Animal Health Law

- What do we need to know about it?

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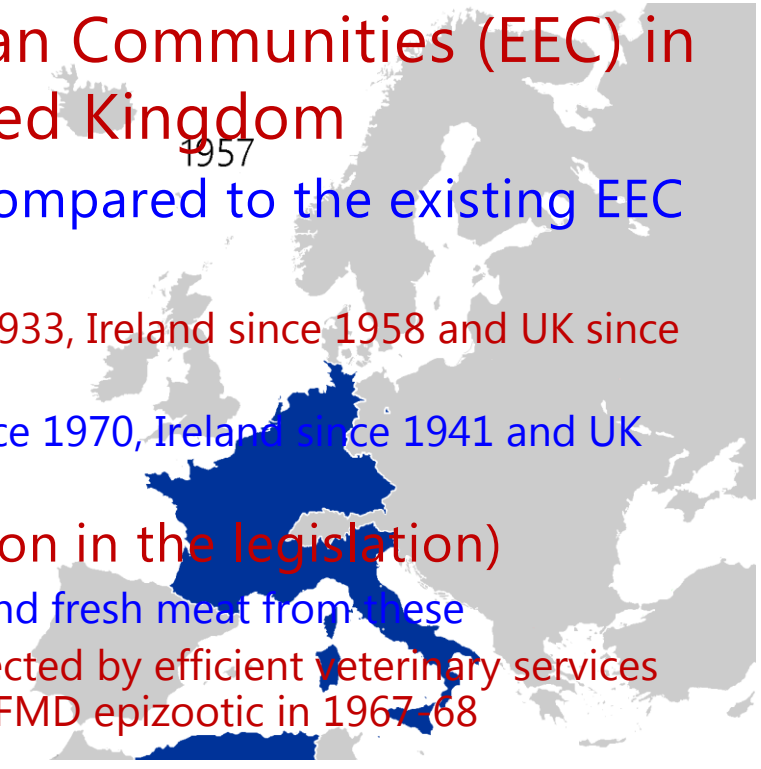
Animal Health Law (AHL)

- "Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')"
- Rules of transmissible diseases of terrestrial and aquatic animals
  - Disease prevention, awareness, biosecurity, traceability, movements of animal (intra-EU and into EU), surveillance, disease control, eradication
  - Not animal welfare, except when disease impacts welfare
- Most relevant aspects will come into force in 2021
  - Replacing 33 Directives, 2 Regulations and 3 Decisions, e.g. Directive 64/432/EEC
  - All countries have to implement rules that are yet to be defined

