Institution: UDur: University of Durham

Unit of Assessment: Unit 10: Mathematical Sciences

Title of case study: EU Environmental Policy and Guidance: Statistical Reasoning in Ecotoxicological Risk Assessment

1. Summary of the impact

Based on original research by Peter Craig, several risk assessment methods, published in EFSA (European Food Safety Authority) 2005 Scientific Opinion **[1]** on the "possibility of lowering the uncertainty factor ...", have been applied, or agreed as policy, in further official documents concerning risk assessment for aquatic species. The documents, from EFSA and national authorities, e.g. Sweden, are: (i) official EU risk assessments for specific chemicals and (ii) creation of EU and national policy through official guidance for risk assessments.

Supported by further research by Peter Craig, the methodology was recommended by the 2008/9 EFSA guidance on risk assessment for birds and mammals for application in that wider context.

Through changes to risk assessment guidelines and practice, the research has changed the management of the ecotoxicological aspect of environmental risk in the EU.

2. Underpinning research

The original underpinning research is the technical appendix **[2]** written by Peter Craig for the EFSA 2005 Scientific Opinion **[1]** together with the Scientific Opinion **[1]** itself. The subject of the Scientific Opinion **[1]** was "a request from EFSA related to the assessment of the acute and chronic risk to aquatic organisms with regard to the possibility of lowering the uncertainty factor if additional species were tested". The appendix **[2]** was the scientific basis of methods 1 to 5 proposed in the Opinion **[1]**.

Peter Craig's research combined mathematical calculations, statistical modelling and data analysis in order to demonstrate, in the context of aquatic risk assessment for ecotoxicological consequences of pesticides, that: (a) where more species were tested for sensitivity to a chemical than the single species required by legislation, the risk would not be increased by applying standard uncertainty factors to the geometric mean of the measured sensitivities; (b) where two species were required by legislation, the risk would not be increased by applying standard safety factors to an appropriate order statistic of the measured sensitivities when more species where tested and that appropriate adjustment could be made for the knowledge that a particular species tended to more sensitive than average; (c) the method of Aldenberg & Jaworska (2000) for calculating "predicted no effect concentration"s could be improved to draw strength from a database of sensitivity test results for other chemicals. The research was carried out during 2005 by Peter Craig as an *ad hoc* expert providing advice to the EFSA Scientific Panel on Plant Protection Products and their Residues and was published in **[1]** as an appendix **[2]**. Peter Craig also contributed substantially to the main text of the Opinion **[1]**.

In 2008, Peter Craig broadened the findings in the original EFSA 2005 scientific opinion **[1]** with respect to method 1. The research was published in the appendix **[3]** written by Peter Craig for the EFSA 2008 "Opinion on the Science behind the Guidance Document on Risk Assessment for Birds and Mammals"[8]. The appendix was the basis of the new policy recommendation, in the Scientific Opinion[8] and in the subsequent EFSA 2009 "Guidance Document on Risk Assessment for Birds and Mammals"[9], to apply the geometric mean method to risk assessment for birds and

mammals. The appendix addresses the robustness of some of the original conclusions to variations in distributional assumptions and was commissioned by EFSA in 2008 as a funded research contract.

In 2012, an article **[4]** written by Peter Craig with Hickey (then at Durham), Hart (FERA) and Luttik (RIVM, NL) was published by Journal of the Royal Statistical Society Series A (Statistics in Society). It investigates more carefully the issue of non-exchangeability in aquatic ecotoxicological risk assessment. In particular, it provides (i) formal statistical evidence of the existence of non-exchangeability, an assumption which underpins method 2 of **[1]**; and (ii) a more detailed assessment and justification of Bayesian and frequentist methodology requiring specification of a desired level of risk, such as methods 3 to 5 in **[1]**. This research reinforces the validity of application of these methods by ecotoxicological risk assessors.

Peter Craig is a senior lecturer, employed by Durham University since 1989.

3. References to the research

[1] EFSA (2005). Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the assessment of the acute and chronic risk to aquatic organisms with regard to the possibility of lowering the uncertainty factor if additional species were tested**.** *EFSA Journal,* **301**, pp1-45. doi:10.2903/j.efsa.2006.301, http://www.efsa.europa.eu/en/efsajournal/pub/301.htm,

[2] **Craig, Peter** (2005). Mathematical and statistical basis of options for risk calculations – Appendix (pp 46-59) to EFSA (2005). *EFSA Journal,* **301**, pp46-59. doi:10.2903/j.efsa.2006.301

*The opinion **[1]**, including the appendix **[2]**, formed part of Durham's RAE submission in 2008. Although the rating assigned by the RAE panel to this specific item is unknown, it is known that it was rated at least two star by the panel as all articles in the submission received at least two stars.*

[3] **Craig, Peter.** (2008). Consequences of Increasing the Number of Species Tested - Appendix 7 (pp 491-553) to EFSA (2008) Opinion on the Science behind the Guidance Document on Risk Assessment for Birds and Mammals. *EFSA Journal*, **734**, pp 1-790. doi:10.2903/j.efsa.2008.734

*This appendix **[3]** reports research commissioned by EFSA to investigate the robustness, with respect to distributional assumptions, of method 1 of **[1]** and was used to support the recommendation for application of method 1 to the wider context of risk assessment for birds and mammals.*

[4] **Craig, Peter S.**, **Hickey, Graeme L.**, Luttik, Robert. & Hart, Andy. (2011). Species Non-Exchangeability in Probabilistic Ecotoxicological Risk Assessment. *Journal of the Royal Statistical Society Series A (Statistics in Society),* **175**, pp 243-262. doi:10.1111/j.1467-985X.2011.00716.x

4. Details of the impact

The European Food Safety Authority is the European Union (EU) agency established in 2001 by the European Parliament and Council to develop and manage risk assessment policy in the EU regarding food and animal feed safety. EFSA scientific opinions are used as the basis for policy making and implementation by the European Commission and Parliament and by individual EU member states. They also have influence on wider international groups involved in pesticide regulation such as the US EPA, OECD, JMPR and WHO. EFSA is also responsible for overall supervision of EU risk assessment for pesticides and in that role produces and publishes risk

assessment peer reviews of individual pesticides which support licensing decisions made by individual EU member states.

