scale of trade
- 30 Seasonality
- 31 Socioeconomic impact of conflict

Drivers not present in the original papers

- 7 Changes in rate of spread of diseases
- 11 Forced migration
- 19 Gender issues
- 10 International/national/regional interactions
- 11 Public policy
- 15 Quality of health care
- 13 Seasonal workers/ movement
- 19 Social cohesion
- 10 Uncontrolled/unregulated trade



DRIVERS FOR SPILLOVER OF EBOLA VIRUS



DRIVERS

- ① Agro-economic changes
- ② Butchering and preparing wildlife
- ③ Changes in demand for bushmeat
- ④ Changes in host-pathogen interaction
- ⑤ Cultural practices
- ⑥ Dietary and occupation changes
- ⑦ Disease control strategies
- ⑧ Gender issues
- ⑨ Hunting
- ⑩ Hunting technology
- ⑪ Immigration and urbanisation
- ⑫ Increasing population
- ⑬ Industrial plantations
- ⑭ More intensive farming systems
- ⑮ Poverty
- ⑯ Public policy
- ⑰ Quality of health care
- ⑱ Scale of trade
- ⑲ Seasonal workers/ movement
- ⑳ Social cohesion
- ㉑ Socioeconomic impact of conflict
- ㉒ Uncontrolled/unregulated trade

Drivers that do not change distance

- ① Access to forest
- ② Changes in animal husbandry methods
- ③ Climate change
- ④ Deforestation/ forest fragmentation
- ⑤ Demographic changes of wildlife
- ⑥ EBOV spread in wildlife
- ⑦ Ecosystem changes
- ⑧ Food prices
- ⑨ Food security
- ⑩ Forced migration
- ⑪ Global market pressures
- ⑫ International/regional interactions
- ⑬ Lack of reliability of agriculture systems
- ⑭ Livelihoods resilience
- ⑮ Quality of veterinary care
- ⑯ Roads and transport infrastructure
- ⑰ Seasonality

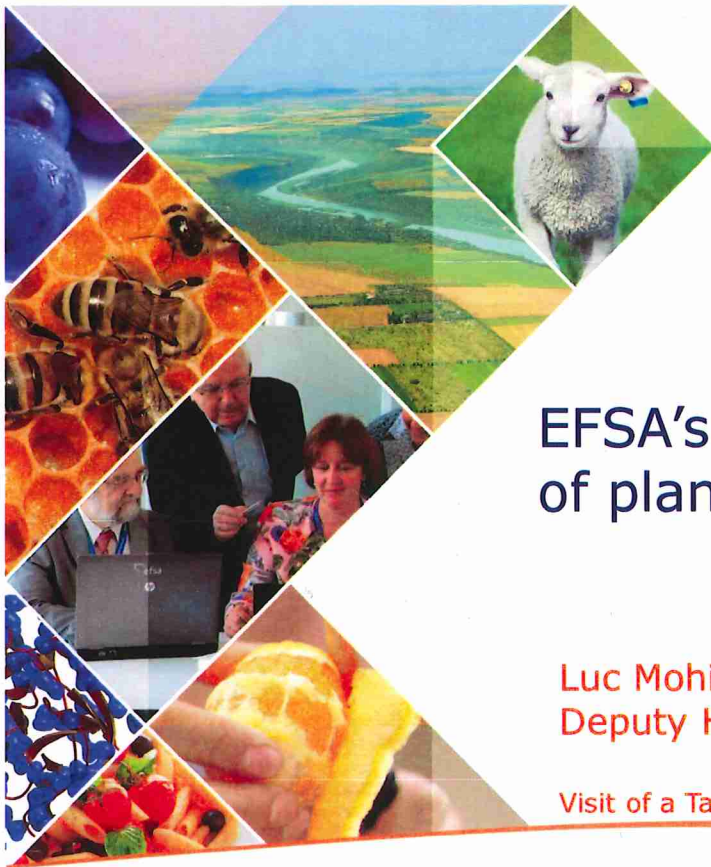


CONCLUDING REMARKS

- Animal health and welfare is a public good; it benefits all segments of the society
- Animal health and welfare has an overall impact on animal condition, including possible incidence on food safety; it is also strongly connected to public health
- It is possible to apply the principles of risk assessment to animal health as well as to animal welfare
- The development, validation, and practical implementation of welfare indicators offers opportunities to collect epidemiological data on the welfare status of animals
- Work on emerging risk points into the direction of drivers as a way to better prepare for, and anticipate crises