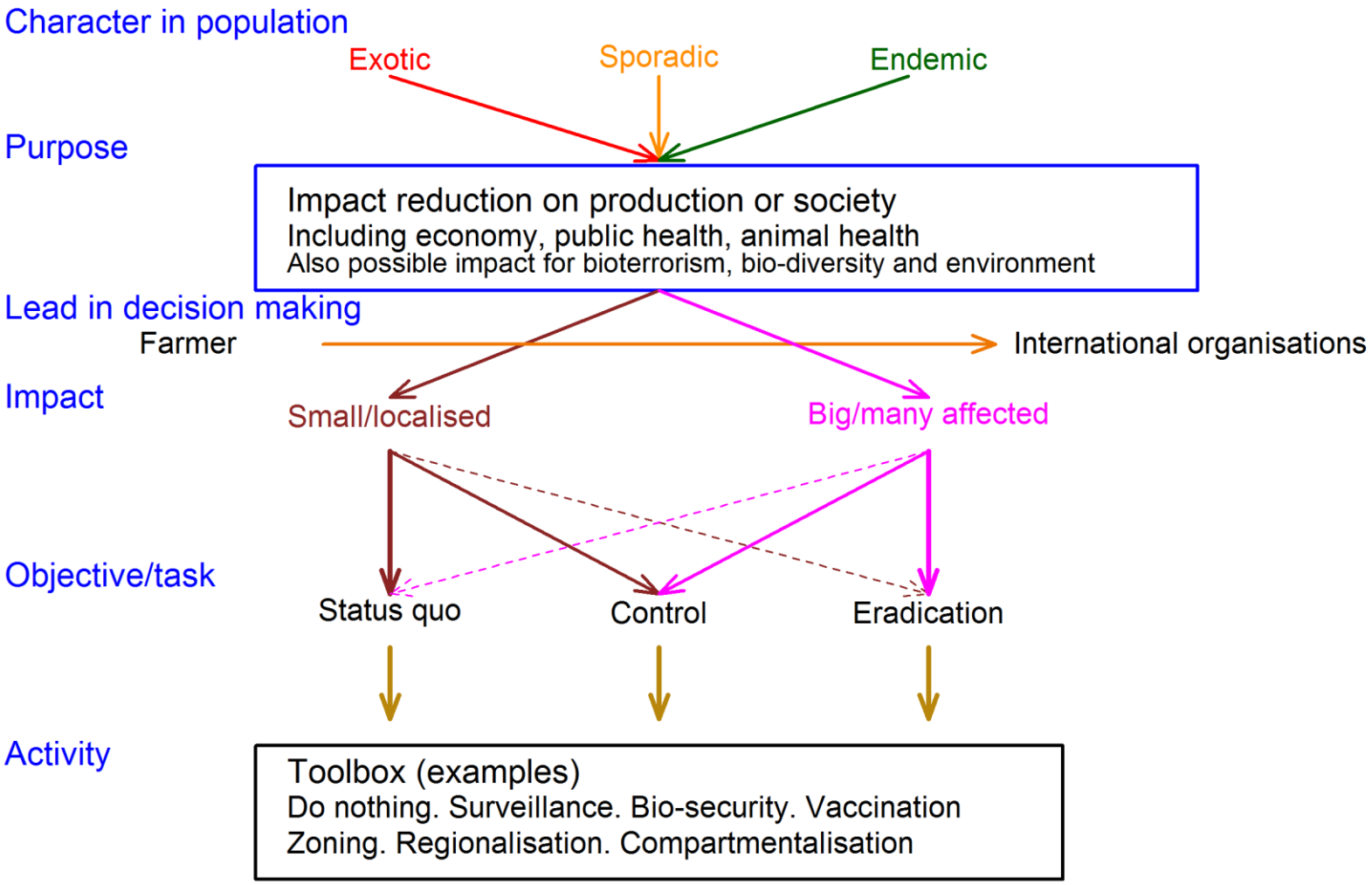
Management of transmissible diseases in EU

- First common veterinary legislation adopted in 1964
  - On health requirements for intra-community trade in cattle and pigs (Council Directive 64/432 EEC)
- Animal Health Law adopted 2016 - implemented by 2021
- Denmark became part of European Communities (EEC) in 1973 along with Ireland and United Kingdom
  - "Better" disease status in the "new" compared to the existing EEC countries, e.g.
    - Denmark had no Classical Swine Fever since 1933, Ireland since 1958 and UK since 1971
    - Denmark had no Foot and Mouth Disease since 1970, Ireland since 1941 and UK since 1968
  - Consequences (needed implementation in the legislation)
    - Ban on imports of cattle, sheep, goats, pigs, and fresh meat from these
    - Immediate elimination by stamping-out – directed by efficient veterinary services established e.g. in the UK following the great FMD epizootic in 1967-68



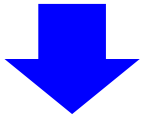
Objective: status quo / control / eradication?

- assessing the individual disease/microorganism



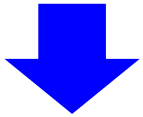
AHL: Assessment and management of listed diseases in the European Union

- Decisions on framework <- European Parliament (decision makers, politicians, lay-persons)



