How to model a "negligible" probability under the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement?

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Background

- 1921: Australia bans imports of apples from New Zealand due to fireblight (*Erwinia amylovora*, a disease of pome fruit)

- 2003: WTO finds Japan's measures affecting the importation of apples from U.S. violate the SPS Agreement

- 2007: Australia permits imports of apples from NZ subject to numerous measures

- 2010: WTO finds Australia's measures violate the SPS Agreement

Background

- Australia – Salmon I (1998): WTO finds Australia's ban of imports of fresh/frozen salmon from Canada violates SPS Agreement.

- Australia – Salmon II (2000): Qualitative risk assessment criticized by expert, but "flaws identified are not so serious as to prevent us from having reasonable confidence in the evaluation made and the levels of risk assigned" (WTO 2000, para. 7.57).

Background

Semi-Quantitative Risk Assessment Scheme		
Likelihood	Qualitative descriptors	Probability interval
High	Very likely to occur	0.7 – 1
Moderate	Even probability	0.3 – 0.7
Low	Unlikely to occur	5×10^{-2} – 0.3
Very low	Very unlikely to occur	10^{-3} – 5×10^{-2}
Extremely low	Extremely unlikely to occur	10^{-6} – 10^{-3}
Negligible	Almost certainly not occur	0 – 10^{-6}

Source: Biosecurity Australia (2001)

Background

- In presenting its findings, the WTO Japan – Apples Panel observed that Dr. Chris Hayward (an Australian bacterial plant disease expert) indicated that the standard scientific definition of "negligible" was a likelihood of between zero and one in one million (WTO 2003, para. 8.149).

Fireblight: Import, Entry, Establishment, and Spread

Importation		
Step	event	probability
1	fireblight present in orchard	**1**
2	fruit infested in orchard	triang(10^{-3}, 3×10^{-2}, 5×10^{-2})
3	clean fruit cross-contaminated going to packing house	triang(10^{-3}, 10^{-2}, 3×10^{-2})
4	fruit remains infested after packing house	triang(0.3, 0.65, 0.7)
5	clean fruit cross-contaminated in packing house	triang(10^{-3}, 2.5×10^{-2}, 5×10^{-2})
6	fruit remains infested during transport	triang(0.7, 0.8, 1)
7	clean fruit cross-contaminated during transport	triang(0, 5×10^{-7}, 10^{-6})
8	fruit remains infested after border inspection	1
Entry, Establishment and Spread		
1	fruit in proximity to host plant	varied (wholesale, retail, consumer)
2	host plant exposed to fruit	**uniform(0, 1×10^{-6})**
3	establishment (commercial and nursery)	**uniform(0.7, 1)**
4	spread (commercial and nursery)	uniform(0.7, 1)

Source: Biosecurity Australia (2006)

WTO (2010) Australia - Apples

- WTO (2010) Panel Report:
  - "[T]he use of a uniform distribution to model the likelihood of 'negligible' events, in combination with the assignment of a high maximum level [1 in a million] for the respective probability interval that is not adequately justified, would tend to overestimate the likelihood of such 'negligible' events" (para. 7.496)

"Negligible" = Uniform$(0, 10^{-6})$

Percentage of sampling from Uniform$(0, 10^{-6})$			
Range			Sampling (%)
0	<->	10^{-12}	0.0001
10^{-12}	<->	10^{-11}	0.0009
10^{-11}	<->	10^{-10}	0.0090
10^{-10}	<->	10^{-09}	0.0900
10^{-09}	<->	10^{-08}	0.9000
10^{-08}	<->	10^{-07}	9.0000
10^{-07}	<->	10^{-06}	90.0000
Total			100

Mean

= (max – min)/2

= 5 x 10^{-7} (1 per 2 million)

Volume

Minimum imports = 50 x 10^6 fruit/yr

Source: WTO (2010) Replies from the scientific experts to questions posed by the Panel, Dr. Sgrillo, para 786.

Alternative Remedies

- WTO (2010, para. 7.495) Panel Report: "In the words of the expert [Dr. Sgrillo], the IRA [Australian import risk assessment] "could have considered a triangular distribution with the most probable value zero and the maximum value one times ten in the power of minus six. This will correct the kind of distortion (of bias) in generating random samples in the range."