THANK YOU FOR YOUR ATTENTION



EFSA's activities in the area of plant protection products

Luc Mohimont
Deputy Head Pesticides Unit

Visit of a Taiwan Delegation to EFSA, 22 July 2015



www.efsa.europa.eu



CONTENT

- Introduction to PPR Panel and Pesticides Unit
- PPR Panel activities
- Peer-review activities
 - New actives and review programme
 - Commission specific mandates on approved substances
- Pesticides residues and MRL
 - MRL Reasoned opinions
 - Commission specific mandates and other activities
 - Annual Report on Pesticides monitoring
- Cooperation activities

Pesticides Unit and Panel activities

Scientific Panel for Plant Protection Product and their Residues (PPR) and unit support to the Panel

- Opinions
- Guidance documents
- Ad-hoc mandates

Coordinates the Peer Review of active substances

Provides **Conclusions** for single active substances to support the EU decision-makers

Pesticides Steering Network
Pesticides Monitoring Network

Maximum Residue Levels MRLs & Annual Report

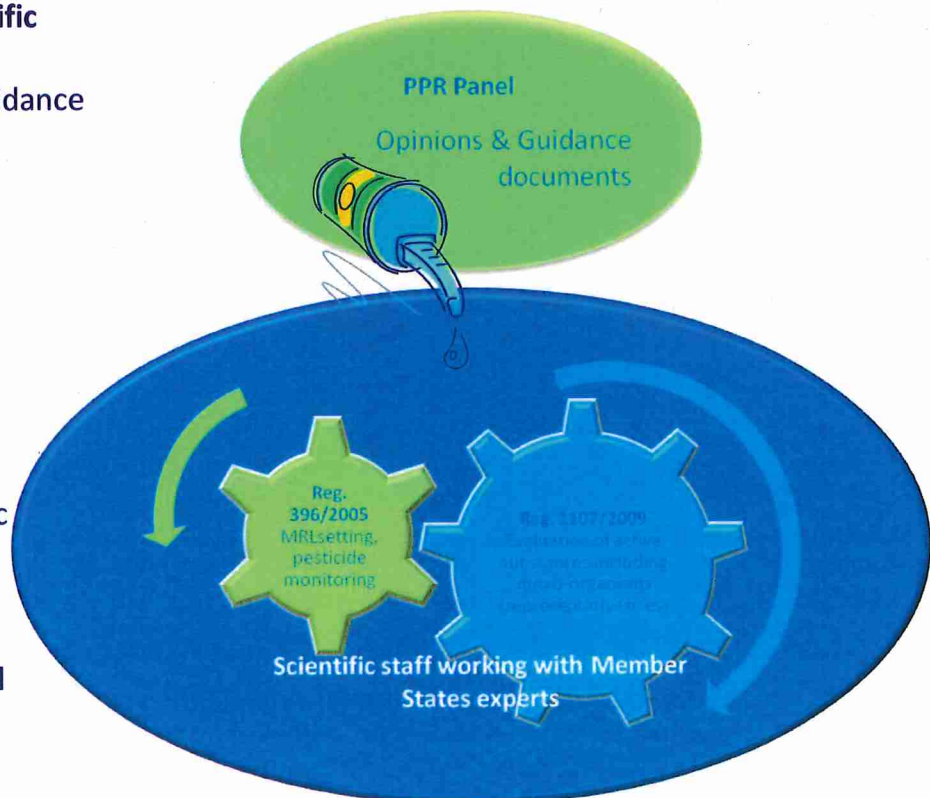
- Reasoned Opinions
- Annual report

Scientific consistency: PPR key role

General Scientific assessment:
Opinions & Guidance

Dossier specific assessment:

Conclusions
MRL Reasoned opinions





PPR 2012-2015 Panel main outputs

Toxicology and Human Health assessment

Cumulative Assessment Groups for Pesticides

Relevance of dissimilar mode of action

Developmental neurotoxicity potential of acetamiprid and imidacloprid

Environmental Fate

FOCUS groundwater: Assessment of Lower and Higher Tiers

Statement on FERA Guidance aged soil sorption studies

Ecotoxicology

Statement on BEEHAVE model evaluation

Good modelling practice

Guidance on tiered risk assessment for edge-of-field surface water

Effects assessment of sediment organisms

Science behind RA of PPPs for non-target arthropods

Science behind the RA for non-target terrestrial plants



PPR ongoing activities

Toxicology and Human Health assessment

Cumulative Assessment Groups for Pesticides

Guidance on residue definition

Use of epidemiological studies in risk assessment and AOP for Parkinson's disease and childhood leukaemia

Environmental Fate & Ecotoxicology

Further opinions covering the revision of current aquatic and terrestrial assessments

Involvement in the MUSTBEE project

Land-scape pan-European risk assessments

Needs for scientific coordination/alignment

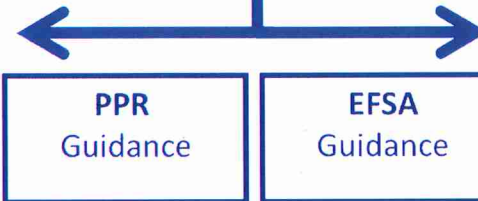


- Scientific opinions: as starting point for further guidance



Public consultations

PSN role



EFSA guidance activities in 2014



Emission routes of PPPs from greenhouses and covered crops 20 March 2014

Guidance Document to obtain DegT50 values 8 May 2014

Guidance on risk assessment on bees Restructuration published 4 July 2014, including a “Bee tool calculator” and a “SHVAL Monte Carlo exposure refinement tool”.

Comments on Bee tool calculator v.1 by 30 September

Guidance document on the pesticide exposure assessment for workers, operators, bystanders and residents (Opex) 23 October 2014

Guidance for predicting environmental concentrations in soil 28 April 2015



Pesticides Unit activities

Scientific Panel for Plant Protection Product and their Residues (PPR) and unit support to the Panel

- Opinions
- Guidance documents
- Ad-hoc mandates

Coordinates the Peer Review of active substances

Provides **Conclusions** for single active substances to support the EU decision-makers

Maximum Residue Levels MRLs & Annual Report

- Reasoned Opinions
- Annual report



The Peer-Review Process

Dossier submission



European Union
Programme for the Reduction of Active Substances
in Active Substances (Regulation (EC) No 1107/2009)
Annex 3 and 4 of Council Directive 91/414/EEC

D/RAR
Draft/Review
Assessment
Report



PEER REVIEW

EFSA,
Rapporteur MS,
other MSs,
EU Commission,
Notifier, Public

1. Commenting phase

2. Evaluation of comments

3. Expert's consultation

EFSA Conclusion



EFSA Risk
Assessment

**Commission + MSs
Standing Committee on Plants,
Animals, Food and Feed**

Approval/Non Approval

National authorisation PPP by MSs

EFSA CONCLUSION

- Output of a scientific peer review
 - Identity and Phys/Chem properties
 - Mammalian Toxicology & Workers/Bystander/residents risks
 - Residues & Consumers risks
 - Environmental Fate and Behaviour
 - Ecotoxicology & Ecosystem risks
- Conducted by EFSA scientific staff and risk assessment experts from the Member States
- The PPR Panel is involved, e.g. request for endorsement, occasionally



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EFSA PEER-REVIEW OUTPUTS 2014

- **40 Conclusions**
 - New active substances
 - First conclusions under Reg. 1107/2009
 - Renewals and amendments of approvals
 - First conclusions of AIR-II renewals
 - Confirmatory data
 - Reviews under Art 21
- **38 Technical reports on a.s.**
 - Basic substances

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SPECIFIC REQUEST FROM EC (ARTICLE 21)

■ Published during 2014

- Health assessment of chlorpyrifos
- Aquatic risk of imidacloprid
- Bee study protocols