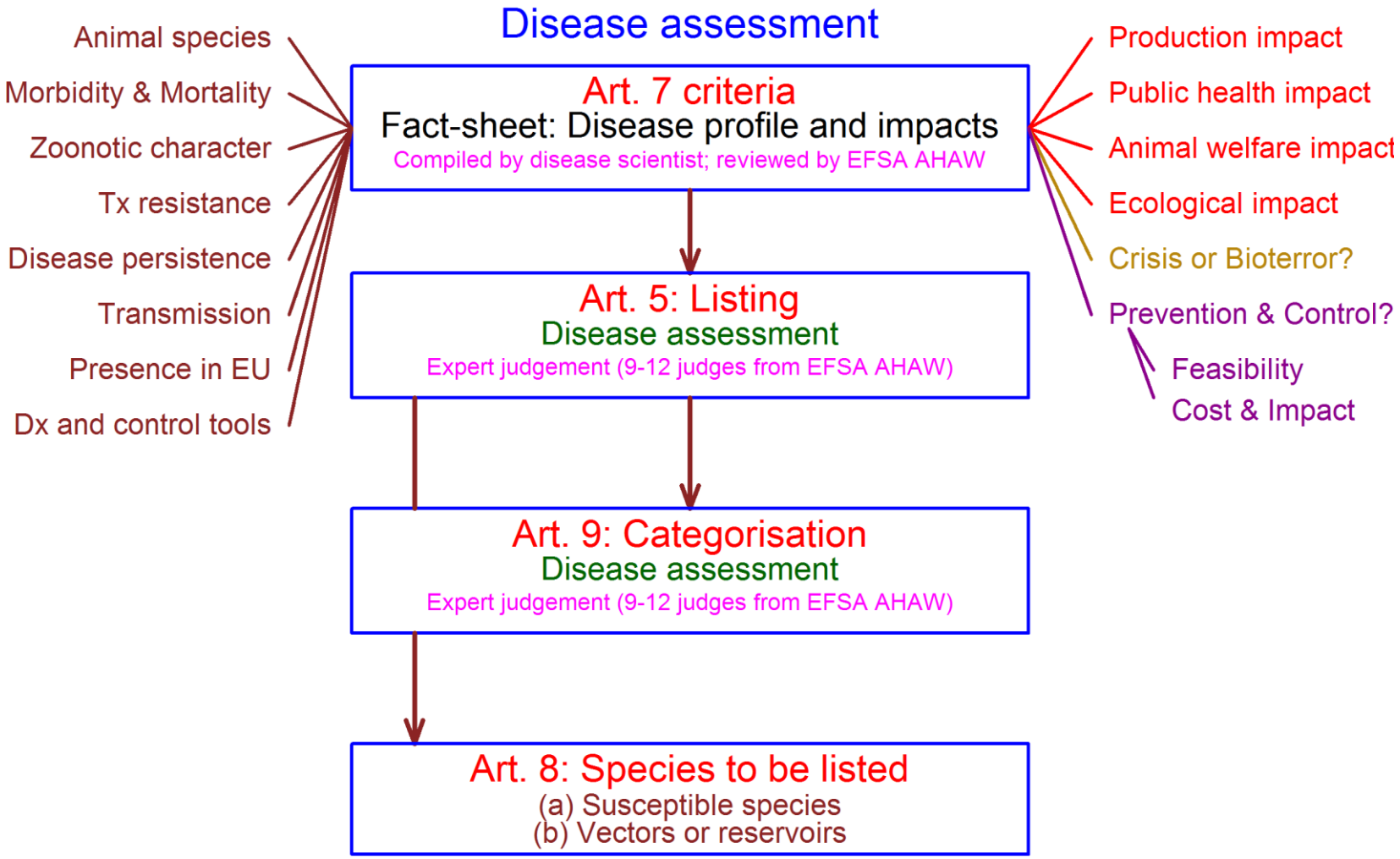
- Assessment of specific diseases <- European Food Safety Authority (EFSA) (assessors, disease experts)

- Decisions on specific diseases <-European Commission (technocrats, managers, politicians)