Uniform vs. Triangular

Range			Sampling (%)	
			Uniform$(0,10^{-6})$	Triang$(0,0,10^{-6})$
0	<->	10^{-12}	0.0001	0.0002
10^{-12}	<->	10^{-11}	0.0009	0.0018
10^{-11}	<->	10^{-10}	0.0090	0.0180
10^{-10}	<->	10^{-09}	0.0900	0.1799
10^{-09}	<->	10^{-08}	0.9000	1.7901
10^{-08}	<->	10^{-07}	9.0000	17.0100
10^{-07}	<->	10^{-06}	90.0000	81.0000
Total			100	100

Triang(0,0, max)

$$F(x) = 1 - \frac{(\max - x)^2}{\max^2}$$

Triang(0,0, 10^{-6})

mean =

(min+mode+max)/3

= 3.3 x 10^{-7}

(vs 5 x 10^{-7} for uniform(0, 10^{-6}))

Alternative Remedies

- Log-uniform - sampling weights equally distributed among the various orders of magnitude

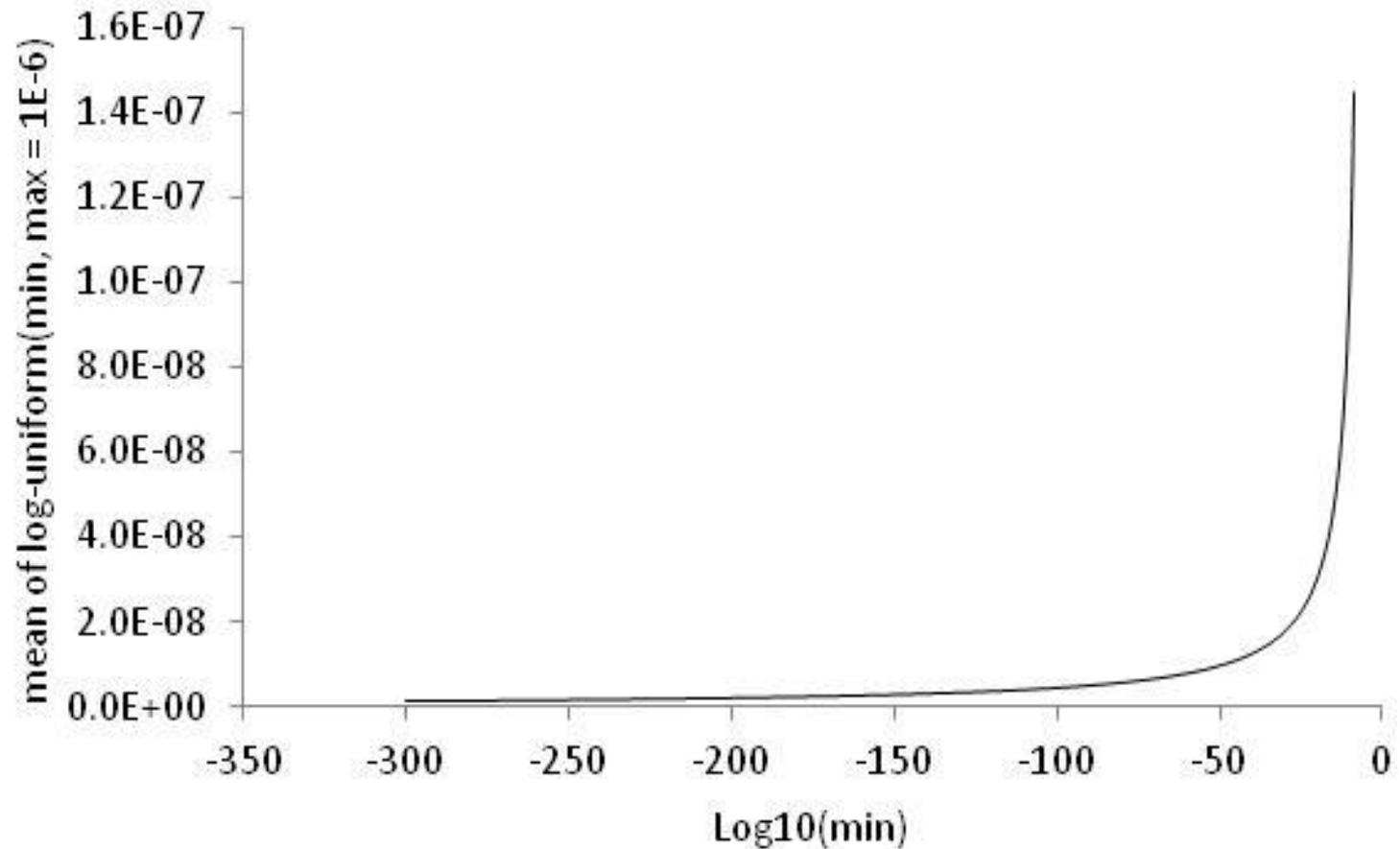- WTO (2010) Replies from the scientific experts to questions posed by the Panel, Dr. Sgrillo, paras. 771, 788