In the period for consideration of impact for REF2013, EFSA peer review reports for 3 pesticides (acrinathrin[3], azoxystrobin[4], fenazaquin[5]) made direct use of methods 1 to 5 proposed in **[1]** and reports for two more pesticides (captan[6], folpet[7]) suggested that individual EU member states should do so. *[improvement to existing technology or process]*

KEMI (Swedish Chemicals Agency) advice[1] in February 2012 on applications to license Plant Protection Products (pesticides) states that all the methods (1 to 5) proposed in **[1]** may be applied for assessment of acute risk to fish. *[changes to guidelines informed by research]*

The July 2011 guidance document[2] agreed by Denmark, Estonia, Finland, Latvia, Lithuania, Norway and Sweden on "Work-Sharing In The Northern Zone In The Registration Of Plant Protection Products" states that methods 1 and 2 from **[1]** may be used in all the countries and methods 3 to 5 in some specific countries (Latvia and Sweden). *[changes to guidelines informed by research]*

The original research published in **[1]** and **[2]** was in the context of risk assessment for aquatic species. The 2009 EFSA Guidance Document on Risk Assessment for Birds and Mammals[9] recommends the use of the geometric mean method from **[1]**, citing the EFSA 2008 scientific opinion[8] on the science behind the guidance document; the scientific opinion[8] cites **[1]** and its own Appendix 7 **[3]** which contains the further research commissioned by EFSA in 2008 on the robustness properties of risk calculations for the geometric mean method. *[changes to guidelines informed by research]*

In summary, the *management* of the ecotoxicological aspect of *environmental risk* in the EU has been *changed.*

5. Sources to corroborate the impact

1. KEMI (Swedish Chemicals Agency) Plant Protection Products Guidance for applications (February 3 2012 / April 4 2013)
   - http://www.kemi.se/Documents/Bekampningsmedel/Vaxtskyddsmedel/Vagledning/PPP-Guidance-for-Applications.pdf (accessed 12/11/2013)
   - p27 final paragraph states that all the methods (1 to 5) proposed in **[1]** may be applied for assessment of acute risk to fish.

2. Guidance Document On Work-Sharing In The Northern Zone In The Registration Of Plant Protection Products (July 2011)
   - Agreed by Denmark, Estonia, Finland, Latvia, Lithuania, Norway and Sweden [see page 4]
   - http://www.kemi.se/Documents/Bekampningsmedel/Vaxtskyddsmedel/Northern Zone work-sharing guidance July 2011.pdf (accessed 30/05/2013)
   - p21, method 1 and 2 of **[1]** can be used
   - p35, Latvia approves methods 3 to 5 of **[1]**
   - p44, Sweden approves methods 3 to 5 of **[1]**.

3. EFSA peer review of the pesticide risk assessment of the active substance acrinathrin
   - EFSA Journal 2010; 8(12):1872. [72 pp.]. doi:10.2903/j.efsa.2010.1872
   - p11, **[1]** applied.

4. EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin
   - EFSA Journal 2010; 8(4):1542 [110 pp.]. doi:10.2903/j.efsa.2010.1542
   - Geometric mean (method 1) approach from **[1]** used on page 10.

5. EFSA peer review of the pesticide risk assessment of the active substance fenazaquin
- EFSA Journal 2010; 8(11):1892. [74 pp.] doi:10.2903/j.efsa.2010.1892
- p63 footnote: method 2 of **[1]** applied.

6. EFSA Peer review of the pesticide risk assessment of the active substance captan (2009)
- EFSA Scientific Report (2009) 296, 1-90. doi:10.2903/j.efsa.2009.296r
- On p29, states that the methodology for lowering the uncertainty factor in **[1]** "should be taken into account at Member State level".

7. EFSA Conclusion regarding the peer review of the pesticide risk assessment of the active substance folpet
- EFSA Scientific Report (2009) 297, 1-80, doi:10.2903/j.efsa.2009.297r
- On p26, states that the methodology for lowering the uncertainty factor in **[1]** "should be taken into account at Member State level".

8. EFSA (European Food Safety Authority), 2008. Opinion of the Scientific Panel on Plant protection products and their Residues on the science behind the GD on risk assessment for birds and mammals.
- EFSA Journal (2008) 734: 1-181. doi:10.2903/j.efsa.2008.734
- pp 22-23 discuss the geometric mean approach (method 1) of **[1]**, the additional research commissioned by EFSA in appendix 7 **[3]** and recommend the use of the geometric mean approach for birds and mammals.
- Appendix 7 (pp491-553) is the report **[3]** by Peter Craig to EFSA on the distributional robustness of the conclusions concerning risk properties of the geometric mean in **[1]**.

9. EFSA Guidance Document on Risk Assessment for Birds and Mammals
- EFSA Journal 2009; 7(12):1438 [358 pp.]. doi:10.2903/j.efsa.2009.1438
- pp 21-22 discusses geometric mean approach (method 1) of **[1]** and states that it should be used for acute assessment for birds and mammals.