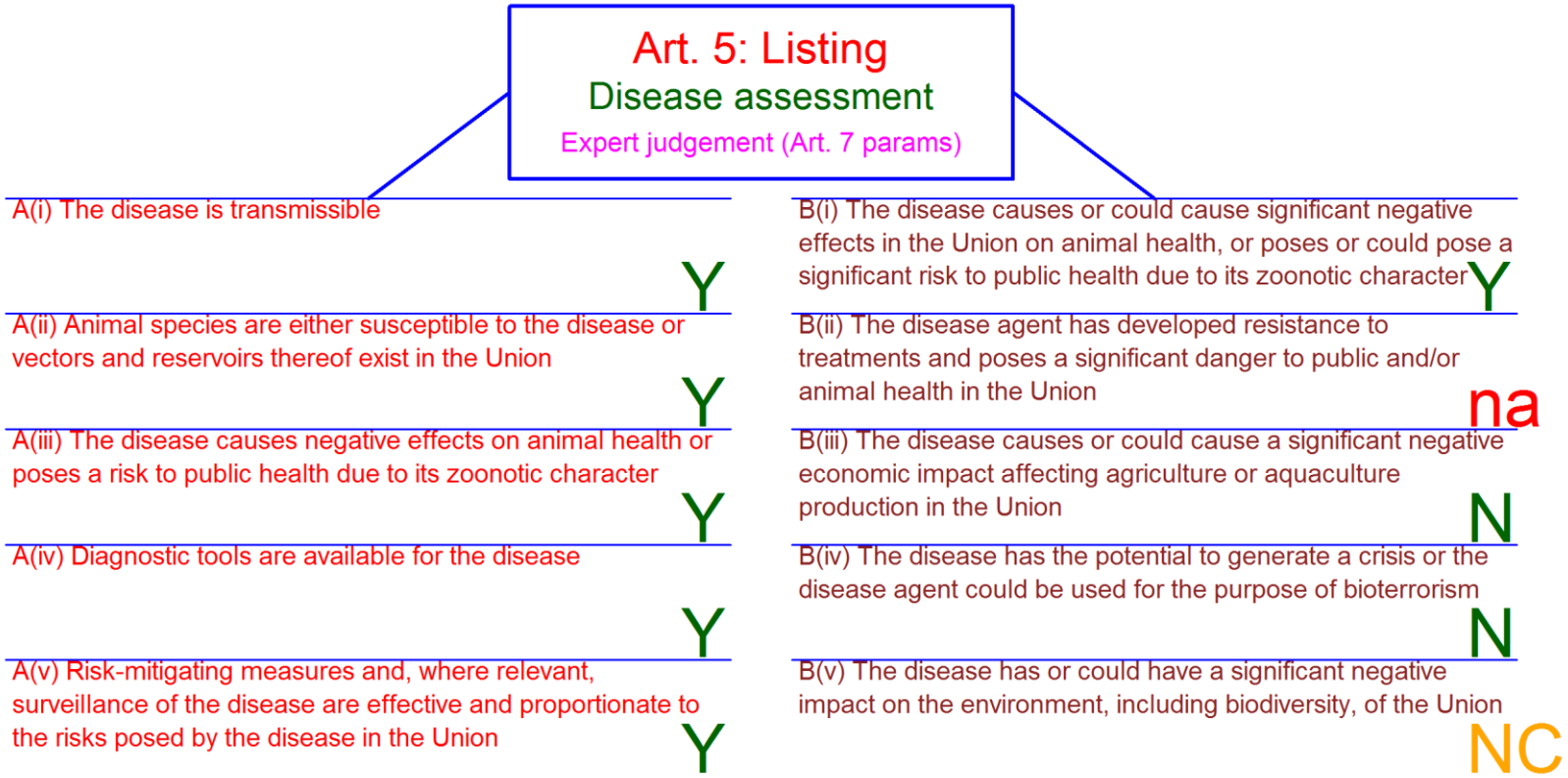
- Implementation in individual countries <- National governments and competent veterinary authorities

Assessment on listing and categorisation of diseases in AHL framework



EFSA AHAW Panel, 2017. EFSA J, 15(7): 4783

Judgement on listing according to Article 5



All A-criteria should be "Y" for listing to be recommended

Over and above all A-criteria, at least one B-criterion should be "Y" for listing to be recommended

Conclusion: Eligible for listing: Y/N/NC

If listed: which intervention ?