Log-Uniform

- $f(x) = \dfrac{1}{x \, ln\left(\frac{max}{min}\right)}$

- $\mu = \dfrac{max-min}{ln\left(\frac{max}{min}\right)}$

- Given: $Var(X) = E(X^2) - \mu^2$

- $\sigma^2 = \dfrac{max^2 - min^2}{2ln\left(\frac{max}{min}\right)} - \left[\dfrac{max-min}{ln\left(\frac{max}{min}\right)}\right]^2$

- As $min \to 0, f(x) \to$ spike at zero

Log-Uniform

"ZERO" log(min)	log(max)	mean
-16	-6	4.34E-08
-15	-6	4.83E-08
-14	-6	5.43E-08
-13	-6	6.20E-08
-12	-6	7.24E-08
-11	-6	8.69E-08
-10	-6	1.09E-07
-9	-6	1.45E-07

Log-Uniform

The Zero Bound Problem

- WTO (2010, para 7.481) "[I]n the case of assigning numbers to probabilities, the numbers you are assigning represent a hypothesis about the real process in the world. And when you assign these numbers you should be based on numbers from sampling of the reality" (quoting Dr. Sgrillo).
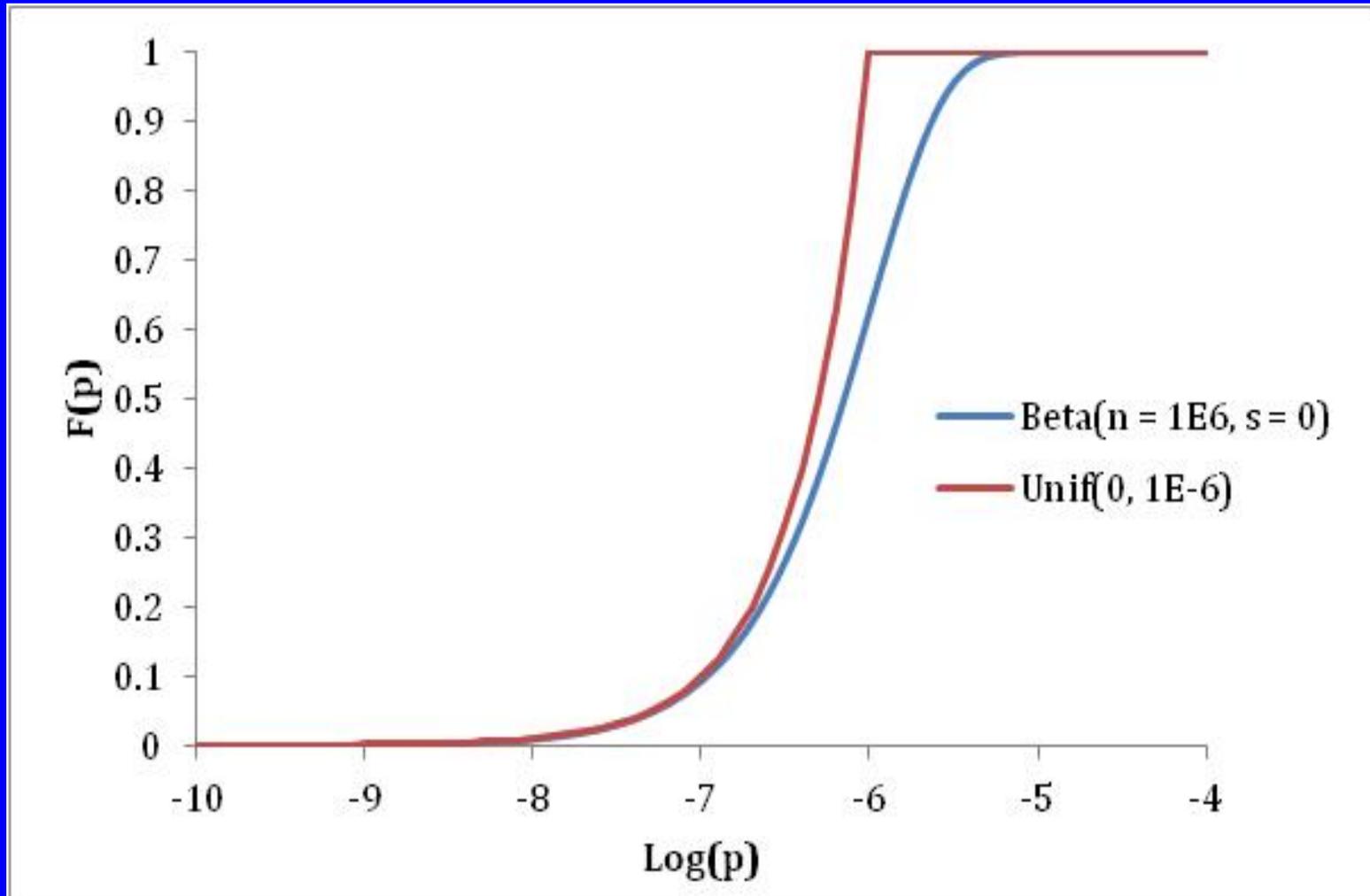
- Sample size (n) required for 95% confidence that prevalence < p:

$$n = \ln(0.05)/\ln(1-p)$$

p	n*
10^{-3}	2,994
10^{-4}	29,956
10^{-5}	299,572
10^{-6}	2,995,731
10^{-7}	29,957,321
10^{-8}	299,573,224
10^{-9}	2,995,732,357

*Assuming a perfect test with zero detections

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The Zero Bound Problem

WTO (2010) Australia - Apples

- WTO (2010) Transcript of the proceedings of the Panel's meeting with the experts:
  - No standard definition for "negligible"
  - Depends on whether the probability is a on per fruit basis, a population, an exposure pathway over a period of time, etc.