■ On going and new requests

- Risk of neonicotinoids foliar uses to bees
- Call for data for Risk assessment for bees
- Pesticides risk assessment and peer review of *Bacillus subtilis* (strain IAB/BS03)
- Need of flumioxazin to control serious danger to plant health

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Pesticides Unit activities

Scientific Panel for Plant Protection Product and their Residues (PPR) and unit support to the Panel

- Opinions
- Guidance documents
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Maximum Residue Levels MRLs & Annual Report

- Reasoned Opinions
- Annual report

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EU MRL legislation

Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels in or on food and feed of plant and animal origin

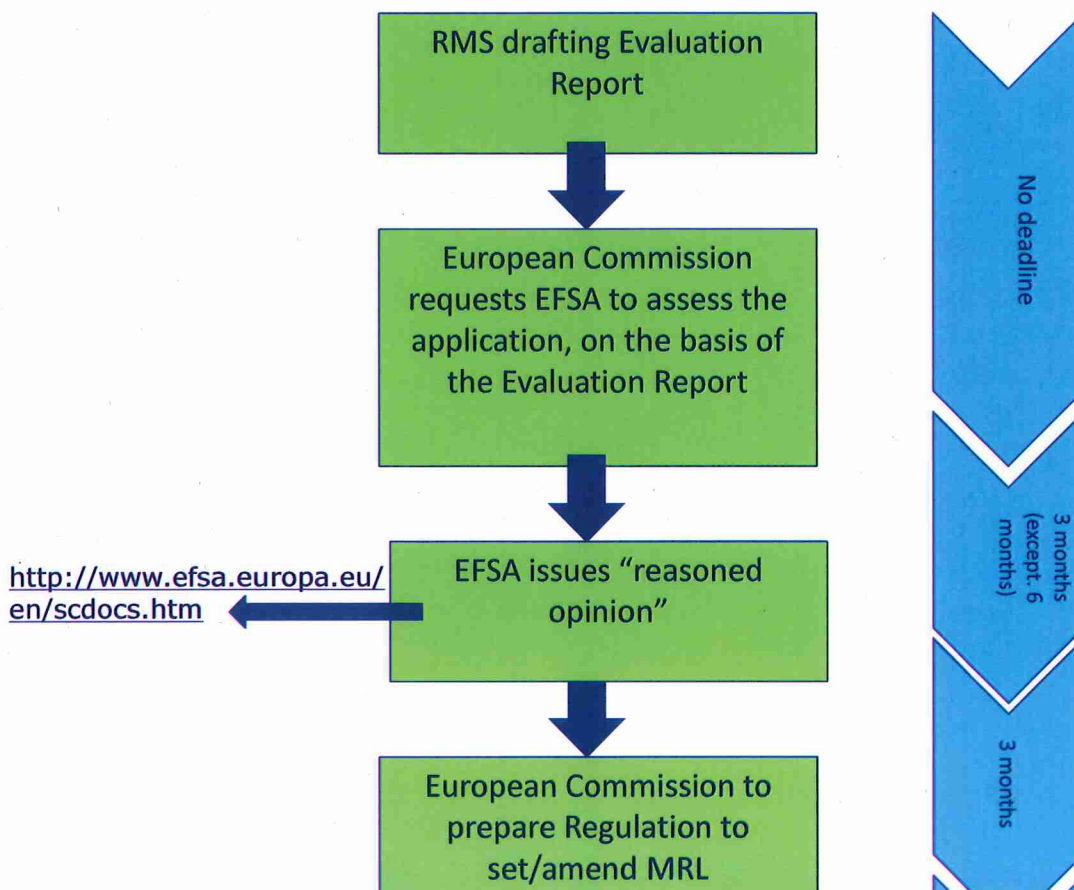
- Procedure for MRL setting
- Official control of MRLs
- Definition of responsibilities (role of Member States, European Commission, European Food Safety Authority, manufacturer of pesticides, food business operator, etc.)
- Annexes
 - Annex I: List of commodities for which MRLs are established
 - Annex II and Annex III: List of MRLs
 - Annex IV: Active substances exempted from setting MRLs
 - Annex V: specific LOQ values
 - Annex VI: processing factors