Judgement on categorisation - Article 9

Category	Article 9 criteria										
	All should be Y					At least 1 should be Y					
	1st set of criteria					2nd set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissi-bility	Routes of transmission	Multiple species	Morbidity & mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	Mostly absent	High	All	Y/N	High-high	Pande-mic po-tential	All prod. systems	Y/N	Y/N	Y/N	Y/N
B	Endemic & free zones	Mode-rate to high	All	Y/N	High-low	Epide-mic po-tential	All prod. systems	Y/N	Y/N	Y/N	Y/N
C	Endemic	Mode-rate to high	Direct and indirect	Y/N	Mainly prod. loss	Significa nt po-tential	Some prod. systems	Y/N	Y/N	Y/N	Y/N
D	Movement control on animals or products effective and proportionate for risk mitigation										
E	Surveillance required for reasons relating to animal health, animal welfare, human health, economy, society or environenment										

Enzootic bovine leukosis – listing (Article 5)

Criteria to be met by the disease: According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		**Final outcome**
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	Y
At least one criterion to be met by the disease: In addition to the criteria set out above at points A(i)–A(v), the disease needs to fulfil at least one of the following criteria		
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	NC
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	na
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	NC
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	N
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	N

All should be Y

At least 1 should be Y

Enzootic bovine leukosis – categorisation (Art. 9)

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	NC	N	Y	Y	N	N	N	N	NC	N	N
B	NC	N	Y	Y	N	N	N	N	NC	N	N
C	N	N	Y	Y	Y	N	N	N	NC	N	N
D	NC										
E	NC										

EBL – Non-consensus: Art. B(i)

Question		Final outcome	Y (%)	N (%)	na (%)
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	Non-consensus	62	38	0

Reasoning supporting the judgment

Supporting Yes

- In endemic areas within the EU, seroprevalence ranges from 0.01% to 12% (2015), 0% to 1–2% of BLV-infected animals can develop lymphomas. Furthermore, there is evidence that BLV-infected herds register a reduction in milk yield

Supporting No

- The probability to develop lymphomas over the lifespan of the animals is low

Disease	Listed in DK	EFSA assessment	Union intervention
Brucellosis	L1	Yes	B, C, D, E
Tuberculosis	L1	Yes	(B), C, D, E
Paratuberculosis	No	Yes	C, D, E
Border disease	No	Yes	C, D, E
Borna disease	No	Yes	C, D, E
Trichomonosis	No	Yes	C, D, E
Bluetongue	L1	Yes (BTV1-24 (not BTV16)	B, (C), E
BVD	L2	Yes	(C), D, E
IBR	L1	Yes	(C), D, E
Campylobacter fetus subsp. fetus	No	Yes	(C), D, E
Contagious bovine pleuropneumonia	L1	No	D, E
Anthrax	L1	Yes	D, E
Enzootic bovine leukosis	L1	No consensus	(D), (E)
Equine encephalomyelitis (eastern and western)	L1 (not cattle)	Yes	(D), E
Venezuelan equine encephalitis	L1 (not cattle)	No consensus	(D), (E)
Trypanosoma evansi	No	No consensus	(D), (E)
Japanese encephalitis	L1	No	E
Aujeskey's disease	L1 (multiple sp)	No (not cattle)	D, E

A = Eradication of exotic diseases	B = Control with an aim of eradication	C = Prevention of spread from infected to free MS	D = Prevention of spread via movement control	E = Surveillance

Disease listing and categorisation

- Eligibility for Listing (Art 5) dependent on disease profile (Set A) and disease impact (Set B)
  - Most challenging for new diseases with limited information, and
  - Old diseases that has been eradicated from most MS and where updated disease information is not available
- Categorisation – for intervention (tools)
  - To great extent based on occurrence, transmission and morbidity and mortality
  - A: Immediate measures must be taken to eradicate disease
  - B: Must be controlled in all MS with a goal to eradicate from EU
  - C: Spread from MS with endemic disease to free areas must be prevented
  - D: Movement control into and between MS to prevent spread
  - E: Need for surveillance
- Animal species
  - List can be very specific or very long

Assessments a reflection of the specific experts' expertise and beliefs