- WTO (2010) Panel Report (para 7.483):
  - "Dr. Latorre [European canker expert] identified 'the range used to numerically explain the negligible descriptor' as '[o]ne of the main weaknesses in the IRA [Australian import risk analysis]…[T]he ordinary meaning of the term "negligible" is something that is '[a]ble to be neglected or disregarded; unworthy of notice or regard; so small or insignificant as to be ignorable' " (citing the Oxford English Dictionary).

Materiality of Faults

- WTO Appellate Body (2010, para 259): "Although the Panel did not in its reasoning explicitly analyze the relative gravity, or magnitude, of the flaws that it found at each relevant importation step or each factor relating to the entry, establishment and spread of fire blight and ALCM [apple leaf curling midge], the Panel clearly indicated that taken together these faults were enough to mean that the IRA [import risk assessment] did not constitute a proper risk assessment within the meaning of Article 5.1 of the SPS Agreement."

Conclusion

- Dr. Marion Wooldridge, UK animal health risk assessment expert:
  - *[I]t really does not matter what people mean by negligible if everybody says 'yes it is negligible and we are happy with that' then fine - nobody is arguing, there is no dispute and there is no problem. The problem, of course, does come when there is a dispute and people do wonder what is meant by 'negligible'* (WTO 1998, Annex 2, para. 56).

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