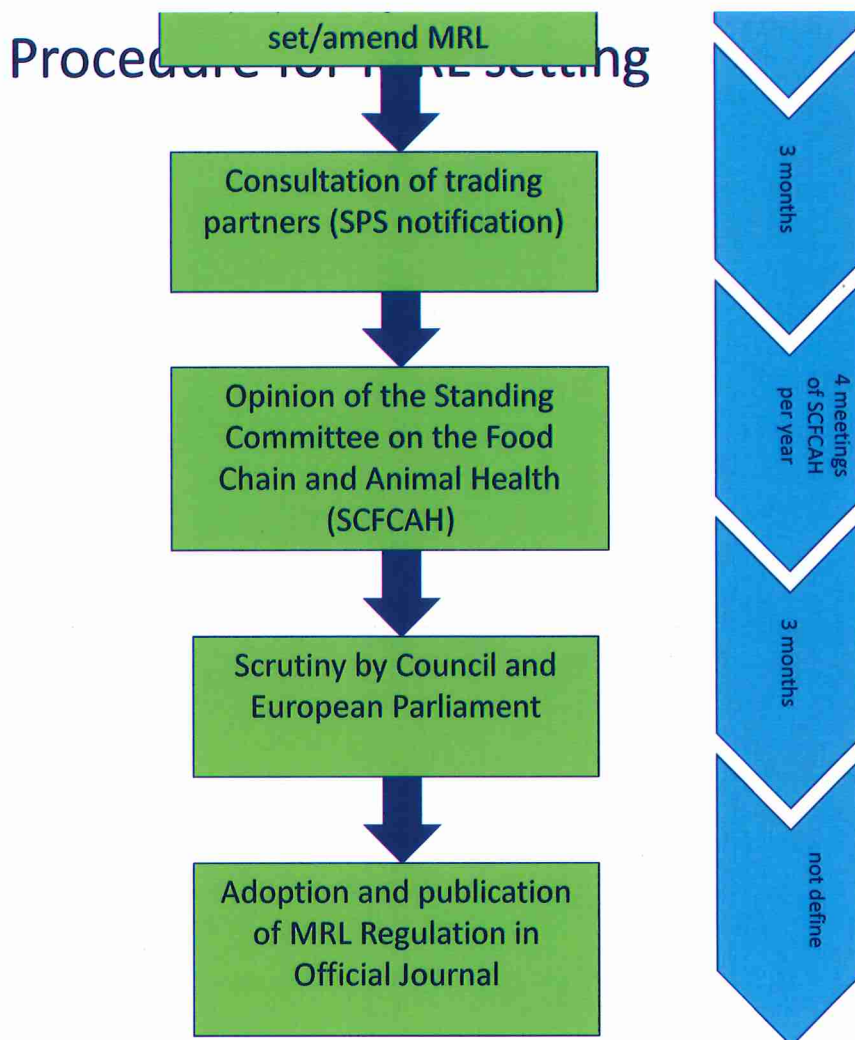
Basic regulation:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:070:0001:0016:EN:PDF>

15

Procedure for MRL setting





KEY ELEMENTS

MRL assessment

- ✓ Dossier compliant with data requirements was submitted (GAPs, field trials, ...)
- ✓ MRL proposals are based on **good agricultural practice and the lowest consumer exposure** necessary to protect vulnerable consumers;
- ✓ chronic risk assessment is acceptable
- ✓ acute risk assessment is acceptable



COOPERATION ACTIVITIES ON PESTICIDES R.A.

- **EU wide: Pesticide Steering Network**
 - Standard and dedicated meetings
 - Documents available upon request
- **EFSA-MSs**
 - Cumulative assessment, Operators-Workers, Epidemiology, microbial pesticides,...
- **EU-Agencies**
 - Cooperation with ECHA on C&L and biocides
 - ECHA-EFSA Workshops
 - Mode of Action and Human Relevance Framework (2014)
 - Topical Scientific Workshop on Soil Risk Assessment, October 2015
- **International organisations**
 - EFSA/WHO/FAO workshop on acute exposure estimations for consumers risk assessment, September 2015

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Thank you

Make a difference to Europe's food safety